***Guidelines for the Acceptance and Use of Externally Funded Grants and Contracts***

[**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)

Tanja F. Blackstone, PhD

Director, Sponsored Programs

[tfblackstone@una.edu](mailto:tfblackstone@una.edu)

University of North Alabama

Box 5041

Florence, AL 35632-0001

(256) 765-4523

FAX (256) 765-4523

**University of North Alabama**

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**Role of the Office of Sponsored Programs**

The University of North Alabama, through the Office of Sponsored Programs, supports the acquisition of external support in the form of grants and contracts to help University faculty and staff fully participate in research and creative activities. Among other things, this office provides assistance to faculty and staff with associated grant and contract pre-award activities such as locating funding sources, reviewing proposals, legal review processing, obtaining appropriate endorsements, and other related efforts. The Office of Sponsored Programs also oversees the post-award administration of grants and contracts as well as maintaining and administering such institutional polices as the Intellectual Property Policy, the Institutional Review for the Human Subject Policy, Conflict of Interest, and the Animal Use Policy. These policies are required by federal and state agencies and provide the ethical framework within which externally funded research and the results of such activities are managed at the University of North Alabama. In addition, this office provides guidance on meeting sponsor requirements for fiscal compliance, record keeping, reporting and evaluation.

**Office of Management and Budget (OMB) Circulars for Education and Non-Profit Institutions**

UNA’s external funding policies comply with the instructions, federal regulations and or information issued by OMB to federal agencies. OMB circulars, A-21, A-110, A-122, and A-133 can be found at <http://www.whitehouse.gov/omb/circulars_index-education/>.

**Budget Procedures for Grants and Contracts**

**I. Budget Preparation - Proposal**

The budget is the financial representation of the statement of work and should provide to the funding agency a clear picture of your anticipated financial needs. The format and/or allowable costs may vary from one agency to another, but the items comprising the budget are generally the same. Sponsors typically require, or encourage, budgets that present the total amount requested for the life of the award by annual increment and budget component (e.g. total salaries, salaries for year one, salaries for year two, etc.).

**Direct Costs:**

Direct costs of sponsored projects are those that can be directly associated with the project with a high degree of accuracy. Direct costs are essential to the project's fulfillment. For proposal purposes, OSP encourages providing budget information in as summarized a form as allowed by the sponsor, but some items may need more detail in order to analyze the budget for sufficiency. Also, more detail will typically be required, if awarded, in order to establish the budget in Banner.

**Examples of Direct Costs:**

**Salaries**

List each UNA person/position to be included. Using annual salary rate and percentage of time to be devoted to the project, compute the salary allocable to the project for each individual. The salary charged to the grant should be an accurate estimate of the percentage of time each person will spend on the project. A cost-of-living increase of 3-5% should be added to each base salary in each subsequent year of the proposal. Grants.gov and some sponsors require proposed effort to be shown in person-months, which can be calculated from the proposed percentage of effort and the number of months in the individual’s appointment (typically 9 months or 12 months). An explanation of person- months and a person-month calculator are available at: [http://grants.nih.gov/grants/policy/person\_months\_faqs.htm#q2.](http://grants.nih.gov/grants/policy/person_months_faqs.htm#q2)

A faculty member on a nine-month appointment can request summer salary of up to 33% of his/her base salary. These additional funds will be paid out during the summer and will not affect the faculty member’s academic year base salary.

Additional pay (supplemental or extra-compensation) during the academic year or for an individual with a 12 month appointments is allowable ONLY in unusual cases. Refer to University’s *Extra Compensation/Supplemental Pay Policy* for guidance. Extra compensation policy also applies to staff on 12 month appointments. See *University’s Extra Compensation/Supplemental Pay Policy* for further guidance.

Some sponsors impose restrictions on faculty salary. For example, many NSF programs will fund only 2 months of faculty salary. Occasionally, a foundation or other sponsor will pay for no faculty salary. If faculty effort will be required but the sponsor’s policy will not allow funding of it, the sponsor is in effect requiring cost share and the University’s *Cost Sharing Policies and Procedures* will apply.

Salaries of administrative and clerical staff are only allowed as a direct charge if the project meets the federal requirements to be considered a major program. Unless direct charging can be justified in accordance with OMB Circular A-21, secretarial and administrative salaries, office supplies, and other costs identified as normally indirect in the University’s policies will be charged as indirect costs.

**EXCEPTIONS** to charging staff to direct costs may be appropriate per OMB A-21 only where a major project or activity explicitly budgets for administrative or secretarial services and individuals involved can be specifically identified with the project or activity. “Major project” is defined as a project that requires an extensive amount of administrative or secretarial support, which is significantly greater than the routine level of such services provided by academic departments.

Once awarded, effort included in the proposal for a PI, Co-PI or other key persons becomes a commitment. For more information see *Budget Management* and *Revision of Budget and Program Plans* below.

**Fringe Benefits**

The fringe rate is expressed as a percentage of salary, and the dollar amount is calculated by applying the appropriate rate to each UNA employee’s salary to be charged to the grant. The proposal fringe benefit rates to be used vary based on employee classifications such as full, part- time, or summer salary. The OSP will assist PI’s in calculating the fringe benefit rates. These rates are an ESTIMATE of the actual costs that might be charged based on University averages. ACTUAL fringe charges will be based on the fringe benefit rate in effect during the grant period of performance. UNA is responsible for reasonably estimating costs, while not knowing for certain what an individual’s fringe benefits will really cost in the future. The Proposal Fringe Benefit Rates are used to accomplish this objective.

Undergraduate students and graduate students are not eligible for UNA paid health insurance and are only subject to federal and state tax rates. Contact the OSP for estimated tax rates for undergraduate and graduate student assistantships.

**Tuition**

If tuition is expected to be an expense of the project but there is not a separate line for it on the sponsor’s budget form, include tuition in Other Direct Costs.

Other programs specifically for the purpose of providing training to participants often allow the cost of tuition, typically in the form of scholarships or fellowships as this is not in return for services. Please see Section Tuition, Stipends and Other Student Payments policy.

**Travel**

List anticipated travel expenses of project personnel by purpose and show basis of computation. Include costs such as conference registration, personal car mileage, transportation (air and/or ground transportation, parking), hotel, and meals. Domestic and foreign travel should be shown separately. If foreign travel is not specified within the budget, prior approval from the agency may be required before travel takes place. Regardless of the funding source, UNA travel policies must be followed and can be accessed at <http://www.una.edu/controller/>.

**Participant Support**

Expenses for Participant Support are for training projects, conferences, symposia, etc. These costs are for non-UNA employees. Additional information regarding both Participant Support Costs and Stipends (Tuition, Stipends and Other Student Payments) can be found in ‘*Participant Support Costs-Policies and Procedures’*.

**Supplies**

Supplies include expendable items with a useful life of less than one year or a unit cost under $5,000. Include a description of each category (e.g. glassware) and best estimate of cost for items directly related to the project and that are to be expended or consumed during the course of the project. Office supplies are generally not allowed as they are items that should be provided by the department or college, and the cost for them is recovered through the indirect cost rate. Office supplies include general purpose computers and computer accessories. Office supplies, postage, local telephone costs, and memberships may not normally be treated as direct costs.

**EXCEPTIONS** to the direct cost accounting policy will be considered only under the following circumstances for direct charging of postage, basic telephone, office supplies, and computer supplies (including software). Exceptions are generally associated with large/complex projects. Requests should be identified in the budget justification and related to a major product or activity of the sponsored project.

**1. Exception to Allow a Direct Charge for Postage.** Due to the high demand for postage required to perform this project, as described in the budget justification, an exception to allow postage as a direct cost is requested. (Shipping costs that are not classified as ordinary postage are acceptable direct costs when beneficial and related directly to the project.)  
**2. Exception to Allow a Direct Charge for Basic Telephone.** Due to the high level of local telephone calls necessary to perform this project, as described in the budget justification, an exception to allow direct charges for local telephone usage is requested. Local telephone charges must be allocable to the specific sponsored project.

**3. Exception to Allow a Direct Charge for Office Supplies.** Due to the high demand for these items on this project, as described in the budget justification, an exception to allow direct charges for office supplies is requested. The cost of such office supplies must be allocable to the sponsored project and specifically related to the work being performed on the project.

**4. Exceptions to Allow a Direct Charge for Computer Supplies (including Software).** An exception to allow a direct charge for computer supplies is requested as such costs are directly related to the performance and benefit of the project, as described in the budget justification.

**5. Memberships and Subscriptions.** An exception to allow for memberships or subscriptions is requested as the membership or subscription is specifically related to the performance and benefit of the project, as described in the budget justification.

**Equipment**

List any item of equipment having a unit cost of $5,000 or more and a useful life of one year or more and include the cost of shipping, installation and fabrication. Items costing less than $5,000 per unit should be included either in “Supplies” or “Other”

General purpose equipment (equipment not limited to research, medical, scientific or other technical activities) is generally not allowable as a direct cost unless used primarily or exclusively for the research project. Allowable general purpose equipment should be specified in the budget as it is specifically unallowable as a direct charge without advance approval of the awarding agency.

**Consultants/Professional Services**

In this category, list each consultant, the specialty or service to be provided to the project, the daily, weekly or monthly rate of reimbursement and the consultant’s total projected cost on the project. Include in the proposal a letter of collaboration and the consultant’s curriculum vitae. List other services to be purchased for the project such as service or maintenance contracts for equipment utilized on the project. Sub-agreements are partially excluded from application of F&A costs and are, therefore, included in a separate category. It is important to appropriately distinguish between a professional service relationship (consultant/vendor) and a sub-agreement as there are budget implications related to the applicable indirect costs and differing monitoring requirements.

University faculty serving as consultants should be presented in the Salary section of the budget by including a portion of their UNA effort in the proposed budget. Intra-university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full time base salary. Additional pay during the academic year or for an individual with a 12 month appointment is allowable ONLY in unusual cases and must be specifically identified in the proposed budget. See *Extra Compensation/Supplemental Pay Policy*.

**Sub-agreements**

A sub-agreement is a contract or award to another organization that conveys a portion of the UNA project’s scope of work. You should obtain an acceptable budget and scope of work, signed by the sub’s authorized organizational representative, which may be required to be included as part of the proposal package. It is important to appropriately distinguish between a professional service relationship (consultant/vendor) and a sub-agreement as there are budget implications related to the applicable F&A (facilities and administrative or indirect costs). It should be noted that PIs have substantial responsibility for monitoring the progress and reviewing the financial reports of their subrecipients. See University’s *Subrecipient Monitoring Policy*

**Other Direct Costs**

Other costs typically include items such as research publications, lab usage fees, animal costs, and/or other project related costs not proposed in the previously mentioned categories. Office supplies, postage, local telephone costs, and memberships may not normally be treated as direct costs. Exceptions may be made ONLY for different purposes or circumstances.

**Indirect costs:**

Indirect costs of sponsored projects are those that cannot be directly associated with the project with a high degree of accuracy. Indirect costs are normally, therefore, recovered by the University through the Facilities and Administrative Cost Rate.

**Facilities and Administrative (F&A) Costs**

Compute and include full F&A costs (also referred to as “Indirect Costs” or “Overhead”) according to UNA’s federally negotiated rate, unless limited or prohibited by the sponsor’s written policy. The negotiated rate is applied to a Modified Total Direct Cost (MTDC) base, which includes all direct costs except equipment, other capital expenditures, tuition remission, rental cost of off-site facilities, scholarships, fellowships and the portion of each sub-agreement in excess of $25,000.[[1]](#footnote-1) The current UNA rate agreement can be found in ‘Institutional Data for Grants and Contracts’.

Waiver of the F&A costs or its use to meet agency cost matching requirements must be approved by the OSP and the Vice President for Academic Affairs.

**Budget Justification:**

The Budget Justification is the narrative explanation of the budget. It helps the sponsor to evaluate the reasonableness of the budget. The budget justification should explain and defend each major budget category.

Pay particular attention to the items listed below in your budget justification as these costs are often more carefully scrutinized by the sponsor.

Tuition



Travel (especially foreign travel)

Equipment (especially General Purpose, which is not typically a direct cost)

[Administrative Costs](http://ora.stanford.edu/ora/osr/proposal_development/budget_development/admin_charging.asp)

**General/Best Practices:**

Compare the statement of work (SOW) to the budget and make sure all costs are accounted for in the budget (e.g. if the SOW mentions travel, make sure travel expenses are included in the budget) and all expenses in the budget can be explained by the SOW.

All budgets must comply with UNA policies and must be approved by OSP prior to being submitted to the sponsor. Voluntary cost sharing is not generally supported by UNA. It is the recommendation of UNA’s Office for Sponsored Programs that cost sharing only be included in a proposal if it is mandatory cost sharing. This includes voluntary cost sharing not included in the budget but quantified (or made quantifiable) in the budget narrative or any other section of the proposal. See *Cost Sharing Policies and Procedures and Instructions* .

Be conservative when listing senior/key personnel. While the federal government’s standard Research Terms and Conditions (<http://www.nsf.gov/awards/managing/rtc.jsp>) require prior written approval for a change of the PI or for an absence of the PI for a continuous period of more than 3 months or a 25 percent reduction in time devoted to the project, NIH expands applicability of this requirement to also include ANY senior/key personnel named in the Notice of Award.

**II. Budget Modification for Award Reduction**

Awards are reduced for a multitude of reasons, including a sponsor’s budget constraints, the number of awards funded, and the review committee’s belief that the proposed aims can be accomplished on a leaner budget. In the event a proposed budget is reduced or requires modification, the agency program officer will provide you with specific cost reduction/modification changes. The PI will need to assess if the proposed research can be completed within the agency proposed budget constraints. If the proposed effort can be completed, the PI will need to draft a revised budget reflecting the new funding levels and submit the budget to the OSP for approval and submission.

**Budget Reduction and Cost Share**

Whenever re-budgeting is necessary and cost-share is mandatory, the cost-share also needs to be re- budgeted. The cost-share portion needs to be reduced in the same proportion as was the sponsor portion. If your budget was cut 10%, then 10% of the sponsor’s funds would be cut and 10% of the cost- share should be cut.

**III. Budget Management**

**Spending in Advance of Award Notice:**

When it has been communicated by the sponsor that a particular project will be funded but the award instrument will be delayed, it may be appropriate to establish a grant fund to which allocable costs can be charged. Spending in advance of receipt of award notification must be approved by the OSP and the Vice President for Business and Financial Affairs. While the federal government’s standard Research Terms and Conditions (<http://www.nsf.gov/awards/managing/rtc.jsp>) state that the recipient is authorized “to incur pre-award costs 90 calendar days prior to award”, they also state that “All costs are incurred at the recipient's risk (i.e., the Federal awarding agency is under no obligation to reimburse such costs if for any reason the recipient does not receive an award or if the award is less than anticipated and inadequate to cover such costs).” In addition, the terms and conditions do not apply to all programs and or sponsors. Program specific rules related to advance spending should be followed.

UNA will not authorize charges to a grant or cost share fund for costs that are not allocable to it, even temporarily, because another sponsored project agreement has not yet been received.

**Original Budget:**

The budget as awarded by the funding agency is followed by the OSP to establish the award in the University's accounting system, Banner. The sponsor’s budget format, however, may not provide all the information needed for creation of the budget in Banner. If not included in the sponsor approved budget, the OSP will work with the PI to expedite establishment of the grant budget. The PI will need to provide the following information:

* Salaries - Any salaries need to be identified by category such as faculty, professional (non- faculty), graduate students, etc. in order to budget in the correct Banner account code (expense line). Remember, an exception must be approved for charging the salary of clerical and/or administrative staff. PI and co-PI salaries need to be identified by the individual.
* Travel – Domestic and foreign travel should be shown separately. If foreign travel
* is not specified within the budget and prior approval from the agency is
* required, the approval must be obtained before the travel begins.
* Other direct costs – Other costs need to be identified in sufficient detail to budget
* them within the appropriate account code in Banner (e.g. lab supplies, consulting,
* subcontracts).
* Tuition – Although included as “other” in most sponsor budgets, tuition must be budgeted separately within Banner.
* Facilities and Administrative (F&A) rate – The OSP will assess allowable F&A costs.

Once the budget has been established in Banner, the OSP will provide a copy of the budget to the PI for his/her records.

**Revision of Budget and Program Plans:**

The University does not have the authority to revise agency approved budgets where prior approval of the agency is required. Standard Federal Terms and Conditions for Research Grants, <http://www.nsf.gov/awards/managing/rtc.jsp>, state that the recipient must obtain prior written approval from the Federal awarding agency before making any of the following project changes:

1. Change in scope or objectives (even if no budget revision is requested). A change in labor allocations is also considered a change in scope or objectives.

2. Absence (> 3 months or 25% reduction in effort) or change of PI

3. Need for additional federal funds.

4. Transfer of a significant part of the research (e.g. sub-agreement)

PIs requesting revisions to agency approved budgets should work with the OSP to provide the appropriate documentation. In general, budget change requests for sponsored funds must include an adequate explanation which answers the following questions:

* Why are funds available in the current expense line?



* Why are funds needed in the new expense line?
* In addition, the PI will need to provide information, by line item, on dollar amounts to be reallocated.

The OSP will work with the PI in submitting the budget revision request to the agency. It is important to note that approvals can take as long as 90 days, therefore, PI’s should plan accordingly.

Once the OSP has been notified of the agencies decision, the PI will be contacted within 3 business days. It is incumbent upon the PI to contact the OSP to input approved budget revisions into Banner.

**No-Cost Extensions:**

A no-cost extension (“NCE”) extends the end date of a project without additional funding. NCE’s may be necessary in order to complete the work of the project. The PI or the OSP can submit a NCE. While the OSP does its best to notify the PI of pending program expiration dates, it is the responsibility of the PI to monitor grant/contract expiration dates and if necessary submit NCE requests and other appropriate documentation either directly to the funding agency or via the OSP. If the OSP is to submit the NCE, the PI must contact the OSP 90 days prior to the contract/grant expiration date. At a minimum the OSP must be included in all NCE correspondence submitted to the sponsoring agency.

NCE requests should conform to the sponsors requirement, provided in the contractual agreements or on the sponsoring agencies websites. In general, NCE requests must explain the reason for the extension and provide a budget for the remaining work.

**General Guidelines**

Be aware of the sponsor’s timeline for granting NCE’s. In general, requests should be made at least 90 days before the program end date; noting that, some sponsors require more advanced notice.

Projects that are spent out or in a budget deficit will not be extended without additional funding.

Spending out remaining funds is not a sufficient reason for requesting an NCE, and such requests will be denied.

**NSF** allows a one time 12-month grantee-initiated NCE when it is submitted by the authorized institutional official on behalf of the PI through the Fastlane system under the following circumstances:

There will be no change in the project’s originally approved scope or objectives, and at least one of the following applies:

* 1. Additional time beyond the established expiration date is required to ensure adequate completion of the originally approved project.
* 2. Continuity of Sponsor grant support is required while a competing continuation application is under review.
* 3. The extension is necessary to permit an orderly phase out of a project that will not receive continued support.

NSF must approve subsequent NCE requests. All requests will be submitted via the FastLane system. If approved, an amendment to the grant will be issued to extend the end date of the grant. Approval is not automatic and PIs are cautioned not to incur expenditures after the expiration date in anticipation of a no-cost extension.

**NIH** allows a one-time 6, 9, or 12-month grantee-initiated NCE for awards. The NCE is in effect as soon as the authorized institutional official submits the notification via eCommons. Notification may be made no earlier than 90 days prior to the end date of the project and no later than 1 day before the end date.

See NIH website for procedures involving second NCE requests.

**Budget Management Best Practices:**

**Monitor Budgets**

It is incumbent upon the PI to monitor budgets throughout the life of the grant. Expenditures and obligations should be reviewed frequently, ideally monthly, and at least quarterly. Timely identification of the need for a budget change will ensure the necessary processes (including potential sponsor approval) can be completed before problems occur.

In cases where a grant lists multiple PI’s, for purposes of financial accountability and oversight, designation of a single PI with financial and program oversight is required. The designated PI will be responsible for overall financial and program management, including submission of agency required progress reports, NCE’s, time and effort reporting, and other compliance requirements.

**Monitor Expenditure and Obligation Rates**

Sponsors consider expenditure rates to be an indication of project progress. If, for example, the project is half way through the period of performance but only 25% of the funds have been expended, the sponsor may question whether appropriate progress is being made, even if progress reports have been submitted. Expenditures rates as a measure of progress are a reflection on the PI and the university. Research efforts failing to meet agency set expenditure benchmarks can be at risk for funding reductions and or termination of the research effort. As such, requests for NCE’s are not encouraged.

**COST SHARING POLICIES AND PROCEDURES**

**Federal Definitions of Cost Sharing**

Cost sharing is defined as program or project costs not borne by the sponsoring agency. Cost sharing may include contributed effort, other University matching funds, unrecovered facilities and administrative costs, (F&A, or indirect costs) and third‐party in‐kind contributions. OMB Circular A‐110 entitled “Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non‐Profit Organizations”, Subpart C, Section 23, requires that all cost sharing must:

• Be necessary and reasonable for proper and efficient accomplishment of project objectives;

• Be readily verifiable from the university’s official records;

• Not be paid by the federal government under another award (except where authorized under federal statute to be used for cost sharing);

• Be provided for in the approved budget (when required);

• Not be included as cost sharing for any other sponsored award; and

• Be allowable under applicable cost principles and conform to other applicable Circular provisions.

There are two types of cost sharing: mandatory cost sharing and voluntary cost sharing.

• “**Mandatory cost sharing**” is cost sharing that is legally required by the awarding agency as a condition of the award.

•“**Voluntary cost sharing**” is not required by the awarding agency as a condition of the award. However, some federal agencies expect some cost sharing commitment to be identified in the proposal. **If voluntary cost sharing is included in the proposal, it will become mandatory cost sharing if accepted by the sponsoring agency as a part of the award (grant or contract).**

The University will track all cost share commitments, ensuring commitments are met and that cost share complies with general requirements and specific agency or award requirements. All committed cost share is subject to review and approval by the President, Vice President for Academic Affairs, Vice President for Business and Financial Affairs, and the OSP, for allowability, appropriateness and sufficiency.

**Voluntary Uncommitted Cost Sharing**

On January 5, 2001, the Office of Management and Budget (OMB) issued a policy statement clarifying the OMB Circular A‐21 treatment of “Voluntary Uncommitted Cost Sharing.”

“**Voluntary Uncommitted Cost Sharing**” is defined by OMB as university faculty or senior researcher effort that is over and above that which is committed and budgeted for in a sponsored agreement. This differs from mandatory or voluntary committed cost sharing which is cost sharing specifically pledged in the proposal’s budget or award.

To be considered voluntary uncommitted cost sharing, percentage of effort and/or dollar amounts cannot be included in the proposal. If voluntary uncommitted cost sharing is defined in such a way that time and effort can be accounted for, the proposed effort becomes voluntary committed cost sharing.

An example of voluntary uncommitted cost sharing:

* + - 1. You have included 5% of your effort in the proposed grant budget with no cost

sharing proposed.

* + - 1. In order to reflect additional support without committing to cost share, your

budget justification might state, “The percent of effort included in the budget represents only the portion that will be charged to the grant. The PI will provide the time and effort necessary to satisfactorily complete the project objectives. Effort in excess of the 5% included in the budget for the PI represents voluntary uncommitted cost share of his/her time in order to reduce the salary burden and maximize the availability of grant funds for other direct research costs. UNA allocates at least XX% of the PI’s academic year time and salary in support of sponsored and non‐sponsored research activities.”

**Appropriate Use of Voluntary Uncommitted Cost Share**

The University receives federal funding for a variety of research and other sponsored activities. The federal government has clarified that, except in very unusual circumstances, each federally funded project should have allocated to it some level of committed Principal Investigator/Project Director (PI) effort. As the federal government requires that it be charged no more than any other sponsor, the University is generally required to charge all sponsors for some portion of faculty effort related to any sponsored activity.

**Definition:**

Voluntary uncommitted cost share (VUCC) is an acceptable means for the University to show its support of a project without the need for separately budgeting and accounting for the effort expended. The definition of and parameters for VUCC, as described in OMB Memorandum M-01-06 dated January 1, 2001 (link [http://www.whitehouse.gov/omb/memoranda/m01-06.html](http://www.whitehouse.gov/omb/memoranda/m01-06.html))), must, however, be well understood and closely followed.

The definition of VUCC provided in the OMB memorandum applies only to effort and defines voluntary uncommitted cost sharing effort as "university faculty (including senior researchers) effort that is over and above that which is committed and budgeted for in a sponsored agreement." Although it states that this type of uncommitted effort is not to be included in the research base, it stipulates that, "most Federally-funded research programs should have some level of committed faculty (or senior researchers) effort, paid or unpaid by the Federal Government" and "Such committed faculty effort shall not be excluded from the organized research base by declaring it to be voluntary uncommitted cost sharing."

If there is no restriction on the reimbursement of salary costs and no other cost share requirement, the University must ensure that some level of committed faculty effort is included in the proposed, sponsor paid budget. The University would, otherwise, be agreeing to voluntary committed cost sharing, which would require the necessary approvals. .

The significance of the level of uncommitted effort expected and/or provided must also be taken into consideration when determining whether it can be excluded from separate accounting. As the payroll distribution requirements of OMB Circular A-21 (section J.10.b) require that our system "encompass both the sponsored and all other activities on an integrated basis" and that "significant changes in the corresponding work activity must be identified and entered into the payroll distribution system", the OMB memorandum states that, "As such, when an institution reduces a faculty member’s level of activities dedicated to other institutional responsibilities in order to shift his/her activities to organized research activities, the institution must reflect this reduction in the payroll distribution system (as an increase to the research effort component)." Any case where the uncommitted effort appears to be significant will be reviewed by the Vice President for Business and Financial Affairs for a determination of how to account for or otherwise manage the situation.

If the written policy of a sponsor or program specifies that it will not pay for salaries, that sponsor is, in effect, requiring cost share. Cost share required due to a sponsor's policy of not paying salary cost, will be treated like any other required cost share.

**Exception:**

The OMB memorandum does provide for exceptions in that, "some types of research programs, such as programs for equipment and instrumentation, doctoral dissertations, and student augmentation, do not require committed faculty effort, paid or unpaid by the Federal Government." There may be an exception in other cases where there is a very minimal amount of time/effort devoted to the project by the PI (e.g. an award for travel to a conference for which the PI will only be away from the University for one or two days). Any exception not specifically identified in the OMB memorandum must be thoroughly justified, in writing, approved by OSP and maintained in the grant files.

An exception may also be granted if the total funding under an award is no more than $5,000 and the school/college/unit agrees to fund and account for the PI’s time committed to the project through Voluntary Committed Cost Share. This exception will require that cost shared PI time be treated like Mandatory Committed Cost Share (i.e. a separate cost share fund must be established in Banner and the PI's unit must charge via a Personnel Action Form (PAF) the allocable portion of the PI's salary to the cost share fund and provide the funding to cover the salary charges).

**UNA Policy on Cost Sharing**

If a PI wishes to submit a proposal where voluntary or mandatory cost sharing is needed, the PI is required to meet with the Director of Sponsored Programs at least 14 business days prior to submission of the proposal to discuss what funds may be available for cost sharing purposes. The OSP and the PI will identify possible sources of cost sharing funds and submit for approval the commitment of cost sharing funds to authorized parties from which non-sponsored funds are being committed. Authorized parties include but are not limited to: department chairs, Deans, Vice President for Business and Financial Affairs, Vice President for Academic Affairs, and the University President

Voluntary cost sharing is not routinely supported by UNA. It is the recommendation of UNA’s Office of Sponsored Programs that cost sharing only be included in a proposal if it is mandatory cost sharing. However, the OSP recognizes that there are activities and agencies, especially those dealing with assistance awards, which look favorably on voluntary cost sharing by the university.

Cost Sharing commitments of $250,000 or greater require Board of Trustees approval. All cost share requests of $250,000.00 or greater must be submitted to the OSP 90 days prior to the proposal submission deadline.

If cost sharing is provided via the Office of Advancement, a letter of commitment from the Vice President for Advancement indicating the level and type of cost sharing must be submitted to the OSP seven business days prior to the proposal submission deadline.

**Cost Transfer Policy**

A cost transfer is a shift of an expense to or from a sponsored project when that expense was previously charged elsewhere. Examples:

• transfer pre-award costs from other university accounts/funds

• correction of a clerical error

• reallocation of salary distribution to reflect actual effort

The cost allowability and allocability requirements of OMB Circular A-21 necessitate thorough explanation and justification for any transfer of charges to federal awards from other federal, non-federal or University Funds. Allocability requirements do not allow transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns. All federal and non-federal sponsors are sensitive to the risks associated with cost transfers and expect that they also be accomplished in a timely manner (typically within 90 days). The NIH policy on *Cost Transfers, Overruns, and Accelerated and Delayed Expenditures* found in the NIH Grants Policy Statement at <http://grants1.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Toc54600120>is representative of the perspective of all federal and most other sponsors.

**It is never acceptable to charge costs to a sponsored project unless those costs are allocable to that project, even on a temporary basis.**

To ensure compliance with the policies of federal and non-federal sponsors, the University requires that all cost transfers be accomplished in a timely manner and be supported by documentation that fully explains the cost transfer.

**Sponsored Research Compensation and Salary**

**Academic Year Supplemental/Extra Compensation Policy**

Federal rules and regulations, including OMB Circular A-21 and the NIH Grants Policy Statement, do not allow for an individual’s institutional base salary to be increased as a result of obtaining grant funding. These federal rules and regulations also restrict the payment of overload, bonuses, or other payments outside the individual’s institutional base salary. In addition to the University’s general policy regarding the allowability of supplemental compensation, the following principles must be applied when salary is to be paid from a sponsored project.

**Summary of OMB A-21 Principles:**

Charges for work performed on sponsored agreements by faculty members must be based on the individual faculty member’s regular compensation during the period of performance. Charges must be made at the allowable **base** rate; the faculty member cannot receive additional compensation for his or her participation in a sponsored project over and above the appropriate portion of the **base salary** allocated to the project.

The only exception to allow for compensation above the base salary during the academic year is a very specific exception for consultation across departmental lines. The general rules for faculty compensation during the academic year and the specific requirement for the exception to those rules are found in OMB Circular A-21, section J.10.d. and are as follows (emphasis added):

Salary rates for faculty members.

(1) Salary rates for academic year. Charges for work performed on sponsored agreements by faculty members during the academic year will be based on the individual faculty member's regular compensation for the continuous period which, under the policy of the institution concerned, **constitutes the basis of his salary**. Charges for work performed on sponsored agreements during all or any portion of such period are allowable **at the base salary rate**. In no event will charges to sponsored agreements, irrespective of the basis of computation, exceed the proportionate share of the base salary for that period. This principle applies to all members of the faculty at an institution. Since intra university consulting is assumed to be undertaken as a university obligation requiring no compensation in addition to full time base salary, the principle also applies to faculty members who function as consultants or otherwise contribute to a sponsored agreement conducted by another faculty member of the same institution. However, **in unusual cases where consultation is across departmental lines or involves a separate or remote operation, and the work performed by the consultant is in addition to his regular departmental load, any charges for such work representing extra compensation above the base salary are allowable provided that such consulting arrangements are specifically provided for in the agreement or approved in writing by the sponsoring agency**.

**Payment of Stipends to Faculty during the Academic Year**

Faculty on nine month contracts are eligible to receive extra compensation or stipends in excess of base salary if the sponsored research work or tasks are conducted during non-business hours. Individuals must agree to and provide documentation showing tasks completed and date and time of task in order to be eligible for additional compensation.

UNA recognizes that the time period that constitutes standard business hours, 0800-1630, may vary by position or individual faculty/staff work schedule.   In cases where faculty/staff work hours differ from standard business hours and where stipends will be charged to a grant for performance of tasks, faculty/staff must submit to the OSP a written request for change in business hours.  Requests for a change in business hours will be considered on an individual basis and must be submitted and approved 90 days prior to incurring stipend expenditures during non-standard business hours.  Requests must be approved by the OSP, the Vice President for Business Affairs, and the Vice President for Academic Affairs.   Approved requests are only valid for a period of 120 days.

**Summer Salaries and Compensation Policies**

Academic year compensation rules are *not applicable* to summer salary for nine (9) month faculty. See OMB Circular A-21 §J10d(2)(a). Research compensation during the summer months or other periods not included in the base salary period is to be calculated for each faculty member at a rate not in excess of the base salary divided by the period to which the base salary relates. A faculty member on a nine-month appointment can request summer salary of up to 33% of his/her base salary.

Per OMB Circular A-21, the maximum allowable compensation above and beyond base salary is 33%, with the 33% including compensation charged to grants or contracts, and inclusive of compensation earned for summer school appointments. Compensation received for course overloads, research supplements, independent studies, continuing education, and large class overloads are not counted in the 33% cap. Under exceptional circumstances, a faculty member can request a waiver of the 33% cap. Exceptions would include cases where a waiver is necessary in order to avoid negative consequences to the University, students, or faculty research.  Waivers must be approved by the Office of Sponsored Programs.

Funds paid out during the summer will not affect the faculty member’s academic year base salary.

Individuals requesting salary outside of the academic year or salary reimbursed as stipends must submit Personnel Action Forms (PAF) to the OSP . All PAF’s must be accompanied by a progress report justifying the requested salary. PIs are asked to be cognizant as to UNA payroll deadlines for salary reimbursements.

**Base Pay**

The base pay used to calculate salary charges to a grant is the contractual base pay in effect at the time that the work was performed and as documented on time and effort reporting

**Part-time Faculty Compensation Charged to Grants and Contracts**

Rates of compensation for part-time faculty members are based on a salary schedule for the academic year of two semesters (nine months). The salary schedule recognizes academic rank, highest degree level, appropriate experience, and merit or market value in a system in which numerical weights are assigned to each category. Rates of compensation for part-time faculty charged to grants or contracts will be based on their full time equivalent nine month per hour rate.

**Course Buy-outs**

A course ‘buyout’ situation provides the faculty with an academic year course release so that the faculty member can work on an externally funded grant or contract. The corresponding percentage of the person’s appointment is directly charged to the grant during the term of the buy-out. In effect the external grant or contract ‘buys’ the faculty members released time by paying for that portion of their salary so that the equivalent amount of effort can be spent working on the grant or contract.

Policy:

1. Course buy-out requests must be included in the proposal budget submission.  All proposal budgets and narratives must be submitted to the OSP for review and approval a minimum of 7 business days prior to proposal submission deadline.
2. Faculty requesting course buy-outs must secure the approval of the Department Chair and Dean of the College.
3. The cost of a course buy-out is 1/8th of the faculty member’s nine-month academic year compensation, where compensation is defined as base salary plus fringe benefit.
4. Compensation (salary plus fringe benefits) savings derived from course buyouts will accrue to the university.  In cases where the college incurs costs associated with course buyouts, such as payment of course overloads or the hiring of adjunct faculty, the university will reimburse the college for these costs.  University reimbursement to the college will not exceed funding agency approved levels for a course buyout.

**Extra Compensation and Salaries for 12-month Appointments and Staff**

Individuals on 12 month contracts (including administrative and clerical support staff) are only eligible to receive extra compensation in excess of base salary, if the sponsored research work or tasks are conducted during non-business hours. Individuals must agree to and provide documentation showing tasks completed and date and time of task in order to be eligible for additional compensation. ‘Extra Compensation’ salaries must be included in the budget submitted to the funding agency and addressed in the budget justification.

For individuals on 12 month contracts, allowable compensation in excess of base salary must be approved by the Vice President for Business and Financial Affairs, with notification of approval sent to the OSP prior to proposal submission.

**Institutional Base Salary for Sponsored Projects**

**I. Definition**

Institutional Base Salary (IBS) is the compensation paid by the University for an employee’s appointment, whether that individual’s time is spent on research, teaching, administration or other activities. IBS includes an individual’s regular salary (e.g. academic appointment), exclusive of any salary/stipend from any additional assignment (e.g. chair of a department). The IBS does not include incidental, one- time payments. Also excluded from the IBS is salary paid directly to an individual by an organization outside the University.

**II. Policies, Procedures and Sponsor Requirements**

If a faculty member has academic, administrative (e.g. department chair stipend) or other non-research responsibilities (including writing new, competitive proposals), less than 100% of the individual’s effort is available to be requested from sponsored projects. The individual’s total IBS must, however, be used to calculate the percentage of effort (or person-months) proposed/requested and is used in the calculation of the percentage of effort on the individual’s Effort Certification Report.

All salary from sponsored projects is subject to the time and effort reporting policies discussed in *‘Time and Effort Reporting’*

Certain sponsors (e.g. NIH) impose a limit/cap on the rate of salary they will reimburse. The difference between the capped rate and the individual’s IBS is considered mandatory cost sharing), rather than a reduction in the individual’s IBS.

IBS may not be increased as a result of replacing University salary funds with sponsored project funds.

**Minimum Allowable PI Effort**

**Summary**

The University receives federal funding for a variety of research and other sponsored activities. The federal government has clarified that, except in very unusual circumstances, each federally funded project should have allocated to it some level of committed Principal Investigator/Project Director (PI) effort. As the federal government requires that it be charged no more than any other sponsor, the University is generally required to charge all sponsors for some portion of faculty effort related to any sponsored activity.

**Application**

The minimum allowable PI effort for purposes of proposing, accounting, and reporting is 1% of a PI’s salary. The 1% can be:

1. Allocated and charged to each sponsored project or

2. \*Allocated and charged to the project's related cost-sharing amount

The only federal exception to this policy is for "programs for equipment and instrumentation, doctoral dissertations, and student augmentation" [1] that involve only an insignificant amount of the PI’s time and effort.

**Reference:**

This policy is derived from an OMB Clarification memo referenced in the footnote below and viewable at the following link: <http://www.whitehouse.gov/omb/memoranda/m01-06.html>

Office of Management and Budget, M-01-06, Memorandum for the Heads of Executive Departments and Establishments, Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Remission Costs, January 5, 2001

**Application of On/Off-Campus Facilities & Administrative (F&A) Cost Rates**

The classification of on- or off-campus is solely for the purpose of applying the correct

F&A cost rate. UNA’s federally approved F&A cost rate can be found at http://www.una.edu/sponsored-programs/. This cost rate applies to all on-campus research projects. As of FY11, UNA does not have a federally approved off-campus F&A cost rate. To cover the cost of administering an off-campus grant or contract, a pass through rate of 8% will be applied to that portion of a sponsored research program classified as off-campus.

**I. Off-campus**

A project, or part of a project, is considered to be performed off-campus if:

 The activity is conducted at a location other than the property owned or leased by

the University of North Alabama, and;

 University personnel will work on the project at the off-site location, and;

 The majority of the Facilities costs that are normally associated with facilities owned or leased by the University are not applicable, and;

 The project is located in leased space and the lease is charged directly to the project (rent), or

o In exceptional circumstances, another entity may house the project or otherwise pay for the Facilities cost and provide certification of third-party in-kind cost share that it, therefore, is providing to the University project.

**II. On-campus**

A project, or part of a project, is considered to be performed on-campus if it does not

meet all of the criteria above for off-campus. This includes situations where the project is not charged directly for lease cost (rent) but the University is paying lease cost (e.g. the University leases a building in which this project, along with other University activities, takes place).

**Projects Conducted Partially Off-Campus**

The on- or off-campus determination shall be based on only The University of North Alabama’s portion of the project costs and not include costs of collaborating entities. No portion of a project will be considered off-campus unless it meets the criteria in I. Off-campus, above.

 Projects under $100,000 in Modified Total Direct Cost (MTDC):

o Will not be apportioned between their on- and off-campus components.

o If 50% or more of the project’s MTDC is to be expended on-campus, the

entire project is classified as and charged the on-campus F&A rate.

o If more than 50% of the project’s MTDC is to be expended off-campus, the project will be classified as off-campus and charged the off-campus F&A rate.

 Projects at or above $100,000 in MTDC:

o Will be apportioned between their on- and off-campus components if, after apportionment, the lesser component constitutes 20% or more of the MTDC of the project.

o If the lesser component is under 20% MTDC of the entire project, the entire project is classified as and charged the rate of the larger component

(e.g., if the on-campus component is 82%, the entire project will be classified as on-campus and will be charged the on-campus rate).

Costs of travel between the University or employee home base (see University travel policy) and the off-site location are to be included in the on-campus MTDC base when apportioning the project.

**III. Related Definitions**

Facilities Costs – operations and maintenance (e.g. utilities, repairs, cleaning), building depreciation, building improvements, equipment depreciation.

Modified Total Direct Cost (MTDC) – is the base to which F&A cost rates are applied and is defined in OMB Circular A-21 as:

Modified Total Direct Costs consist of “salaries and wages, fringe benefits, materials and supplies, services, travel, and sub-grants and subcontracts up to the first $25,000 of each sub-grant or subcontract (regardless of the period covered by the sub-grant or subcontract). Equipment, capital expenditures, charges for patient care, tuition remission, rental costs, scholarships, and fellowships as well as the portion of each sub-grant and subcontract in excess of $25,000 shall be excluded from modified total direct cost.”

Project – For purposes of this policy, project is defined as an individual competitive segment of a grant or contract.

**Participant Support Costs – Policies and Procedures**

**Definition**

Costs paid to (or on behalf of) participants of a workshop, conference, seminar, symposium, or other information sharing activity. These costs include stipends or subsistence allowances, travel allowances, and registration fees paid to the participants or trainees. The participants are not required to provide any service to the university.

Participant support costs are commonly awarded on National Science Foundation (NSF) and Department of Education (DED) grants and are subject to sponsor restrictions (see below).

These funds cannot be used to pay for costs of the project staff to travel to a conference, costs of bringing collaborators together for a meeting, etc. or for the Principal Investigator (PI) to attend a seminar, workshop or training event.

**Who is a Participant?**

A participant is a non-University of North Alabama (UNA) employee who is a recipient of a service or training session associated with a workshop, conference, seminar, symposium or other information sharing activity. These participants are not required to deliver anything to UNA in return for these support costs.

**Budgeting and Accounting for Participant Support Costs**

The budget narrative should provide a detailed justification that describes the purpose for the costs along with the benefit to the scope of the project.

Participant support costs will be established in a separate fund in order to meet any requirements to account for these costs separately, restrict budget changes, and avoid charging F&A costs.

**Restrictions**

Participant support costs are often subject to special sponsor regulations. For example, NSF and the Department of Education:

o Do not allow rebudgeting from the participant support cost category into other categories without prior approval.

o Do not allow the university to apply Facilities & Administrative (F&A)

cost to participant support costs.

o Require the university to return any unexpended participant support costs to them.

o Are associated with special programs such as Research Experience for Undergraduates (REU) and Research Experience for Teachers (RET) on National Science Foundation grants. Additional sponsor regulations:

• Do not allow participant support costs budgeted on REU and RET

sub accounts to be spent in other categories.

• Cannot offset a deficit in the parent account.

• Allow an administrative allowance of 25% of the participant stipend support only.

**Authority Policies and Procedures for Grants and Contracts**

The Principal Investigator (PI) is the individual primarily responsible for management of his/her sponsored research project, including financial management. While it is acceptable and practical for the PI to have assistance in financial management, standards for delegation of signature authority to acquire goods and/or services purchased on sponsored project funds must ensure that the PI maintains oversight and only appropriate expenditures are approved. Therefore, delegation of financial responsibility is not allowed. For purposes of financial accountability and oversight, designation of a single PI with financial and program oversight is required. The designated PI will be responsible for overall financial and program management, including submission of agency required progress reports, NCE’s, time and effort reporting, and other compliance requirements.

Only the authorizing PI can initiate the following actions:

1. **Approval of personnel action forms (PAFs) and Time and Effort Certification Reports.** Salary and stipends charges should be subject to careful review throughout planning, charging, (monitoring of budget/account statements) and confirmation (effort certification).

2. **Approval of sub‐contractor payments.** PI’s must review and approve sub‐recipient’s invoice. Prior to approving, the PI should consider the reasonableness of the invoiced amount based on the sub‐ recipient’s progress on the project and an assessment of whether the sub‐recipient is meeting the objectives of the sub‐agreement.

3. **Approval of Purchase Orders.** In addition to following UNA’s process for purchase orders, <http://www.una.edu/purchasing/po-process.html>, the signature of the primary PI and Director of the Office of Sponsored Programs is required on all purchase order requests. Co-PI’s and/or administrative staff cannot be delegated as authorized signatories.

4. **Approval of travel requests.** Signature of the primary PI is required on all travel order requests. Co-PI’s and/or administrative staff cannot be delegated as authorized signatories.

If there is an immediate need for approval of a transaction, the OSP will accept an email from the designated PI, explaining why a signature cannot be provided and that the charges are allocable and allowable on the sponsored project. As soon as possible, the PI must sign a copy of the transaction (PAF, PO, p‐card, etc.) and forward to the OSP as documentation to support the earlier email.

The PI must maintain fiscal control of the sponsored project. The PI is expected to review budget and expenditure reports for his or her sponsored projects on a regular basis (monthly is suggested but not less frequently than quarterly) to detect any errors and irregularities.

**Tuition, Stipends and Other Student Payments**

The University of North Alabama will follow federal regulations under OMB Circular A-21 Section J.45 for the payment of student support (scholarships, fellowships, tuition, health insurance benefit and other student financial aid).

*Scholarships and student aid costs.*

*a. Costs of scholarships, fellowships, and other programs of student aid are allowable only when the purpose of the sponsored agreement is to provide training*

*to selected participants and the charge is approved by the sponsoring agency. However, tuition remission and other forms of compensation paid as, or in*

*lieu of, wages to students performing necessary work are allowable provided that --*

*(1) The individual is conducting activities necessary to the sponsored agreement;*

*(2) Tuition remission and other support are provided in accordance with established educational institutional policy and consistently provided in a like*

*manner to students in return for similar activities conducted in nonsponsored as well as sponsored activities; and*

*(3) During the academic period, the student is enrolled in an advanced degree program at the institution or affiliated institution and the activities of the*

*student in relation to the Federally sponsored research project are related to the degree program;*

*(4) the tuition or other payments are reasonable compensation for the work performed and are conditioned explicitly upon the performance of necessary*

*work; and*

*(5) it is the institution's practice to similarly compensate students in nonsponsored as well as sponsored activities.*

*(b) Charges for tuition remission and other forms of compensation paid to students as, or in lieu of, salaries and wages shall be subject to the reporting requirements stipulated in OMB Circular A-21 Section J.10, and shall be treated as direct or F&A cost in accordance with the actual work being performed.*

Tuition Remission:

Tuition remission and other forms of compensation paid as, or in lieu of, wages to students performing necessary work are allowable provided that the payment is:

1. for activities necessary to the sponsored agreement

2. provided in accordance with established institutional policy

3. for a student enrolled in an advanced degree program at the institution and the grant compensated activities of the student are related to that degree program

4. reasonable compensation for the work performed and conditioned upon

performance of that work

5. part of a consistent institutional practice to similarly compensate students in

non-sponsored as well as sponsored activities

Tuition remission costs do not have to be treated as employee salaries and wages for Internal Revenue Service purposes in order to be allowable as described above (OMB Clarification memorandum M-01-06).

Stipends:

A **stipend** is defined in the NIH Grants Policy Statement as “A payment made to an individual under a fellowship or training grant in accordance with pre-established levels to provide for the individual’s living expenses during the period of training. A stipend is not considered compensation for the services expected of an employee.” There are University departments that may apply the term “stipend” to other types of student payments. The substance and purpose of the payment, rather than the form or the name for it, are the factors that must be considered when determining allowabilty.

**Policy on Subrecipient Monitoring**

**Subrecipient Monitoring**

The University of North Alabama, as a prime recipient, is responsible for ensuring that all awarded project activity, including that of its subrecipients, is compliant with award terms and conditions and applicable federal regulations.

**Roles and Responsibilities**

***Principal Investigator (PI):*** Before selecting a potential subrecipient, the Principal Investigator (PI) should be aware of the “Codes of Conduct” section Subpart C.42 of OMB Circular A-110, at the following link http://www.whitehouse.gov/OMB/circulars/a110.html#42. It is the PI’s responsibility to ensure that there is no conflict of interest in the sub-award to a subrecipient, as sub-awards should not be authorized to subrecipients where the PI has ownership, substantial equity, and where he/she will receive individual gain from such arrangement.

The Federal Government places primary responsibility for management of federally funded projects with the PI. This includes monitoring of subrecipients, particularly the subrecipient’s technical and programmatic activities. The PI is responsible for verifying the subrecipient work is conducted in a timely manner and that the results delivered are in line with the proposed statement of work. Other responsibilities include reviewing and approving subrecipient invoices (reviewing expenditures to ensure allowability, allocability and reasonableness of cost and ensuring charges are within the period of performance) and maintaining regular contact with the subrecipient.

***The Office for Sponsored Programs (OSP):*** OSP is responsible for the oversight of subrecipient monitoring. These responsibilities include, reviewing whether a subrecipient or vendor relationship exists; determining whether or not the subrecipient or its PIs are debarred or suspended from receiving Federal funds; including identification of federal awards in subagreements; advising subrecipients of requirements imposed on them; requiring subrecipients to permit access, as necessary, to their records; monitoring activities of subrecipients, as necessary, to ensure compliance; ensuring that subrecipients subject to OMB Circular A-133 are in compliance with its requirements and reviewing and following up on the results of those A-133 reports; assessing the potential risk associated with subrecipients and taking necessary action if a subrecipient is determined to be a high risk (such as, pre-award audits, monitoring during the contract, post-award audits or requiring documentation to support invoices).

**Vice President for Business and Financial Affairs (VPBFA) :** VPBFA is responsible for ensuring that UNA has received a fully executed subagreement before any payments are made to the subrecipient; invoices are within the period of performance; charges (expenditures) add correctly on subrecipient invoices and that charges appear to be on a cost reimbursable basis and not based on allocation of budget; F&A (IDC) calculates correctly, if applicable; cost share is included in the invoice, if required; invoice is certified/signed by subrecipient officials; PI has reviewed invoice and signed approval form, verifying that the subrecipient is performing as expected and required progress reports have been received; final invoices are marked final and that a subcontractor release form is received; and post award audit of any expenditures that do not appear allowable, allocable, and/or reasonable.

**Related Policies**

**Faculty Development Leave, Sabbaticals and External Grants and Contracts**

Faculty on research development leave or research sabbaticals are eligible for compensation as discussed in ‘*Time and Effort Reporting*’. Faculty cannot be dually compensated during the same time period for performing equivalent tasks from two separate funding sources.

See Faculty Handbook for policy on Faculty Development Leave; http://www.una.edu/administration/handbook/

**Indirect Costs (IC) and Residuals – Internal Allocation and Uses**

At the completion of the grant, accrued indirect costs monies will be allocated as follows:

50% to the VP Business and Financial Affairs

10% to the Office of Sponsored Programs

15% to PI(s)\*

15% to the Primary/Designated PI’s Department\*

10% to the PI(s) Dean\*

Once the OSP has verified that all monies have been received and all expenditures cleared, indirect funds will be distributed as above. In addition, the PI(s) will receive a one-time notification of the amount of the fund distribution. In cases where a sponsored program was comprised of multiple PIs, indirect costs monies will be allocated in accordance with time and effort.

On multi-year awards, IC will be credited to the parties, at the end of the previous year closeout. Multi-year is defined as those awards funded by the agency for a period longer than 1 year, and where UNA’s assigned fund number is continuous throughout the life of the award. IC will be credited at the end of the fiscal year.

PIs will have two years to expend indirect costs monies. Indirect cost monies not expended within two years of the disbursement date will revert back to the OSP. These funds will be used to support internal research awards following guidelines set forth in ‘*Internal Research Awards*‘

PI’s requesting disbursement of indirect cost monies must complete and submit ‘Indirect Cost Form’ to the Office of Sponsored Programs.

Indirect costs monies can be used to support continuing research efforts including conference participation, travel, data collection, equipment, and software. Indirect cost monies cannot be:

a. Paid out as salary or stipends.

b. Used for course buyouts.

c. Used as matching funds.

d. Used to pay for expenses that directly support a current active grant.

e. Used to supplement funding on a current active grant.

\*Department indirect costs are for department use in care of the Chair. Departmental funds are to be used by the chair for the professional development of all faculty within the department.

**Residuals**

Residuals – are those funds awarded and pre-paid to the University, but not expended, and which the funding agency does not want remitted. Any funds remaining at the end of the period of performance, will be placed in a residual fund. The PI will be notified of the amount of the residual and can use those funds strictly as it relates to the original grant contract. Examples include conferences, training, continued data collection ect..

Residual funds not expended within two years of PI notification will be allocated to the Dean of the PI’s college. These funds are to be used to support faculty research and development efforts.

**Patents, Copyrights, Intellectual Property, and Commercialization**

Patents, copyrights, intellectual property, and or product commercialization originating from a sponsored research program shall adhere to the policies prescribed in UNA Faculty Handbook, <http://www.una.edu/administration/handbook/>.

**Equipment**

All equipment purchases in excess of $5000 are considered capitalized assets. Refer to the Office of Procurement Website http://www.una.edu/purchasing/ for the specific policy regarding inventory control. PI’s must verify that all equipment purchases using external funds adhere to UNA’s policies in this matter. Refer to the Controller’s Office for specific policy information; <http://www.una.edu/controller/>.

In the event that equipment, stipulated for use in conducting research, is loaned, stored, shared, or is not physically located on UNA property, a signed Memorandum of Agreement (MOA) between the Vice President for Academic Affairs and all relevant stakeholders must be submitted to the Office of Sponsored Programs. The MOA must stipulate the terms of the equipment loan, storage, and or sharing, including effective time period, storage, maintenance responsibility, rental fees (if any), purpose of equipment with respect to research tasks, and the conditions for returning equipment to the rightful owner.

If property insurance must be adjusted for any period of time to accommodate the additional value of contents, the PI must notify the Director of Facilities with the appropriate value of equipment, depreciation terms, expected life on campus (if applicable) and location. Upon movement to a different location on campus or removal from campus, the PI must notify the Inventory Control Analyst located in the Office of Procurement. The Inventory Control Analyst will notify facilities of the removal of property when applicable.

**Data ownership and Retention**

The University of North Alabama has both rights and responsibilities for the retention of research or other data acquired or developed as a result of a grant, contract, or other sponsored agreement. Accurate and appropriate research and programmatic records are an essential component of any research or sponsored project. The University and the Principal Investigator/Project Director (PI) have responsibilities and rights concerning access to, use of, and maintenance of original data including scientific data. Except where precluded by the specific terms of sponsorship or other agreements, tangible research or sponsored project property, including all data and other records conducted under the auspices of UNA, belong to UNA. Furthermore, data produced from federally sponsored research are increasingly subject to requirements not only from the OMB Circular A-110 Section 36(d) Intangible Property and Section 53 Retention and Access Requirements for Records but also from 45 CFR, as amended by 56 FR 28003 Use of Human Subjects in Research.

**II. APPLICABILITY**

This policy shall apply to all UNA faculty, staff, students and any other persons at UNA involved in the design, conduct or reporting of research or sponsored projects at or under the auspices of UNA, and it shall apply to all research or sponsored projects on which those individuals work, regardless of the source of funding for the project. UNA must retain research and sponsored project data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy and compliance with laws and regulations governing the conduct of the research or sponsored project. It is the responsibility of the PI to determine what needs to be retained under this policy. Where research or a sponsored project is funded by a contract with UNA that includes specific provision(s) regarding ownership, retention of and access to technical data, the provision(s) of that agreement will supersede this policy.

**III. DEFINITION**

Research and sponsored project data include laboratory notebooks and field notebooks as well as any other records that are necessary for the reconstruction and evaluation of reported results of research or a sponsored project and the events and processes leading to those results, regardless of the form or the media on which they may be recorded. Furthermore, the term includes software (computer programs, computer databases and documentation thereof), and records of scientific or technical nature. In practice scientific data include both intangible (statistics, findings, conclusions, etc.) and tangible data.

Tangible data include but are not limited to notebooks, printouts, computer disks, photographs, slides, negatives, films, scans, images, videotapes, autoradiograms, electrophysiological recordings, gels, blots, spectra, samples, specimens, IRB consent forms, research reports, analytical results, analysis, data contained in theses and dissertations and all other materials that are relevant to the research or sponsored project.

**IV. OWNERSHIP AND ACCESS**

A. The University's ownership and stewardship of the scientific record for research and sponsored projects conducted at UNA, under the auspices of the UNA, or with UNA resources is based on both regulation (OMB Circular A-110, Sec. 53) and sound management principles. UNA's responsibilities in this regard include, but are not limited to:

1. complying with the terms of research or sponsored project agreements;

2. ensuring the appropriate use of animals, human subjects, hazardous, biological, chemical materials, and the like;

3. protecting the rights of students, postdoctoral scholars, and staff, including, but not limited to, their rights to have access to data results from research or sponsored projects in which they participated;

4. securing intellectual property rights; and,

5. facilitating the investigation of charges, such as scientific misconduct or conflict of interest.

B. Both the PI and UNA have responsibilities and rights concerning access to, use of, and maintenance of original research or sponsored project data. Research or sponsored project data belongs to UNA. UNA can be held accountable for the integrity of the data even after the PI(s) has left the university. Although the primary data should remain with UNA where it originated, consistent with the precepts of academic freedom and intellectual integrity, the PI may be allowed to retain copies of the research records and materials created by him/her. Also see Section VI below.

C. Where necessary to assure needed and appropriate access, UNA has the option to take custody of the data in a manner specified by the Vice President for Academic Affairs. When a collaborative team is dissolved, UNA will allow each member of the team to have reasonable access to the data and materials with which he/she had been working, unless some other agreement was established at the outset. The unique materials prepared in the course of the research or sponsored project should be available/accessible under negotiated terms of a transfer agreement.

**V. COLLECTION AND RETENTION**

A. The retention of accurately recorded and retrievable research or sponsored project data is of utmost importance for the progress of scientific integrity. The PI is responsible for the recording, collection, management, and retention of research or sponsored project data. These records should include sufficient detail to permit examination for the purpose of replicating the research or sponsored project, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions.

B. PIs should adopt an orderly system of data organization and should communicate the chosen system to all members of a research or sponsored project group and to the appropriate administrative personnel, where applicable. Particularly for long- term research or sponsored projects, PIs should establish and maintain procedures for the protection of essential records in the event of a natural disaster or other emergency.

C. The experimental notebook and field notebook are the most common mediums for documentation of experiments and field work and their proper maintenance is of utmost importance. In addition to the study title, the investigator’s name(s), and

the study hypothesis, the experimental notebook should include detailed

information on the materials used, sources of the materials, experimental methodology, statistical treatments, results and conclusions so as to enable replication of the experiments by others at any time. In the event that it is not possible, explicit instructions as to where the data can be found (e.g. location of disks, samples, specimens, etc.) should be included in the notebook.

D. For studies involving several investigators/collaborators, possibly in more than one setting, it is recommended that the PI of record maintain a master log that catalogues the experiments of the whole study and provides the location of other experimental and/or field notebooks, data, and relevant materials stored in other locations.

E. There are state and federal regulations prescribing the length of time researchers must maintain the original data. The times required to retain data vary from three to seven years depending on the governmental organization. Unless a longer period is specified by the State of Alabama or the sponsor, research data should be kept for a minimum of three years after the project ends or, if funded research, three years after all of the final project close-out documents have been sent to the government. In addition, any of the following circumstances may justify longer periods of retention:

1. data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;

2. if any charges regarding the research or sponsored project arise, such as allegations of scientific, scholarly or financial misconduct or conflict of interest, data must be retained until such charges are fully resolved; and/or,

3. if a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

F. Beyond the period of retention specified herein, the destruction of the research or sponsored project record is at the discretion of the PI and his or her department. Records will normally be retained in the unit where they are produced. Research and sponsored project records must be retained on the UNA campus, or in facilities under the auspices of UNA, unless specific permission to do otherwise is granted in writing by the Vice President for Academic Affairs or his/her designee.

**TRANSFER OF SPONSORED PROJECT AND DATA IN THE EVENT A PI LEAVES UNA**

1. As grants and other external funds are awarded to the University, all externally funded projects will remain with the University unless otherwise negotiated.
2. In the event that the PI or other key researchers or project managers leave UNA, they may negotiate an Agreement for the Disposition of Research or Sponsored Project Data for projects on which they have worked. Original data, however, must be retained at UNA for the period specified in Section V.E. above.

1. A written Agreement on Disposition of Research or Sponsored Project Data may be negotiated by the PI or other key researcher or project manager and the Department Chair or Department Manager and approved in writing by the Dean and the Vice President for Academic Affairs or his/her designee to allow transfer of research records. Without an Agreement on Disposition of Research or Sponsored Project Data in place, no PI, other key researcher, or project manager may take data with him/her when he/she leaves UNA.

Agreement(s) on Disposition of Research or Sponsored Project Data will be kept in the Office of Sponsored Programs.

2. If a PI leaves UNA with a funded research project and the project is to be moved to another institution, ownership of the data may be transferred with the approval of the Vice President for Academic Affairs or his/her designee and with written agreement from the PI's new institution that guarantees:

a) the new institution’s acceptance of custodial responsibilities for the data; and,

b) UNA’s access to the data, should that become necessary.

3. All Agreements on Disposition of Research or Sponsored Project Data must include a provision that UNA has the right of access to all research records and materials for a reasonable cause after reasonable prior notice regardless of the location of the PI, other key researcher, or project manager for the period of time specified in Section V.E. above.

**TRAVEL AND PURCHASING POLICIES AND PROCEDURES**

Travel and purchases must comply with the funding agencies guidelines, the agency approved budget and UNA’s policies. UNA’s travel and purchasing policies can be found at <http://www.una.edu/controller/>.

**Relationship with the University of North Alabama’s Foundation**

All efforts to seek external funding through private foundations and corporations are coordinated with UNA’s Office of University Advancement and must be approved by the Vice President for Advancement upon consultation with the Vice President for Academic Affairs. This approval process is required to optimize benefits to the faculty, the University, and the Office of Advancement.

In cases where a funding agency requires external cost-sharing, the OSP and PI will coordinate proposal submission and budget approvals with the Office of Advancement. The Office of Advancement will have sole oversight over all proposal submissions awarded directly to Advancement and where no proposal budgetary line items fall under UNA’s adherence to Office of Management (OMB) guidelines.

**Time and Effort Reporting**

OMB Circular A21, *Principles for Determining Costs Applicable to Grants, Contracts, and Other Agreements with Educational Institutions,* outlines the regulations governing time and effort reporting and the verification of salary distributions.

Specifically, OMB Circular A21, Section (J)(10)(c)(2) (b) requires Time and Effort Reports to be completed to provide after the fact verification of the salary charged to sponsored projects: “[effort reports] will reflect after the fact reporting of the percentage distribution of activity of employees.”

Time and Effort (T&E) reporting is required by Federal regulations. These reports are used to certify the amount of labor expended on a federal grant corresponds to the salary allocated to the project.

The effort reporting process is a method for certifying that the effort expended is at least equal to the salary charged to sponsored awards. Activities included in T&E reports includes effort devoted to grants, contracts and cooperative agreements sponsored by non-University entities, i.e., state, local, federal governments, foundations, corporations, etc., for purposes of training, public service, clinical trials, and research. Per OMB A-21 “…Charges to sponsored agreements may include reasonable amounts for activities contributing and intimately related to work under the agreements, such as delivering special lectures about specific aspects of the ongoing activity, writing reports and articles, participating in appropriate seminars, consulting with colleagues and graduate students, and attending meetings and conferences ,***but NOT writing new funding applications…”,*** and includes mandatory and voluntary committed cost sharing (i.e. effort commitments made in proposal but funded by the University rather than by the sponsor).

A T&E reporting tutorial can be found at [**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)**.**  Questions regarding time and effort should be directed to the Office of Sponsored Programs.

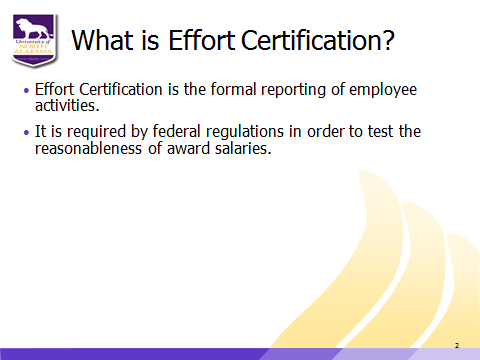
Outline of T&E Procedures:

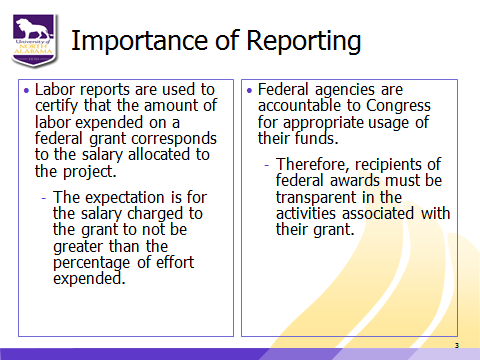
* At the end of each quarter, the OSP will complete on behalf of the PI the T&E Certification Report, (see example below )and forward to the PI for his/her review and signature.
* Within two weeks of receipt of the T&E, PI’s must return the signed T&E form along with a progress report justifying the level of effort to the OSP. The PI’s signature on the T&E report is a verification that the PI has reviewed and concurs with the level of effort reported in the relevant quarter.
  + - For sponsored projects with multiple PI’s, the primary PI must certify T&E for all co-PI’s. The progress report must address the aggregate level of effort.
* Progress reports must show evidence relating the hours of reported effort to progress made on the fund research. Evidence of progress must reasonably reflect all the activity for which an individual is compensated through UNA payroll. Method for documenting progress per OMB Circular A-21 is ‘a suitable means of verification that the work was performed and includes written documentation such as detailed calendars, log books, technical reports, survey instruments, or other written documentation.
* The OSP will complete a post review of T&E submissions to ensure compliance with federal and state regulations.
* T&E forms can be found at [**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)**.**

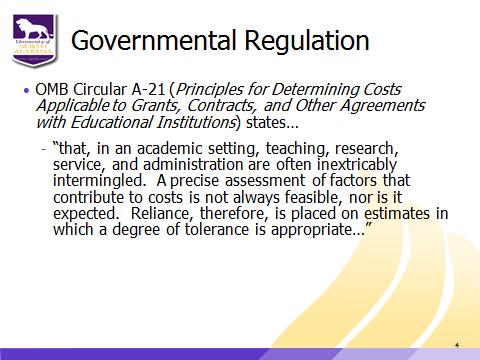


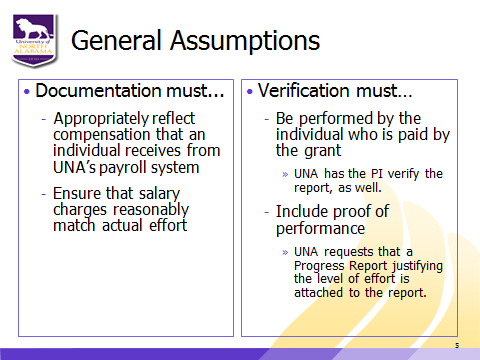
**Time and Effort Reporting Tutorial**

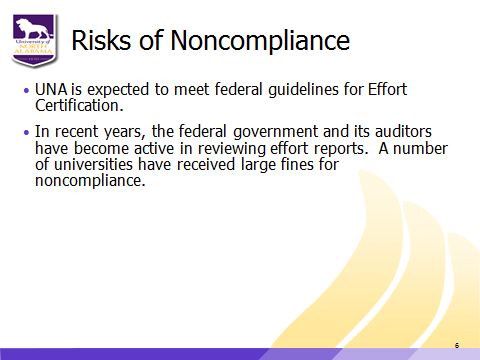
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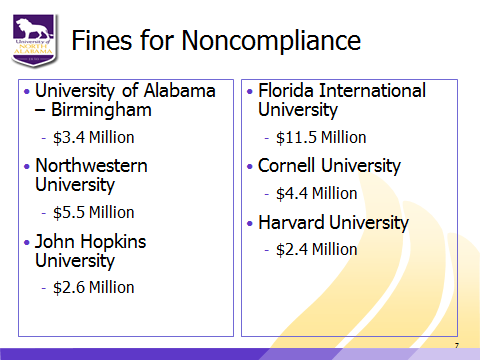
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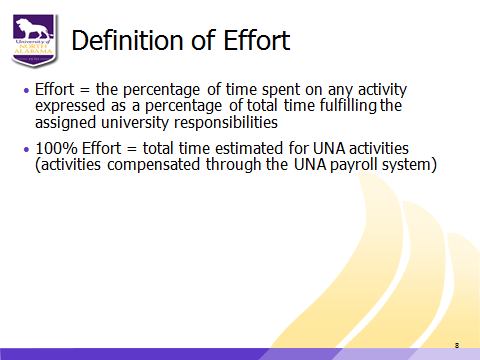
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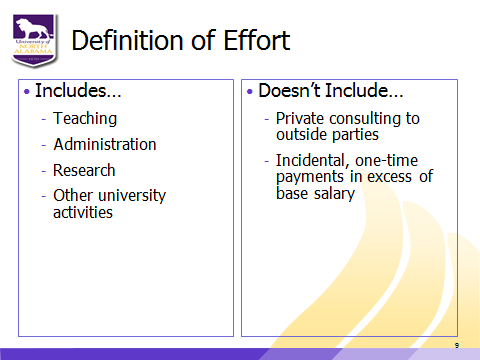
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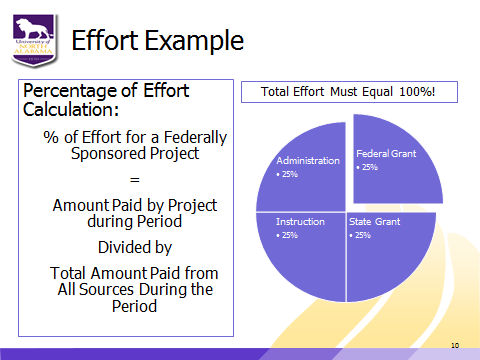
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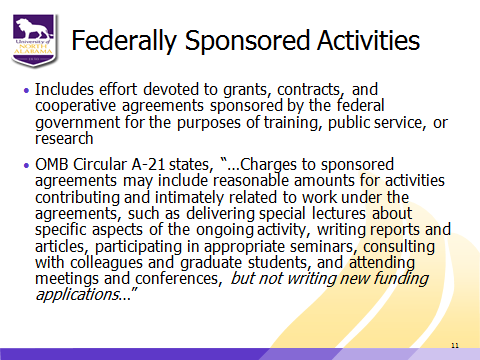
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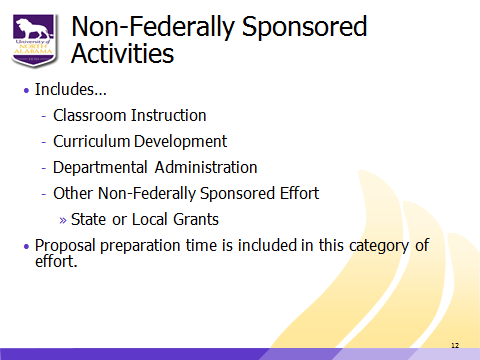
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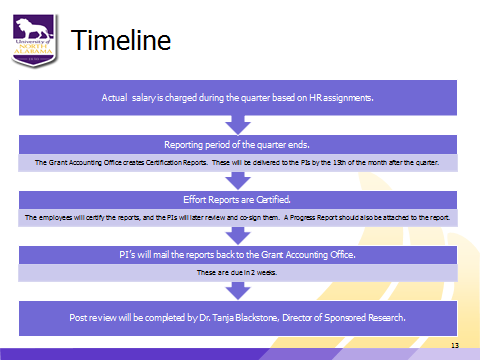
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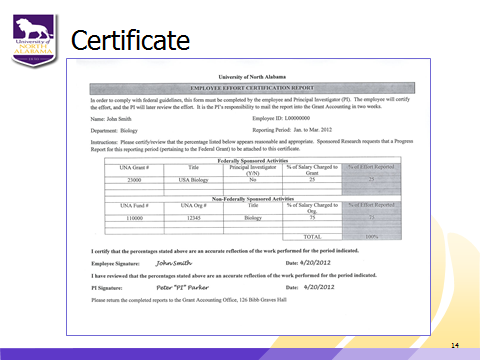
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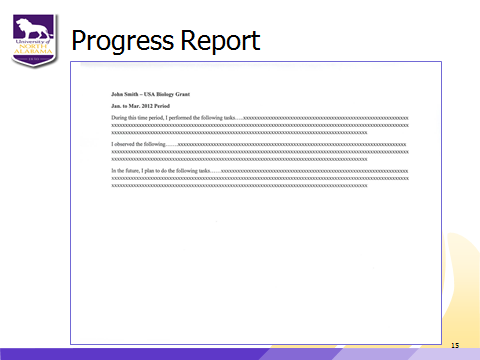
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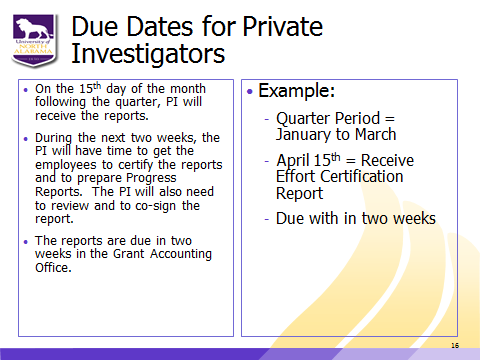
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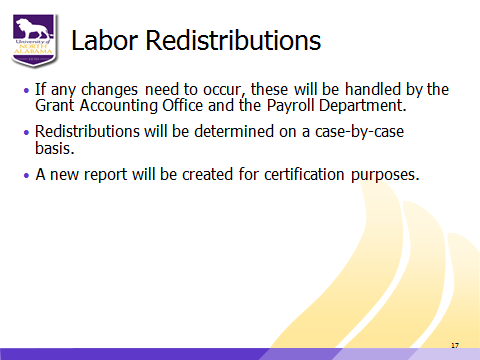
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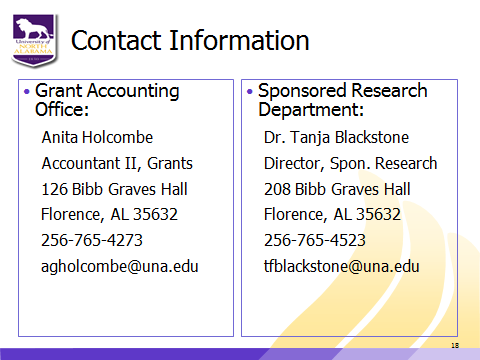
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**Use of Private Contractor or Consulting**

Periodically, sponsoring agencies require that the PI include in the budget a line item to support the use of external consultants or evaluators for a myriad of purposes. Once the PI has identified a qualified individual, he/she must submit to the OSP (a) Consultant Agreement and (b) Private Contractor Services Agreement. Examples of these forms can be found at [**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)**.**

Upon receipt of the forms, the OSP will negotiate and verify the terms of the agreement on behalf of the PI. The OSP will secure all necessary signatures and notify the PI once the agreement is in place. In order to ensure timely execution of any agreements, PI’s should provide a 30 day notification of this requirement to the OSP.

**UNIVERSITY OF NORTH ALABAMA**

**PRIVATE CONTRACTOR SERVICES AGREEMENT[[2]](#footnote-2)\***

The following agreement describes the terms and conditions for private contractor services to be provided to the University of North Alabama by the private contractor hereinafter named. This agreement, together with the detailed information provided in the referenced attachments (if any), constitutes the entire private agreement between the University of North Alabama and

hereinafter referred to as the contractor and supersedes all prior agreements, either written or verbal.

**Section 1 – Description of Services**

**Section 2 – Payment Rate and Terms**

**Section 3 – Additional Conditions or Terms**

Contractor is not an employee or agent of the University of North Alabama. Further, contractor agrees to indemnify, defend and hold harmless the University of North Alabama and its Trustees, Officers, and employees for and from suit, liability, injury or other loss arising from the acts of the contractor, whether as the result of negligence or otherwise.

The signatures below indicate acceptance of this agreement as of the date specified.

**CONTRACTOR** **UNIVERSITY OF NORTH ALABAMA**

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name: Name: W. Steven Smith

Vice President for Business & Financial Affairs

Tax #:

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_



**Internal Research Proposals and Awards**

One of the priorities of the Research Committee is to provide “seed money” for research projects that show potential appeal to external sponsors. Pending funding availability, UNA encourages faculty development and research through an internal research award program. Pending funding availability, the OSP will announce the availability of research funds, criteria for submission, and deadline for proposal submission. Proposal submission process, as outlined in ‘Proposal Submission and Award Guidelines’ enable University Research Funds to be leveraged maximally. All scholarly activities, in particular those for which little or no external funding is available, will receive equal consideration by the Committee.

**Proposal Submission and Award Guidelines**

Individuals interested in submitting a proposal must submit ‘*Application for Research Grant’* and a research proposal. Internal research proposal guidelines are provided below in *‘Guidelines for Final Research Grant or Contract Report’.*  Application and proposals must be submitted to the Office of Sponsored Programs electronically no later than 1630 of the application deadline. Individuals seeking assistance with proposal development are encouraged to contact the Office of Sponsored Programs.

Requests Considered for Support:

* 1. Scholarly projects expected to result in a publication or professional exhibition, and
  2. Requests aimed at equipping members with a research record on which they can base future requests for research funds from outside sources, and
  3. Requests for travel and/or *per diem*, or for creation or exhibition of innovative artistic products will be considered as they relate to the above priorities and available resources.

1. Who May Submit a Proposal:

Any full-time University faculty member with rank of instructor or above is eligible to apply for a research grant.

1. Requests not Considered for Support:

The Research Committee will not consider proposals for:

* 1. Preparation and writing of textbooks and other standard teaching material;
  2. Research projects having course development as the primary goal; and
  3. Preparation and editing of a scholarly journal.

1. What to Submit:

In addition to the application form, the following information is required:

* 1. A narrative that includes a complete, yet brief, research design of the project to be undertaken as well as justification for each item requested on the attached budget form. Narratives longer than eight double-spaced pages will not be considered;[[3]](#footnote-3)\* Research proposal should follow the guidelines provided in ‘*Guidelines for Final Research Grant or Contract Support*’.
  2. A short vita of the principal investigator(s) should be included;
  3. If human or animal subjects are to be used, or hazardous waste materials produced, evidence of clearance for your procedures from the appropriate University committee must be received by the Assistant Vice President for Academic Research before funding can be released.

1. When to Submit:

The specific deadline for receipt of proposals is announced three months before application deadline as determined by the OSP and the University Research Committee.

1. Where to Submit:

The grant application along with the proposal are to be submitted electronically to the **Office of Sponsored Programs.** Questions concerning the submission of proposals may be directed to the Chairperson of the Research Committee or to any of its members.

1. Review of Proposals by the Research Committee:

The Committee reviews each request individually, assessing the merits of each proposal. (At times the Committee may call upon other faculty members and/or University administrators for assistance in reviewing the merits of research/creative work applications). The Committee also reviews the application on the basis of costs as they relate to the project and the availability of resources.

Proposals will be evaluated based on the following criteria:

1. Purpose of the Project (Objects: specific and attainable)
2. Significance of the Project (Contribution to discipline or genre).
3. Procedures/Design Appropriate for objectives (subjects, site, tools, time frame, type of analysis or evaluation planned).
4. Skillfulness/Creativity-Review of Literature or Genre Development-Bibliography (Previous Research/Theory Base).
5. Intended use of Study Results (Expected Outcomes and Dissemination).
6. Applicant’s qualifications to achieve stated research objectives.
7. Notification of Applicants:

Applicants will receive the results of Committee evaluations from the Chairperson of the Research Committee via e-mail or telephone within 90 days of the submission deadline.

The recommendations of the University Research Committee will be forwarded to the Office of Sponsored Programs for final action.

1. Grant Management:

All University-supported research/creative work projects are administered in accordance with established University fiscal procedures and research policies. These include (but are not limited to) all travel expenses, purchasing, and regulations relating to the protection of human subjects, animals, and hazardous material.

Upon completion of a University-supported project, a final written report[[4]](#footnote-4)\* must be filed with the Office of Sponsored Programs within 30 days of the project completion date. If the grant extends beyond the allotted time-frame, a progress report must be completed and submitted.

All publications, exhibitions, or performances must acknowledge the support of a University Research Grant from the University of North Alabama.

**GUIDELINES FOR**

**FINAL RESEARCH GRANT OR CONTRACT REPORT**

1. **Report Format and Submission** 
   1. Length of report is limited to no more than 8 double-spaced pages.
   2. Report must be submitted to the Office of Sponsored Programs by date determined by the University Research Committee.
2. **Elements and Themes Common to Final Grant and Contract Reports:**

The following provides a brief outline of some of the elements and themes contained in the final grant or contract report:

* 1. Brief Statement of the Problem or Rationale of the Need for this Project
  2. Brief Statement of the Proposed Approach to the Problem or Opportunity
  3. Outcomes of the Project:
     1. Specific objectives accomplished (What was done?);
     2. Cost/benefit analysis (How well was it done? Did benefits outweigh costs? Was this a prudent investment?); and
     3. Value-added accomplishments (Were there any additional or unexpected benefits?).
  4. Problems and Difficulties Encountered;

* + 1. “Lessons-Learned” from these problems and difficulties (What would you do differently with 20/20 hindsight? How have you benefited by the experience? What might help others facing a similar challenge?); and
    2. Creative solutions employed to overcome problems and difficulties (How were problems accommodated or resolved? Were there any problems that could not be corrected?).
  1. Implications of the Project:
     1. Value and importance of project (What is the project’s merit?);
     2. Potential dissemination (Does this project have any elements worthy of duplication elsewhere?); and
     3. Potential “spin-off” enterprises from this project (Does this project establish a foundation or provide direction for other projects?).
  2. Budget Reconciliation:

* + 1. Appropriations by line item;
    2. Expenditures by line item;
    3. Line item transfers(with justification); and
    4. Ending balance.
  1. Summary and Conclusions.
  2. Appendices:
     1. Products generated by the project (e.g., publications, reports, photographs of artwork or other research and creative expressions);
     2. Data collecting instruments or evaluative instruments used to assess the project;
     3. Other evidence of project success (letters expressing participant satisfaction, letters of appreciation or congratulation, criterion or norm referenced outcome measure, press or media coverage, and other items indicating project success).

***Office of Sponsored Programs Compliance Policies:***

***Human Subjects, Animal Use Policy, Conflict of Interest, and Drug Free Workplace***

**Drug-Free Workplace**

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D, as amended) requires that all organizations receiving grants from any Federal agency agree to maintain a drug-free workplace. By signing the*Employee Agreement to Drug-Free Workplace Requirements*

the University agrees that the grantee will provide a drug-free workplace and will comply with the requirement to notify the funding agency if an employee is convicted of violating a criminal drug statute. Failure to comply with these requirements may be cause for debarment. HHS implementing regulations are set forth in 45 CFR Part 76, “Government wide Debarment and Suspension (Non-procurement) and Government-wide Requirements for Drug-Free Workplace (Grants).”

All faculty, staff, and students must provide a signed copy of the *Employee Agreement to Drug-Free Workplace Requirements*to the Office of Sponsored Programs prior to commencing work on any federally funded grant.

**University of North Alabama Drug and Alcohol Abuse Policy**

It is the policy of the University of North Alabama that the unlawful possession, use, or distribution of illicit drugs and alcohol by students and employees on its property, or as a part of any of the University's activities, is prohibited.

Students, faculty, staff, and service employees who violate a local, state, or federal drug or alcohol statute may be referred to the appropriate law enforcement officials for prosecution. Additionally, an individual who violates the law or the provisions of this University's drug and alcohol policy will be referred to the appropriate supervisor or student judicial bodies for appropriate disciplinary action. University-imposed sanctions may include suspension or termination. As an alternative to disciplinary action, the University may require an individual to complete successfully a drug or alcohol recovery program in an approved treatment facility.

An individual who has drug, alcohol, or related problems may voluntarily seek counseling and follow prescribed treatment without fear of recrimination. Assistance may be given in referring persons to various community agencies which are trained and equipped to treat persons with drug or alcohol problems. These referral services are available at the University Health Center for students and through the faculty, staff, or service employee's supervisor, department head or Human Resources Director for faculty, staff and service employees.

The provisions of this policy shall apply to all students and to all University employees, full-time or part-time, including professional and nonprofessional employees, as well as persons on the University Campus for any purpose.

The University Of North Alabama Board Of Trustees empowers the University President, or his administration, to administer this policy. The University President is further empowered to take all actions necessary to comply with the United States Department of Education Drug Free Schools and Campuses Regulations, as currently written, or to be promulgated in the future.

**Employee Agreement to Drug-Free Workplace Requirements**

In accordance with the federal Drug-Free Workplace Act of 1988, employees involved in the performance of a federal grant, on either a “direct charge” or “indirect charge” basis, must, as a condition of employment under the grant, agree to the following:

1. To abide by the terms of the attached University policy,
2. To notify the University of North Alabama in writing of any conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction.

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have received a copy of the policy and agree to the above.

(printed name)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Employee Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature Date

*Should a conviction such as the one detailed in item (2) occur, the University is required to notify the Commission, in writing within ten calendar days after receiving notice from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must: (a) provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, (b) take appropriate action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended, or, (c) require such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency, and (d) make a good faith effort to continue to maintain a drug-free workplace through implementation of its policy.*

**UNIVERSITY OF NORTH ALABAMA**

**POLICY ON THE USE OF HUMAN SUBJECT IN RESEARCH**

**Scope.**

This policy provides guidance on the use of human subjects in any activity at the University of North Alabama (UNA) deemed to be research, which is defined as a systematic investigation designed to contribute to generalizable knowledge. This policy applies to all entities of UNA (faculty, administration, staff, students, and contracted consultants) engaged in any research activity using human subjects that is directly or indirectly supported by UNA. The Human Subject Committee (HSC) of UNA will administer this policy.

UNA is committed to the responsible and ethical conduct of research and the protection of human subjects used in that research. In all work governed by this policy, the welfare of human subjects is considered preeminent and, along with full compliance with applicable regulations and institutional policy, takes precedence over specific research programs.

**Background.**

Proper attention to the protection of human research participants is of vital importance to UNA’s research activities. Ethical considerations form the foundation for protecting participants, and today regulatory law embodies the ethical review procedures for the vast majority of medical and behavioral research in the United States. This summary is intended to provide investigators with a synoptic overview of the ethical and legal approach to human research participant protections at UNA. Since federal regulation dominates the research landscape in this area, much of the material has general applicability.

A significant advance in the application of ethics to human research was the development of specific codes of ethics for research. The first and most widely known of these codes is the Nuremberg Code, which was published in 1947 following the trial of Nazi physicians for human research-related atrocities. Subsequently, other ethical codes for human research protections were developed such as the Declaration of Helsinki, the Belmont Report, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects. Links to these important publications on ethics in human research are available from the Office of Sponsored Programs Human Subject Research web page, Ethical Principles tab.

For its human research activities, UNA applies the ethical principles published in the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," authored by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report provides the ethical basis for the United States’ federal regulations pertaining to the protection of human research participants. The Declaration of Helsinki published by the World Health Organization has been adopted by many nations outside of the United States, and investigators doing international research at UNA should inquire about what ethical principles apply in the country where their studies are taking place.

The Belmont Report contains three basic principles:

* Respect for Persons
* Beneficence
* Justice

*Respect for persons* refers to a competent individual’s prerogative to make a knowing and voluntary decision to participate in human research without the threat of undue influence or coercion. Frequently termed the principle of autonomy, this principle demands that participants give informed consent. *Beneficence* refers to the concept of overall benefit to the participant. Whether or not beneficence is attained is determined by weighing both the potential absolute benefits and harms to the participants. Potential harm to research participants should always be minimized and, secondarily, benefits maximized. Generally, individual rights may not be sacrificed to achieve an overall societal good. The third principle, *justice*, refers to fairness. In the context of human research participation, this is frequently determined by whether the benefits to be gained from the research justify the burdens placed on the individuals studied.

Federal agencies have addressed human protections for research under their jurisdiction by promulgating regulations using federal administrative law. A federal regulation has the force and effect of law and when valid may preempt state laws. The major federal regulations pertaining to human research protections are the Federal Policy for the Protection of Human Subjects (The Common Rule, 45 CFR 46 Subpart A) adopted by several federal agencies; the Supplemental Protections for Pregnant Women and Fetuses, Prisoners, and Children promulgated by the Department of Health and Human Services (DHHS); the Food and Drug Administration (FDA) regulations on human subject protections; and the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations administered by the Office for Civil Rights in DHHS. In most instances, more than one set of these regulations apply to a research protocol; when this is the case, each set of regulations must be satisfied independently of each other. Links to these regulations are available from the Office of Sponsored Programs Human Subject Research web page, Regulations tab.

Under the regulations, all institutions receiving funds from any of the departments/agencies under the Common Rule are required to establish institutional review boards (IRB) to review and monitor all funded research involving humans. At UNA the IRB will be known as the Human Subject Committee (HSC). UNA shall review all research proposals involving human subjects, whether funded or not. It is UNA’s policy to apply the regulations to all research and research-related activities which involve human subjects.

To receive research funding from the DHHS, each institution must hold an assurance with DHHS to abide by its regulations for human research protections. The same requirement for agency assurance holds for research sponsored by other federal agencies that have adopted the Common Rule. UNA holds a federalwide assurance which is valid for federally funded research sponsored by any of the agencies requiring an assurance. UNA’s federalwide assurance is the institution’s written, binding commitment filed with the Federal Government that promises to comply with applicable regulations governing human subjects research and states the procedures which must be utilized to achieve compliance. Through its federalwide assurance, UNA applies the DHHS regulations for human research protections (45 CFR 46 Subparts A, B, C, D) to all applicable human research activities regardless of the source of funding for a study. In addition, UNA must satisfy the applicable FDA regulations on human subject protections and HIPAA regulations.

Finally, state law controls the legal age for consent. In Alabama, the age of majority is 19 years; therefore, an 18-year-old does not hold adult status and cannot be legally bound without parental consent. This differs from most states where the age of majority is 18 years. Confusion sometimes arises because in Alabama several exceptions exist that allow individuals under 19 to consent to medical treatment. For instance, Alabama statute §22-8-4 states that any minor who is 14 years of age or older may give effective consent to any legally authorized medical, dental, health, or mental health services for himself or herself, and the consent of no other person shall be necessary. This statute has not been applied to medical research activities per se even though it may apply to standard medical procedures within the context of a research protocol. Because of Alabama’s age of majority, UNA review of research protocols including 18-year-olds as eligible enrollees utilize DHHS and FDA rules for additional protections in children.

Public and federal emphasis on human research protections will likely intensify in the future, as evidenced by increased federal oversight and current emphasis on accreditation for human research protection programs. Having a good understanding of the overall framework for human subjects protection will assist stakeholders in the research enterprise to meet their responsibilities in this area. Infractions of the regulations could have very serious consequences. Not only could grant or contract support be withdrawn from a single offending project, but the host institution could lose all federal funding. Consequently, UNA takes the protection of human subjects very seriously for fiscal was well as ethical reasons.

**Glossary.**

**Adverse Event:** Any undesirable and unintended event that involves human subjects which could be reasonably related to participation in the study, regardless of whether it was listed on the informed consent document as an expected risk.

**Amendment:** Change to research protocol or supporting document after approval.

**Anonymous Data:** The identity of the respondent cannot be determined; no links exist between the data and the individual about whom the data are recorded.

**Assent:** Agreement to participate in a research study signed by research participants who cannot legally give informed consent (e.g., children) or do not have the capacity to give informed consent.

**Assurance:** The authority to conduct research involving the use of human subjects.

**Certification of Approval:** The official notification that a research project involving human subjects has been reviewed and approved by the HSC per UNA’s approved assurance and delegated approval authority.

**Coded Data:** Identifiers have been removed from the dataset under consideration but can readily be replaced through the use of a master list that is accessible to the investigator.

**Common Rule:** The regulation adopted by multiple federal agencies for the protection of human subjects in research. The overall guiding Department of Health and Human Services regulation is at 45 CFR Part 46.

**Confidential Data:** Data that contains information that would permit identification of the individual(s) about whom the data were collected but is maintained in a manner that protects the information from release to unauthorized individuals.

**Consent:** See Informed Consent.

**Continuing Review:** A periodic administrative reevaluation of ongoing human subject research based on the requirements in 45 CFR 46.109(e), conducted at least annually on ongoing protocols.

**De-identified Data:** Identifiers have been removed from the dataset under consideration; links between the data and the individual about whom the data are recorded exist but are not readily accessible to the researcher.

**Exempt Research:** A specific research project that is both minimal risk and meets one of the criteria for exemption listed in the Human Subject Committee Review, Review Categories section below.

**Expedited Review:** A review of proposed research, modifications to protocols, or continuing reviews by either the Human Subject Committee (HSC) Chair or by one or more designated voting members of the HSC (rather than the full HSC) in order to facilitate approval prior to the next regularly scheduled HSC meeting without sacrificing protection of the subjects.

**Federalwide Assurance (FWA):** Assurance of an institution’s commitment to comply with federal regulations (45 CFR Part 46 and the Terms of Assurance) when engaging in non-exempt human subjects research. Granted by DHHS Office of Human Research Protections (OHRP), FWAs are recognized for research supported by DHHS and other federal departments and agencies that have adopted the Common Rule. UNA’s current assurance is available from the Office of Sponsored Programs.

**Generalizable knowledge:** The knowledge that is expressed in theories, principles, and statements of relationships that can be widely applied to our experiences. Generally, the term is used to refer to the intent to disseminate the research results and conclusions beyond an individual or internal group. Generalizable knowledge is usually created to share with other people, for example through publication of an article in a journal, presentation at a local or national conference, or preparation of a thesis or dissertation.

**Greater than Minimal Risk:** A probability and magnitude of harm or discomfort to a human subject exceeding that defined as minimal risk (as determined by the element or elements of greatest risk).

**Human Subject Committee (HSC):** UNA’s institutional review board established per 45 CFR Part 46 to review research under the authority of UNA’s current Federalwide Assurance to ensure the protection of the rights and welfare of human research subjects.

**Human Subject or Participant:** A living individual about whom an investigator (whether professional or student) conducting research obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information.

**Identifiable Data:** The identity of the subject can be determined directly (e.g., through a Social Security Number (SSN) recorded on the data collection instrument) or indirectly (e.g., by cross-referencing a unique identifier (such as a student identification number) on a data collection instrument back to the SSN or other identifier of the person with whom it was used).

**Informed Consent:** A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. Subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or agents thereof from liability for negligence. See also the Human Subject Committee Review, Special Consideration for Certain Human Subject Populations section below.

**Institutional Review Board (IRB):** A committee established per 45 CFR 46 to review research to ensure the protection of the rights and welfare of human research subjects. UNA’s IRB is the Human Subject Committee (HSC).

**Interaction:** Communication (oral or written) or interpersonal contact between researcher and subject.

**Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

**Investigator’s Agreement:** A pledge signed by all investigators and associate investigators on a research project in which they acknowledge their responsibilities for the protection of human subjects.

**Investigators (or Co-investigators):** Individuals who possess the required education, knowledge, skills, experience (credentials) to assist the Principal Investigator in the design and conduct of research.

**Minimal risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Non-compliance:** Deliberate or inadvertent departure from or failure to comply with federal regulations, UNA policies, or HSC requirements for the protection of human subject research; or deliberate or inadvertent deviation from an HSC-approved protocol.

**Principal Investigator (PI):** An individual who has primary responsibility for the design and conduct of a research project or task. The PI is an individual who possesses the required education, knowledge, skills, experience (credentials) to initiate, conduct, and oversee human subject research, and has completed the required training. PIs must be staff or faculty of UNA.

**Private Information:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). In order for the collection of such information to constitute human subjects research, the private information must be individually identifiable; i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**Publicly Available Dataset:** Data that are available to anyone regardless of occupation, purpose, or affiliation, and have legitimately attained such status; i.e., those individuals who are responsible for posting the dataset had legitimate access to the data and have employed the necessary mechanisms to ensure the privacy and confidentiality of the individuals about whom the data were collected. In general, while the use of such data may meet the regulatory definition of research, the definition of human subjects is not met because data about a living person is not obtained through interaction or intervention, and no private, identifiable information about a living individual is obtained.

**Research:** A systematic investigation to develop or contribute to generalizable knowledge, to include any project, task, test, experiment, evaluation, or similar undertaking. This includes activities undertaken where results are intended for, or contribute to, publication, distribution, or use outside of UNA or for future research activities.

**Risk:** The possibility of harm, discomfort, or injury (physical, psychological, sociological, or other) as a consequence of any act or omission resulting from participation in a research study. Risk can range from minimal to high.

**Training Requirements for Human Subject Research:** All investigators and research assistants involved in a human subject research project are required to complete the Protecting Human Research Participants training. A link to the training module is available from the Office of Sponsored Programs Human Subject Research web page Education and Training tab.

**Unanticipated Problem:** Any incident, experience, or outcome involving risks to subjects or others that is unexpected (in terms of nature, severity, or frequency), not foreseen, or not previously described in the research protocol or informed consent form.

**Human Subject Research Determination**

When is a human being a subject of research? The borderline between being a human being with whom we work, play, and exchange information and being a human subject of research is not a line at all. It is a misty frontier. Seeing the boundaries and knowing when to treat a human being as a human subject of research requires keen judgment on the part of the PI. In general, UNA prefers to make the judgment on the conservative side, treating most doubtful cases as involving human subjects. By doing this, careful thought is given to ensure protection of the rights of people participating in the research.

All research involving human subjects must be reviewed by the HSC. To help a PI decide if a planned study activity meets the criteria of being human subject research, two concepts must be applied: (1) what constitutes research, and (2) how is participation of human subjects defined.

**Definition of Research**

According to the regulations, research is any systematic investigation designed to develop or contribute to generalizable knowledge. Any activity that meets this broad criterion and that is conducted by UNA faculty, administration, staff, students, and contracted consultants or that uses UNA facilities is research for the purposes of this discussion. It does not matter whether the activity takes place within and as a part (however large or small) of some other activity, such as a demonstration or service program, or whether the research is the whole of a project.

**Some tests for research:** When dealing with data gathering within the context of training, demonstration, or service projects, the PI should examine several questions to determine if any aspect of the work is research as it might be related to human subjects review:

* Will you seek out subjects (or settings that contain subjects) for your training, demonstration, or service project, rather than the subjects seeking the service or training from you in their normal pursuit of professional services?
* Do you anticipate (in advance of conducting the project) that you will analyze, interpret, and disseminate the findings of your investigation?
* Might the knowledge you will gain from your encounter with the subjects be applied beyond the service or training project to similar encounters so as to lead to a new procedure or process?
* Will the project employ invasive procedures? (An invasive procedure is a medical procedure in which part of the body is entered, as by puncture or incision, which might alter the normal physiology of the person)
* Will the project use subjects that are minors (under the age of 19 in Alabama)?

If the answer is “Yes” to any one or more of these questions, then the training, demonstration, or service project has a research component.

**Some instances not considered research:** There are numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations. Here are some examples:

* Data gathering for classroom training in research methods for which the only foreseeable purpose is teaching. In other words, neither the instructor nor the student can foresee or anticipate any dissemination of the data gathered beyond the classroom situation. The assumption here is that the classroom training method does not employ invasive procedures; otherwise, the data gathering will be considered to be research under this policy.
* Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to improve services or operations. In other words, no dissemination of the information outside the unit or institution is foreseen or anticipated.
* Evaluation data gathered for a contractor about a project or operation for which the contractor is responsible, if neither the researcher nor the contractor intends or anticipates the dissemination of the data. (Note: In general, evaluation data gathering for federal and state agencies usually results in reports to the agency that is public record, and such reports constitute public dissemination of the information.)

All these categories of data gathering fail to meet the definition of research because there is no foreseeable dissemination of the data. Any record of the data (or interpretations and analyses of the data) remains private, used only for purposes that are appropriate to the class, institution, or agency in the normal conduct of its work.

**Definition of Human Subject Research**

Regulations define a human subject as a living individual about whom an investigator obtains either (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention generally includes both physical procedures by which we gather data (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Much more common are interactions which include communication or interpersonal contact between the investigator and the subject. Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place. Thus, the individual will have provided the information for specific purposes and can reasonably expect that the information as associated with his or her identity will not be made public.

Figure 1 provides a quick-reference decision tree for determining if a project is human subject research and must be submitted to the HSC for review.

**Figure 1. Does My Project Require HSC Review?**

***Research*** is a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

**Does your project involve a *systematic investigation* or collection of information?**

**YES**

**NO**

**NO**

**Does your project have potential to contribute to generalizable knowledge (e.g., through presentations or publications)?**

**STOP!  
Project does not meet definition of research. No HSC approval  
needed.**

**YES**

***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) information, specimens, or other data through intervention or interaction with the individual, or (2) identifiable private information.

**YES**

**NO**

**Does your research involve interaction or intervention with one or more living human individuals?**

**Will your research involve obtaining private information about living human individuals?**

**NO**

**STOP!  
Project does not meet definition of human subject. No HSC approval  
needed.**

**Your research must be submitted for approval to the HSC.**

**YES**

**Some forms of interaction in research:** The idea of interacting with a human being is perhaps the key idea in determining whether or not he or she is a subject with respect to the regulations. All forms of interaction are included by the regulatory definitions. Among the most common are these types of research interactions:

1. Mail or electronic questionnaires or surveys;
2. Personal interviews, structured or unstructured, with or without recognized instruments;
3. Personal (i.e., face-to-face) surveys;
4. Telephone interviews or surveys;
5. Classroom instruments, evaluations, or exercises;
6. Examination of private records (e.g., medical, psychological, or school records); and
7. Observations of public behavior by identifiable individuals (e.g., in a classroom).

Remember that there may be non-research occasions for all these forms of interaction. However, if the context of the interaction is research, as discussed above, then the project that includes any of these modes of interaction calls for submission of an HSC review form.

**Common forms of research requiring submission:** Many of the types of interactions on the list of common forms of research present little, if any, risk to human beings but nevertheless require either review or certification of exemption, simply because they are research and have human subjects. Some of the more common types of these are:

1. Oral history;
2. Case studies of events or individuals, if interviews are involved;
3. Workplace and school observations, whether activities are controlled or uncontrolled; and
4. Surveys for information, attitudes, opinions, and similar matters for publication or for reporting to a federal, state, or local government agency.

Included on the list are surveys seeking information. Many types of information are sought from one or more people via surveys, some of which does not seem to fit the part of the definition of a human subject that specifies a subject as an individual about whom the investigator obtains information or data. Rather, in many cases, individuals surveyed are colleagues from whom—not about whom—information is obtained. One of the questions HSC will often face concerns where, if anywhere, to draw a line between the two types of surveys. The idea of a survey used here is to include any form of systematic data gathering.

HSC recognizes the difficulty of drawing a hard and fast line in this matter. However, it equally recognizes that survey instruments, even those ostensibly designed to obtain “simple facts,” lend themselves to interpretation by the individuals who complete them. Often, surveys inadvertently implant viewpoints within questions. Some survey instruments ask for data that are not clearly or wholly public. The end result is that the completed survey instrument contains either explicit or implicit information about the individual who completes it or about his or her business or professional activities or situation. Consequently, virtually all survey research should be submitted for review or for certification of exemption from review. Only where a survey instrument (formal or informal) obtains data that exist in the public record and constitutes merely an easier way to obtain the data can the instrument be considered, in strictest terms, one that obtains information from individuals with no inherent potential for obtaining information about them. Such instruments use the individuals to whom they are sent essentially as librarians.

Submitting all survey research for certification of exemption from review is far simpler than any other method of verifying the non-private, non-personal, nature of a survey, such as submitting survey instruments to experts in instrument design who are qualified to ascertain that no explicit or implicit information about the subject will be obtained through the use of the instrument. Even if one were to opt for such an alternative procedure, UNA would need to know, for the record, that such an inspection of instrument design had occurred. Submission of an HSC review form eliminates the need for such steps and assures UNA that inquiries from outside about human subjects’ interactions will not come as a surprise.

**Federalwide Assurance (FWA) Number**

The Federalwide Assurance of Compliance (FWA) is the contract which the University of North Alabama has signed with the federal government allowing research involving human subjects to take place. The terms of the FWA can be found at <http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html>. The Office of Sponsored Programs is responsible for renewing the FWA. A copy of the FWA is available from the Office of Sponsored Programs.

**Human Subject Research Review Guidelines**

Once the PI has determined that a protocol is research involving human subjects, the protocol must be submitted to the HSC for review among these three categories using criteria as indicated.

**Review Categories (Exempt, Expedited, Full)**

**Category 1—Exempt Research.** HSC determines protocol is exempt based on circumstances such as the following:

* Project involves collection of data through the use of opinion surveys, questionnaires or interviews (e.g., surveys of faculty instruction, marketing surveys, exit interviews) for which response is voluntary and completely anonymous. When data gathered concern issues of personal sensitivity (e.g., drug use, criminal behavior, sexual behavior), investigators should include in their project proposal how anonymity will be guaranteed.
* Project is limited to activities involving normal education practices in commonly accepted educational settings (e.g., in-class demonstration studies, laboratory exercises, studies of curriculum or teaching strategies). Usually, any study which requires that subjects be removed from their normal classroom situation for testing is not exempt.
* Project is limited to the observation of public behavior for which anonymity of subjects is maintained.
* Project is limited to the examination and analysis of existing data or specimens so long as these are publicly available and individual subjects will not be identified in any report of the research.

**Category II—Eligible for Expedited Review.**

The project does not meet the criteria for Category I and involves no more than minimal risk to the subject. *Minimal risk* is defined as risk of harm anticipated in the proposed research that is not greater, considering probability and magnitude, than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Projects that may qualify for expedited review include the following:

* Most laboratory investigations of cognition, perception, social behavior and personality.
* Any long-term investigation of the same individuals where identifying information (including coding schemes) must be maintained with the subject’s data (i.e., longitudinal studies).
* Studies that require the examination of existing data or specimens that are not publicly available.
* Studies involving the collection of voice or video recordings.
* Studies of healthy individuals involved in moderate exercise.

**Category III—Research Activities Subject to Full HSC Review.**

* Projects that do not meet the criteria for Category I or Category II because subjects will be exposed to *greater than minimal risk* (e.g., use of invasive techniques or unusual therapeutic techniques such as hypnosis).
* Projects requiring the use of deception.
* Projects requiring the use of subjects from populations in need of special protection (e.g., prisoners, mentally disabled individuals, pregnant women, and in some cases children). General information concerning research with populations requiring special consideration is included below. Assent and parental consent forms for children are included in this policy, but PIs doing research with other special populations must obtain additional guidance as to their consent to participation from the agency sponsoring the research.

**Special Consideration for Certain Human Subject Populations**

**Children**

Federal regulations require special protections for "children" in research. The protections are in 45 CFR Part 46 Subpart D and, as applicable, 21 CFR Part 50 Subpart D, and 34 CFR Part 97 Subpart D. However, the criteria that define "children" come from local laws and institutional policy. When research procedures are to be performed in another state, investigators should contact the Office of Sponsored Programs for assistance in obtaining guidance on meeting local requirements.

For research involving children, the HSC may require the investigator to obtain both assent from the child (agreement to participate in the research) and consent from one or both parents or guardians (agreement to allow the child to be a subject of research) depending upon level of risk inherent in the research. In general, assent from a person under the age of 19 (the age of majority in Alabama) is required for participation in research except under the following conditions. Mere failure to object should not, in the absence of affirmative agreement, be constructed as assent.

* Children under 6 years of age are assumed to be incapable of giving assent.
* Assent from children over the age of 6 may be waived by the HSC if the capability of the child to give assent is judged limited by age, maturity, or psychological state (e.g., mental retardation or psychosis).
* Assent from children who are over 14 years of age, or who have graduated from high school, or are married, or having been married are divorced or are pregnant may be waived by the HSC under certain circumstances where medical treatment is involved in the research.

Consent of one or both parents to allow a child to be a subject of research is required as follows. Guardian consent should be substituted for parental consent under appropriate legal constraints. Parental/guardian consent for children who are over 14 years of age, or who have graduated from high school, or are married, or having been married are divorced or are pregnant may be waived under certain circumstances where medical treatment is involved in the research.

* If the proposed research involves no more than minimal risk, or is of possible direct benefit to the child, then the consent of one parent is required.
* If the research involves greater than minimal risk without direct individual benefit, permission must be obtained from both parents unless there is only one reasonably available parent.
* The investigator may request a waiver of parental or guardian consent if the research design does not require such consent to protect the subjects (for example, neglected or abused children), provided an appropriate protection mechanism is substituted (to be assessed by the HSC).
* Special provisions must be made for children who are wards of the state or any other agency, institution, or entity to be included in research involving greater than minimal risk without direct individual benefit.

Investigators who propose research involving persons younger than 19 years of age must provide protocol-specific information about their involvement. The HSC must be able to determine that the proposed research meets the requirements of all applicable federal regulations. Links to assent and parental consent forms are included under the Research Proposal Submission Forms and Guidelines heading below.

**Cognitively Impaired**

Cognitively impaired persons are individuals who have a diminished capacity for judgment and reasoning due to a psychiatric, organic, developmental, or other disorder that affects cognitive or emotional functions. Other individuals who may be considered decisionally impaired are individuals under the influence of or dependent on drugs or alcohol, terminally ill patients, and persons with severely disabling physical handicaps. Capacity should be evaluated on an individual basis to avoid incorrect assumptions as to an individual’s ability to make decisions. In cases where research involving cognitively impaired individuals is reviewed, the HSC shall consider additional safeguards (e.g., involvement of subject advocates, independent monitoring, formal capacity assessment, waiting periods between consent and participation) as part of the research plan to protect participants. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance.

**Military**

It is recognized that military populations in general, and recruits in particular, may have reduced autonomy. Appropriate safeguards shall be employed to ensure that consent to participate in research is informed and voluntary. These safeguards will include not allowing the presence of Officers or senior Non-commissioned Officers at recruitment sessions of Enlisted personnel for greater than minimal risk research and other research as appropriate; ensuring that consent documents are written to be comprehendible to all potential participants; repeating in consent documents that the activity constitutes voluntary research, and providing ample opportunity to participants to have their questions and concerns addressed by investigators before signing the consent documents. In some instances, an independent ombudsman may be required to oversee the consent process. Before recruiting directly from a military unit, investigators must provide the HSC with written authorization to recruit subjects obtained from the senior level of that organization. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance.

**Pregnant Women, Neonates, Fetuses**

If the targeted research population is pregnant women, then the review of the research project would come under category III above. In this case, if any pregnant woman qualifies as a potential subject of research, either the activity must meet the health needs of the mother (while placing the fetus at risk only to the degree necessary to meet these needs) or the activity must present the fetus with minimal risk. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance.

If the research project does not specifically target pregnant women and the research activity presents only minimal risk (Category I above) to the research participant, then special precaution concerning the health of the mother and fetus are not needed.

**Prisoners**

In the instance of research using prisoners as subjects, the HSC will comply with all aspects of 45 CFR 46, Subpart C and shall ensure that a prisoner or prisoner representative is seated on the HSC, per requirements of 45 CFR 46.304. DHHS OHRP will be promptly notified when the HSC membership list is modified to meet this requirement. If the research protocol includes subjects in this population, contact the Office of Sponsored Programs for additional guidance. Research on prisoners of war is disallowed by Department of Defense directive.

**Students**

Student research and the use of students as research subjects are special considerations under this policy. Since this policy applies to all activities deemed to be research at UNA, it applies equally to students.

Class assignments primarily intended for educational purposes (e.g., to demonstrate how research is conducted) are not subject to HSC review so long as such assignments do not involve placing human subjects at more than minimal risk. However, any student research projects involving populations of special concern (such as pregnant women, fetuses, neonates, prisoners, persons with mental disabilities, children, or economically disadvantaged persons) will require HSC approval. If it is anticipated that the study will be publicly presented, and/or published, HSC approval must be obtained. Instructors are responsible for making the initial determination as to whether HSC review is required.

**Research with Secondary Data Sources**

Research with secondary data sources may call for data from confidential or privileged files. Among such files are school records, medical files, psychological files, attorney files, arrest records, and records held by social service agencies, such as DHHS. By virtue of law or established legal precedent, the data in these files are not open for public inspection without express permission of the file owner. In some instances (e.g., most medical and psychological records), the subject owns the record. In other instances, including school and many social service records, law or regulation forbids an agency or service-provider from disclosing the contents of the files without written permission from the subject of the file or from the subject’s parent or guardian. If the proposed research will involve these data sources and the anonymity of the subject is compromised, then a full review of the project is necessary.

Some research with secondary data sources falls into Category I and only needs to be certified by the HSC as exempt. Among the categories of exempt research is the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are either publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The provision appears to give the researcher the right to copy data from private files so long as he/she does not identify, either directly or indirectly, individual subjects. Even though these activities are exempt under the regulations, the researcher must still gain permission for initial access to the subjects’ files.

**Research Proposal Submission Forms and Guidelines**

**Application and Protocol Forms, Training Certificates and Investigator’s Agreement**

In order for the HSC to have adequate information on which to base their review of a proposed project, the investigator or instructor submitting a proposal must attach an application form providing descriptive information, written description of the project protocol, proof of completion of training requirements (automatically generated upon successful completion of the training session), and signed Investigator’s Agreements.

The protocol description must at a minimum specify the following:

1. The purpose and significance of the project including a statement of hypotheses to be tested and an indication of the theoretical, biomedical, and/or social significance of potential findings.

2. A description of the population of human subjects that will be used and a description of the procedures that will be used for recruiting subjects, for obtaining informed assent/consent (a copy of the proposed informed assent/consent form(s) must be attached), for assuring the confidentiality of their data and for debriefing the subjects, and safeguarding their well-being.

3. A description of the materials to which subjects will be exposed during the course of the study, procedures for conducting the study, and a description of the independent and dependent variables under study.

Application Form

Research Protocol Form

Investigator’s Agreement

All PIs, co-investigators, and research assistants working directly with human subjects, data, or specimens that can be linked back to individual human subjects (including exempt research) must complete the Protecting Human Research Participants training. A link to the module is available from the Office of Sponsored Programs Human Subject Research web page, Education and Training tab. Completed training certificates for all individuals must be submitted along with Human Subject Research Review Form and research protocol. PI training certificates are valid for the duration of the approved protocol, but not to exceed three years from the certificate date. PIs who submit certificates with their Protocol Submission Form due to expire during the approved protocol research period, must retake the training and submit an updated training certificate. Investigator’s Agreement forms signed by all investigators and research assistants must also be included with the application package.

**Informed Assent and Consent Forms and Guidance**

For most research involving human subjects at UNA, an informed consent form must provide the following information.

1. A fair explanation of the procedures to be followed, their purposes, and their duration.
2. A description of any discomforts, risks or benefits (if any) to be expected by the subject to himself/herself or others as a result of participating in the research.
3. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
4. A statement that participation is voluntary, refusal to participate will involve no penalty and that the subject may discontinue participation at any time without penalty.
5. An indication of whom to contact for answers to pertinent questions about the research.

For research involving children an assent form may also be required as described above. For projects involving experimental therapeutic procedures or more than minimal risk to subjects the above information may not be sufficient. Investigators should consult the Office of Sponsored Programs for additional information. For consent requirements for other special populations as described above, consult the Office of Sponsored Programs and/or the agency sponsoring the research.

Guidance for Obtaining and Documenting Assent from Children

Child Oral Assent Script

Child Written Assent Form

Parent Consent Form

Adult Informed Consent Form

**Data Security Plan Supporting Document**

Include a description in your protocol of the type of data to be collected. Attach as a supporting document the plan for storing, cataloging, and safeguarding that data per guidelines provided.

Data Security Policy Involving Research Data in Human Subject Research

Investigators are responsible for protecting, securing, and destroying data. UNA strongly recommends that data be stored on a UNA network storage share, biometric secured external hard drive, or encrypted laptop/desktop. You should contact Information Technology Services for assistance with any of these services. Data storage on external commercial websites is not recommended. Storage of data in paper format is not recommended. In cases where data is collected in paper format, investigators should convert hardcopies to electronic format or secure paper copies in a secured safe/vault.

Classified and Proprietary Data: Investigators must contact the Office of Sponsored Programs for any data (human subject or otherwise) if research data is designated as classified, secret, top secret, or proprietary by the sponsoring agency.

**Medical or Safety Monitoring Plan Supporting Document**

Medical or safety monitors are required for all studies classified as “greater than minimal risk” and other studies as stipulated by the HSC. Include with the protocol submission package a supporting document describing the training and relevant experience and the specific duties and responsibilities of the medical or safety personnel who will serve as monitor for the project. If the medical or safety monitor is not a UNA staff member, submit a curriculum vita that includes medical license number or other relevant credentials. Provide qualifications for other medical or safety support personnel. All support personnel dealing directly with subjects in studies of greater than minimal risk should have current certification in basic life support (BLS) and should be referenced in this plan. Append copies of BLS and/or Advanced Cardiac Life Support certifications to the protocol.

**Biohazardous Material Handling and Storage Plan Supporting Document**

All biospecimens collected by investigators should be handled and stored following the best practices available. To ensure proper stewardship of human biospecimens within UNA the Office of Sponsored Programs has developed guidelines for biospecimen storage and tracking. Attach a supporting document with the protocol describing the nature of any biospecimens to be collected, how those specimens will be collected, catalogued, stored, and disposed per the guidance.

Biohazardous Material Handling Plan Guidance – **Under Construction**

**Human Subject Committee**

**HSC Membership**

The HSC is composed of at least twelve members appointed by the Vice President for Academic Affairs or the President. Per the regulations, this committee shall consist of:

* Individuals (total of ten) with expertise in those fields which generate the most research proposals involving human subjects. A minimum of one person should come from each of the following fields:
  + Two (2) from Education and Human Sciences (early childhood, elementary, secondary, special, human environmental science);
  + Two (2) from Nursing and Allied Health (nursing education, nursing interventions, human biology);
  + Two (2) from Chemistry, Biology, or Physics;
  + One (1) from Business (management, marketing, accounting, computer information systems, economics, finance);
  + One (1) from Behavioral Sciences (psychology, child development);
  + One (1) from Social Sciences (social work, sociology, criminology, political science, communications, geography); and
  + One (1) from Health, Physical Education, and Recreation.
* Male and female representation.
* An individual not affiliated with UNA and not part of the immediate family of a person who is affiliated with UNA.
* An individual with primary concerns in non-scientific areas (e.g. English, History, Foreign Languages, Art, Music, Theater, Journalism).
* The University’s administrator in charge of academic research or his/her designee is a non-voting member.
* The Vice-Chair has the authority to act in the role of co-chair when required by federal grant regulations.

The members shall be appointed for a two-year term, may be reappointed, and shall be removed during their term only for stated cause. The Dean of Research shall annually appoint a chairperson of the HSC. The chairperson shall be a voting member of the committee.

The HSC will meet at least once a month during the regular academic semester to review proposals that require full committee review, should there be any proposals of that type pending. A schedule of the meetings will be announced at the beginning of the semester.

The HSC will be empowered to draft by-laws to ensure the orderly conduct of business. Once the HSC has been constituted, the by-laws that are developed will become an addendum to this policy.

**HSC Review Procedures**

To initiate a review, PIs must submit to the HSC Chair the Human Subject Research Review Application Form, protocol description, training certificate, investigator’s agreements, and appropriate supporting documents (consent/assent forms, data security plan, medical monitoring plan, hazardous material handling plan) described previously under this heading. Links to the forms are also provided above. The submission deadline is at least ten working days before the scheduled meeting of the Committee.

Upon receiving the application for HSC review, the HSC Chair will determine under which review category the research is classifiable. If the research is deemed to be exempt under the regulations, it will be certified by the Chair by memorandum to the investigator. Upon receiving the memorandum from the HSC Chair the investigator may proceed with the research.

If the research project is determined by the HSC Chair to present minimal risk to subjects, it is eligible for expedited review. The chair of the HSC, or some other member of the Committee designated by the chair, shall be empowered to perform expedited review, approving proposals, which appear to contain no more than minimal risk. However, in evaluating the project, the reviewer may find that it requires review by the full Committee.

All research which is not certified exempt or certified under an expedited review must be reviewed by the full HSC. In order for the Committee to approve a protocol, it must be determined that the proposed research using human subjects satisfies criteria applied to the following elements of the research: risks, risks vs. benefits, subject selection, informed consent, safety and privacy, and other legal and ethical considerations. A consideration of these review criteria is embodied in the guidelines for preparation of protocols and informed consent.

The results of the review will be forwarded to the applicant within five working days of the meeting of the full committee. The committee may take one of the following actions:

1. approve,
2. request minor modifications,
3. request outside consultant review, or
4. disapprove.

***The investigator shall NOT commence data collection until approval of the protocol is received in writing from the committee.***

**HSC Training and Education Requirements**

All members of the HSC must complete Human Subject Assurance Training Modules 1-3. Upon completion of the training, HSC members are required to submit the module-generated training completion certificate to the Office of Sponsored Programs. Human Subjects Assurance Training certificates must be renewed every two years. A link to this training is included on the Office of Sponsored Programs Human Subject Research web page, Education and Training tab.

**Rights of Appeal**

If a research proposal is disapproved, the investigator may resubmit the proposal to the HSC or appeal the decision. The appeal procedure will be established by the HSC and the hearing of the appeal will be independent of the HSC.

**Protocol Modifications**

Any changes to an approved research protocol, including but not limited to changes to research design, changes to research staff, changes to the assent/consent document(s), or changes to data collection instruments or methodologies must be submitted to the HSC for approval.

Modification of Approved Protocol Form

Any written instruments used in interactions with subjects (consent document, survey, recruitment script, etc.) that are changed must be submitted for review and date-stamping before being used.

The only exception to the requirement for obtaining HSC approval before implementing a change is where a change needs to be implemented to eliminate an apparent, immediate hazard to a subject in the course of the research. The investigator shall immediately notify the HSC Chair of this protocol deviation.

**Other Policies of the HSC**

* All communications with the HSC should be submitted to the Chair of the Human Subject Committee, Office of Academic Affairs, Bibb Graves Room 214.
* All protocols are approved for no longer than 365 days. If a project continues past 365 days, it is subject to a continuing review. See Continuing Review heading below.
* Problems arising at any point during the project involving the use of human subjects must be reported to the HSC. See Unanticipated Problems/Non-compliance Reviews heading below.
* At the conclusion of a project a memorandum must be filed with the HSC indicating its completion/termination and specifying any unexpected difficulties that occurred with the use of human subjects. See Completions/Terminations heading below.
* Informed consent forms must be retained by the investigator/instructor for a period of not less than three years following the completion or termination of the project.
* PIs are responsible for ensuring that all human subjects’ data is protected and stored in a secure location, until otherwise destroyed or properly disposed. Electronic storage of human subject’s data must be protected or encrypted. If the PI believes that the security of human subject’s data has been compromised, the PI must immediately notify the Chair of the HSC. See the Data Security Plan section above for further guidance.

**Continuing Reviews**

All protocols that have not been completed must be reviewed by the HSC within a period of not more than 365 days from the previous review. The HSC may set a period of less than one year for the next review as circumstances of the research warrant.

Continuing review must be substantive and meaningful and include all the elements of the initial review plus additional items, such as number of subjects enrolled, a summary of unanticipated problems/adverse events, a summary of recent literature in the research area and any pertinent research findings, any proposed modifications to the research, and new copies of the informed consent document and any recruitment materials for date-stamping.

If a continuing review does not take place during the preceding approval period, the HSC Chair shall inform the PI in writing that the approval period has expired and that all research must halt until re-approved for continuation.

Continuing Review Form

If the PI is proposing modifications to the research protocol (e.g., design, staff, assent/consent documents, scripts, sample size or population, or data collection methodologies) at the time of continuing review, the PI should also submit a protocol modification form.

Modification of Approved Protocol Form

**Unanticipated Problems and Adverse Events**

An unanticipated problem includes any untoward sign, result, event, misadventure, injury, dysfunction, adverse drug reaction, or any other undesirable happening or unanticipated problem that involves risks to subjects or others not previously reported, and that could reasonably be related to the activities of the study. Unanticipated problems of even questionable relationship to the research study should be reported to the HSC as relationships between incidents and research procedures may only become evident over time.

The PI must notify the medical monitor (if required in the study), Director of Sponsored Programs and HSC Chair of an unanticipated problem as soon as practicable (but no greater than five days) and in a manner appropriate to the gravity of the event. Unanticipated problems should be reported in writing to the HSC Chair and will be documented in all subsequent continuing review reports and in the completion/termination report.

All unanticipated problems and serious adverse events shall be reported in writing using the unanticipated problem report form. As soon as practicable the HSC will meet to consider the report and recommend whether the study should be continued (with or without revision), suspended, or terminated.

Guidance for Reporting Unanticipated Problems and Adverse Events

**Non-compliance**

All instances serious or continuing non-compliance with HSC requirements or instances of failure to adhere to the parameters of an approved protocol (whether deliberate or inadvertent) shall be reported in writing to the HSC Chair within five days for determination of appropriate actions.

Guidance for Reporting Non-compliance/Protocol Deviation

**Completions/Terminations**

A Completion or Termination Report to a protocol is prepared by the PI when data collection and all analyses of data have been completed. Typically this coincides with the end of a grant period of performance. A Termination Report will be required if the HSC disapproves continuation of a protocol approval.

Completion/Termination Report Form

**UNIVERSITY OF NORTH ALABAMA INSTITUTIONAL ANIMAL CARE AND USE**

**A. Introduction**

It is the policy of the University of North Alabama (UNA) that the vertebrate animals that are used by faculty, staff and students of UNA for research are treated with respect and should be cared for humanely and safely. To insure that the UNA policy for the humane and safe treatment of animals is met by all of its personnel, the president of UNA has established the UNA Institutional Animal Care and Use Committee (IACUC). The IACUC has the responsibility and the jurisdiction to oversee all vertebrate animal care and use at the University. Below are procedures and guidelines that should be followed by all university faculty, staff and students that are using vertebrate animals for research associated with UNA. To establish the UNA guidelines and procedures for the humane and safe treatment of animals, the UNA IACUC relies on the federal rules and regulations published in the *Public Health Service Policy on Humane Care and Use of Laboratory Animals,* [*http://grants.nih.gov/grants/olaw/references/phspol.htm*](http://grants.nih.gov/grants/olaw/references/phspol.htm)*.*

Any faculty, staff, or student planning on using vertebrate animals for the purposes of research, sponsored or otherwise, or classroom instruction are required to familiarize themselves and adhere to the federal laws and policies on animal welfare and use. Familiarization and adherence by faculty, staff, and or students to public laws and guides includes but is not limited to (a) ‘Public Law 99-158, Animals in Research’, (b) Public Law 103-43, Plan for Use of Animals in Research 1993, (c) [Animal Welfare Act (7 U.S.C. 2131 et. seq.)](http://www.nal.usda.gov/awic/legislat/awa.htm), and (d)[*Guide for the Care and Use of Laboratory Animals*](http://www.nap.edu/openbook.php?record_id=5140) prepared by the Institute of Laboratory Animal Resources, National Academy of Sciences.

Public laws and guides with respect to the care and use of laboratory animals and animal welfare can be found at [http//grants.nih.gov/grants/olaw/olaw.htm](http://grants.nih.gov/grants/olaw/olaw.htm),

<http://grants.nih.gov/grants/olaw/references/phspol.htm> and <http://grants.nih.gov/grants/olaw/references/phspol.htm#HealthResearchExtensionActof1985> .

**B. Specific responsibilities of the institutional animal care and use committee of the University of North Alabama.**

1. Review and investigate all complaints concerning the welfare and use of animals by faculty, staff and students at UNA.
2. Inspect all facilities that are used to house vertebrate animals for research
3. Review and approve the animal welfare aspects or all research and instruction at UNA; including all forms that request approval by the IACUC for the use of vertebrate animals for research at UNA.
4. Review UNA's program for the humane care and use of animals annually;
5. Prepare and submit reports of its evaluations to the Office of Sponsored Programs.
6. Make recommendations to the Office of Sponsored Programs regarding any aspect of UNA's animal program, facilities, or personnel training;
7. Suspend any activity involving animals that violates applicable regulations, policies, or procedures, or an approved protocol.

**C. IACUC Composition:**

The Committee will be comprised of members, including representatives of the public, qualified to oversee the animal program, facilities, and procedures. The committee must include at least one licensed Doctor of Veterinary Medicine and at least one faculty member with experience in animal use research or use of vertebrates in an institution of higher education. An additional three individuals will be appointed to the IACUC by UNA’s Shared Governance Committee and can be drawn from the public at large, UNA faculty and or staff. Length of committee appointments and committee structure will follow UNA’s Shared Governance Committee policies.

**D. Protocol Submissions and Guidelines for obtaining approval for the use of vertebrate animals for research from the IACUC.**

Prior to initiating, modifying, or extending any research project that entails animal use, Principal Investigators must submit an application to the Institutional Animal Care and Use Committee (IACUC) for review and approval. All protocols submitted to the IACUC for review must be received **30 working days** prior to commencing a research project or classroom instruction that uses vertebrate animals. .

1. Any member of the faculty, staff or student body at UNA that plans to use vertebrate animals for research are required to complete and submit for approval to the IACUC the following:
2. ‘Animal Use Review Form’
   1. By signing the ‘Animal Use Review Form’, the PI is certifying that he/she has read, understands and will comply with all federal and public regulations discussed in section ‘A. Introduction’ above.

UNA Research Animal Use Review Form can be found at **<http://www.una.edu/sponsored-programs/>.**

Approved proposals shall cover the use of animals in research or classroom activities for one year.

1. Reviews, Modifications and Terminations
2. Annual reviews are required of the approved animal use protocol. The ‘Annual Protocol Renewal/Termination Protocol Form’ must be submitted to the IACUC 30 days prior to the end date of the approved protocol.
3. Modifications and terminations to animal use protocols must be submitted to the IACUC, using form ‘Annual Protocol Renewal/Termination Protocol Form’. Modifications to approved animal use protocols cannot be implemented without approval of the IACUC.

The ‘Annual Protocol Renewal/Termination Protocol Form’ can be at [**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)**.**

**E. Procedures for reviewing and investigating all complaints concerning the welfare and use of animals used by faculty, staff and students for research, teaching, or exhibition at UNA.**

Any person concerned about the humane treatment and welfare of animals that are used for research, teaching, or exhibition at UNA can file a complaint with the UNA IACUC. Complaints can be submitted by mail to the Office of Sponsored Programs, ATTN: Tanja F. Blackstone, Director, POB 5041, UNA, Florence, Alabama 35632), or by e-mail (tfblackstone@UNA.edu) or by telephone (256-765-4523). When filing a complaint, include the following information:

a) Your name, address, phone number, e-mail.

b) Time, date, location of alleged incident.

c) If known, the name(s) of people involved with the alleged incident.

d) A brief description of the alleged incident.

*The identity of a person or persons making a complaint is kept strictly confidential.*

**E. Procedures for the inspection of all facilities that are used to house vertebrate animals for a period over 24 hours.**

1. Any facility that houses vertebrate animals for a period of 24 hours on a continuous basis must complete and submit an ‘Animal Housing’. The form can be found in at [**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)**.**  An approved ‘Animal Housing’ allows the facility to house animals for a period of up to three years, subject to routine inspections two (2) times a year, unless a change to the facilities or types of animals in the facility occurs.

2. The UNA IACUC will maintain a list of all sites and locations housing animals that are inspected. Inspections will be unannounced and occur once a year. Site inspections will use ‘Animal Use Review Form’ the form can be found at [**http://www.una.edu/sponsored-programs/**](http://www.una.edu/sponsored-programs/)**.**  Completed inspection forms should be displayed at the facility in a prominent location.

1. Facilities housing vertebrate animals for a period of over 24 hours and that are subject to facilities inspection must submit on an annual basis ‘Animal Housing’ and Animal Use Review’ forms to UNA’s IACUC.

**THE UNIVERSITY OF NORTH ALABAMA**

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

**Animal Use Review Form**

The institutional Animal Care and Use Committee is responsible for the welfare of "any live, vertebrate animal used or intended for use in research, experimentation, testing, training, or related purpose" if these animals are maintained at The University of North Alabama Animal Care Facility (ACF) or used under funds administered by The University of North Alabama.

**For Office Use Only:**

IACUC #: \_\_\_\_\_\_\_\_\_\_\_\_\_ Date Received: \_\_\_\_/\_\_\_\_/\_\_\_\_ Biohazard \_\_\_\_\_

Approval Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Radiation \_\_\_\_\_\_

Veterinary Consultation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

(PLEASE PRINT OR TYPE ALL ANSWERS)

**PRINCIPAL INVESTIGATOR:**

**TITLE OF GRANT/CONTRACT/PROPOSAL OR COURSE NUMBER AND TITLE:**

**FUNDING AGENCY/DEPARTMENT & ID NUMBER (if applicable):**

**PERIOD OF THE PROPOSED ANIMAL USE ACTIVITY:** [ \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_ - \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ ]

As specified in the Animal Welfare Act, the attending veterinarian or his designee must be consulted in the planning of your animal use activity. The attending veterinarian will provide medical care as necessary.

Name of veterinarian consulted: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_

Certification: I will comply with the procedures and methods descried in the NIH Guide for the Care and Use of Laboratory Animals (Pub. 85-23) and with PHS policy, the Animal Welfare Act, and Applicable University of Alabama policies. As Principal Investigator, I acknowledge responsibility for this project and assure that the faculty, staff, and students who participate in it are qualified (or will be adequately trained) to conduct it in a humane manner.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_\_

Signature, Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (typed)

I have reviewed this proposal and concur with its submission.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Signature, University Department Chairperson Date

A. **Description and Objectives:**

1. Write an abstract of the teaching/research project in **layman's language** (100 words or less).

Stress relevance of the proposed teaching/research activity to the general public.

2. Research or Instructional *Objectives*. Briefly state, using easily understandable **Lay Terms**, the *objectives* and the *specific aims* of the research or teaching activity (as for a federal research grant or a course syllabus) and their relevance to advancing scientific knowledge and/or benefits to human/animal health (Note—A section from your grant application, using highly technical terms, is *not acceptable*):

B. **Personnel:**

1. Principal Investigator:

Title/Department:

Campus Mailing Address:

Telephone: Office: Home:

Co-Investigator (s):

Mailing Address:

Telephone: Office: Home:

Laboratory Contact, if any (name): Telephone W:

H:

Technical Staff (name/s): Telephone:

Telephone:

Telephone:

2. Qualifications. Describe the RELEVANT (species/procedures) training of investigators and technicians enabling them to conduct the procedures described in the proposal and to use the animal species chosen. If personnel will be trained for the study, please indicate how and by whom.

(a) Principal Investigator:

(b) Co-Investigator(s):

(c) Technician(s):

C. **CLASSIFICATION BY ANIMAL USE:**

1. Animal Requirements: This information is requested for University record keeping related to USDA and other records.

a. List animal species used in this protocol by scientific and common name. Indicate those that are endangered or threatened. If more space is needed attach list as an addendum.

(1) (2) (3) (4)

b. Check the one most appropriate description under each category (b. 1, 2, 3, and 4) that apply to this protocol. *For multiple species, list each species after descriptors that apply to them*.

(1) *Classification* (3) *Procedure/Study Area*

\_\_\_\_ Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Anatomy/Developmental Research\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Training\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Antibody Production\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(2) *Organ System* \_\_\_\_\_Behavioral Studies Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Cardiovascular\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Disease Induction\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Digestive\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Immunologic Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Endocrine\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Oncologic Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Eye\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Pharmacologic Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Hemato/Lymphatic\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Physiologic Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Integument\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Molecular Biologic Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Musculoskeletal\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Nutritional/Chemical Research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Nervous\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Toxicology\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Respiratory\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (4) *Surgery*

\_\_\_\_Reproductive\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Applicable\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Urinary\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_Not Applicable\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_All Systems (e.g., Pathology)

2. Classification by stress levels:

a. Non-Painful/Non-Stressful

Studies, experiments, and tests causing no pain or distress (e.g., routine procedures causing only transitory discomfort, such as venipuncture, injection, and the use of non-inflammatory adjuvants; cell, fluid, and/or tissue harvest from euthanized animals).

b. Painful/Stressful WITH Analgesia/Anesthesia/Tranquilizers

Painful and/or stressful procedures carried out with the use of appropriate anesthetics (e.g., for surgery), analgesics (e.g., for inflammation), and tranquilizers (e.g., for prolonged restraint) that will prevent and alleviate pain and distress.

c. Painful/Stressful WITHOUT Pain and Stress Relieving Measures

Painful and/or stressful procedures performed without the use of analgesic, anesthetic, and tranquilizing drugs or other measures that will prevent and/or relieve pain and distress; or those procedures not amenable to relief by therapeutic measures (e.g., infectious disease, carcinogen, or toxicity studies in which natural death is the end point; addictive drug withdrawal without treatment; noxious stimulation with escape).

(1) Non-Painful/Non-Stressful - NUMBER OF ANIMALS:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| SPECIES | YEAR 1 | YEAR 2 | YEAR 3 | YEAR 4 | YEAR 5 | TOTAL |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

(2) Painful/Stressful, with analgesia/anesthesia/tranquilizers - NUMBER OF ANIMALS:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| SPECIES | YEAR 1 | YEAR 2 | YEAR 3 | YEAR 4 | YEAR 5 | TOTAL |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

(3) Painful/Stressful with no relief of pain and/or stress - NUMBER OF ANIMALS:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| SPECIES | YEAR 1 | YEAR 2 | YEAR 3 | YEAR 4 | YEAR 5 | TOTAL |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

D. **Assurances:**

1. Lack of non-painful, non-stressful alternatives: The Principal Investigator **must** **consider alternatives** to procedures that may cause pain or distress to animals. For Class (2) and (3) studies (Item C.2) provide a statement that non-painful, non-stressful alternatives are not available and the methods and sources used to determine this. If a computer assisted literature search was conducted, provide the name(s) of the data base(s) searched and the date(s) of the search(es) and keep copies of the search results.

2. Research Duplication: The PI is required by law (CFR9, AWA para.2.31d) to provide a statement that alternative research models or teaching alternatives are not available and that the proposed research or teaching activity does not *unnecessarily* duplicate previous work. If a computer assisted literature search was conducted, provide the name(s) of the database(s) searched and date(s) of the search(es) and keep copies of the results.

3. Rationale for species: Enter a brief statement explaining why the *species described* and the *number(s) requested* must be used. Address reasons such as pertinence to previous work, statistical significance, etc.

E. **RESEARCH OR INSTRUCTIONAL PROCEDURES:**

1. Describe, in general terms, the *study or instructional design* and *all animal procedures*. Include information on the *numbers* and *frequencies* of the *procedures* and the *eventual* *disposition* of the *animals*. Specific details of surgery, anesthetics, etc., are requested later and are not required here. For field collection protocols, note any requirements for permits and copies of the needed permits must be on file before work can begin.

2. Where will procedures be performed (building and room if known)?

3. Where will animals be housed?

4. *Exceptions* to standard Practices:

(a) Unless otherwise approved, ALL DOGS, AND CATS WILL BE HOUSED AND HANDLED SO AS TO PROVIDE FOR ENVIRONMENTAL ENRICHMENT. If this is NOT compatible with the proposed research, state what exceptions are required and provide justification:

(b) Describe special caging, care, diets, or housing required.

(c) Unless otherwise approved, all dogs will be provided exercise. If this is not compatible with the proposed research, state what exceptions are required and provide justification.

F. **MONITORING ANIMALS FOR WELL-BEING** (other than post-operative care requested in paragraph G.9 and G.10).

1. Indicate *known potential painful/stressful effects* on animals listed in Item C.2, Classes (2) and (3).

2. *All animals will be visually inspected at least daily by ACF staff, and all animal rooms are continuously electronically monitored for temperature, with automatic calling of the UA Dept. of Public Safety if the temperature varies from the desired range*. If *additional* monitoring is needed, as for painful/stressful effects from experimental procedures, *how*, *by whom*, and *how often* will animals be monitored?

3. If, due to experimental procedures, pain/stress occurs in animals, how will it be treated?

G. **SURGICAL PROCEDURES (*if no surgery will be performed, check “not applicable” below and skip to H*):**

1. Describe, in a separate paragraph for each animal species, details of each surgical procedure. **Attach description as an Appendix**. *Appendix attached* *Not applicable*

*Total number of surgical procedures to be performed each year*:

2. Anesthesia: Complete table below related to anesthesia:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Animal Species | Drug Used | Dose/frequency | Route |
| Induction Preanesthetic |  |  |  |  |
| Anesthesia Maintenance |  |  |  |  |
| Paralytic Agents |  |  |  |  |
| Post-Operative Analgesic |  |  |  |  |

1. How will depth of anesthesia be monitored?

4. Surgeon's name:

Telephone - Office: Home:

5. Will animals be allowed to recover from anesthesia? Yes No (check one)

6. If the previous answer was YES, will more than one procedure be conducted on each animal? If so, how many?

7. If the previous answer was YES, provide justification for more than one survival procedure. If the previous answer was NO, please enter N/A.

8. Enter site of Operating Room:

Enter site of Recovery Room:

Animal Study Area, if not Operating Room:

9. Describe Post-operative Care, including surveillance and treatment for pain:

10. Person(s) Responsible for Post-operative Care:

Name: Telephone: Office: Home:

Name: Telephone: Office: Home:

H. **ANIMAL TRAINING:**

Describe completely the methods to be used for training of animals (if applicable). Otherwise enter “N/A.”

I. **ANIMAL RESTRAINT:**

Describe completely the methods, frequency, and duration of restraint, *other than routine caging and handling*. If none, so state.

J. **EUTHANASIA:**

If euthanasia is the end point of the study, indicate the method to be used. INCLUDE agent and dose for each species. Euthanasia shall be performed in accord with methods approved by the AVMA guidelines, subject to prior consultation with the investigator.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SPECIES | METHOD | AGENT | DOSE | COMMENTS |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

K. **ENDPOINT**

For those experiments without a defined endpoint, list criteria to be used to remove an animal from the protocol and how these conditions will be monitored. For example: Breeders will be euthanized if a.) the litter size drops below X, b.) there is an infection that does not respond to treatment, c.) stops eating, or d.) the animal shows other objective signs of pain or distress. If these conditions are observed the investigator and attending veterinarian will be notified and they will determine if the animal should be removed from the protocol.

L. **OTHER DRUGS & TISSUE COLLECTION:**

1. Blood/body fluid collection:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SPECIES | FLUID | AMOUNT | FREQUENCY | SITE/METHOD |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

2. Tissue Collection:

a. Tissue to be harvested:

b. Is this a post-mortem harvest? YES NO (If No, complete c. below)

c. Minor or non-surgical procedures (e.g., biopsies, endoscopies) to obtain tissue or fluid from live animals:

3. Tissue/Fluid/Drug Administration

Describe agents to be administered not listed above:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SPECIES | AGENT | ROUTE | DOSE (mg/kg) | AMOUNT | POSSIBLE COMPLICATIONS |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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M. **Biosafety:**

Is there any *in vivo* use of infectious agents or biological or chemical toxins? YES NO

If YES, specify agent(s):

Date of approval from the Biosafety Research Committee: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

Is there any *in vivo* radioisotope use? YES NO

Date of approval from the Radiation Safety Committee: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

(a) Labeled compound(s):

(b) radioisotope(s):

(c) Dose per animal:

**THE UNIVERISTY OF NORTH ALABAMA**

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

**ANNUAL PROTOCOL RENEWAL /TERMINATION PROTOCOL FORM**

**IMPORTANT NOTE**: The United States Department of Agriculture (USDA) and the PHS require you to submit proposed significant changes regarding the care and use of animals in ongoing activities for IACUC review and approval *before* implementing the changes**. Failure to obtain IACUC approval of a modification to your protocol could result in suspension of the study that was previously approved, if the IACUC determines that the activity is not being conducted in accordance with the original approved protocol.** If this occurs, you will be required to cease all activities with animals used in your study until further reviewed by the IACUC and the Institutional Official. If your protocol is suspended and you continue to use animals, this is considered a violation of federal regulations that govern the use of animals in research. Such violations must be reported to the Federal government and to University officials. Termination of your research and your funding by the government and/or the University may occur. **INSTRUCTIONS:** Please complete and submit this form (typed) to the Office for Sponsored Programs, Bibb Graves, Room 208. Questions should be directed to UNA’s IACUC.

**General Information**

**IACUC Protocol #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Original Approval Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dept.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**E-Mail \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone (Office)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Project Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Today’s Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Funding Agency \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Section A: Status Report**

**Section B: Animal Usage**

**During the past year (check one):**

* The study was not active, and no animals were used. *Complete section D.*
* The study was active. *Complete sections B, C and D.*
* The research was completed on \_\_\_\_\_\_\_\_\_\_\_\_\_. Please close out protocol. *Complete section B, C and D.*

For the next year (check one, if applicable)

* This research will continue without change. *Complete sections B, C and D.*
* This research will continue with change. *(Please submit a protocol modification form along with this form).*

|  |  |  |
| --- | --- | --- |
| **Species** | **Stress Category** | **# of Animal** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Section C: Protocol Summary**

**1. Please provide a summary of the project results to date in language that a layperson could understand, avoiding jargon and specialized terminology.**

**2. Have objectives and specific aims been achieved?**

**Section C: Protocol Summary (continued)**

**Section D: Assurance and Signature**

For active and/or continuing protocols, **I certify** that the use of animals has been and/or will be in accord with U.S. Department of Agriculture Animal Welfare regulations, the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the National Research Council *Guide for the Care and Use of Laboratory Animals,* and the policies established by the University of North Alabama. **I** **further certify** that no significant change in this protocol will be implemented without prior IACUC approval.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date

**3. Why is the continued experimental use of laboratory animals needed? Include details from a recent literature search to determine that your experimentation is not duplicative.**

**4. Please list, as complete citations, all presentations and publications resulting from this work.**

**ANIMAL HOUSING**

UNA INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

ANIMAL CARE AND USE APPLICATION

1) Colony/Housing Supervisor

Name

Department

Campus address

Campus phone number  Email

Rank:  Faculty  Student

If student, name of supervisor

Address and phone number of supervisor

Project status: new \*\*renewal

2) Colony/Housing Location**:**

3) Number and species of each animal held**:**

**Species Number Source**

*Completion and signing of this form are the responsibility of the faculty/staff member in charge. Completion of the approval process will fulfill Public Health Service and USDA Animal Welfare Act requirements, and will serve to remind users and the public of UNA’s commitment to humane care and use of animals.*

*In signing this form, I assure that discomfort and injury to animals will be avoided. I assure animals will be given adequate water and food. The living environment will be cleaned and maintained on a regular basis. I will consult with a veterinarian or euthanize the animal when an animal becomes seriously ill. I will immediately notify the IACUC of any serious illness in my colony. I further assure that licenses and permits for collecting wild animals (if appropriate) have been obtained and are attached to this document. I agree to comply with all UNA IACUC policies, procedures, all applicable state, and federal laws governing animal welfare.*

Faculty/Staff Member \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_

For IACUC USE ONLY:  Approved  Disapproved

IACUC CHAIR/Authorized signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_

Attending Veterinarian (large mammals and birds only) –

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_

\*\*This application must be submitted on a new complete form every **three** years, or more often if changes are made to the facility or species of animals held.

4) Briefly describe feeding and watering schedules for each species.

5) Indicate the maintenance schedule for cleaning of cages, tanks, etc. for each species.

6) Give name/names of personnel responsible for feeding and maintaining animal facilities as of the date this form is signed. Briefly describe prior experience of these individuals or training these individuals will receive**.**

7) Veterinary Care: Name of Veterinarian (include: address and phone number) who will be contacted in case of an animal emergency (large mammals and birds only).

8) Provide an emergency plan for your colony. This should include handling of the animals incase of power failure, natural disaster etc., that would result in any danger to the animal’s welfare.

9) Include emergency phone numbers of faculty and/or staff responsible for the colony. Also, include phone numbers of knowledgeable backup persons. The animal colony must be covered 24 hours a day, seven days a week including University holidays. (This information will be provided to the UNA Public Safety office for their use in case of an emergency). If none of the emergency contact individuals are available, Public Safety will contact the Dean of your college along with a local Veterinarian to address the emergency. The faculty member responsible for the colony will be financially accountable for any or all veterinarian charges and/or related charges.

**THE UNIVERSITY OF NORTH ALABAMA**

**POLICY ON CONFLICT OF INTEREST/FINANCIAL DISCLOSURE IN RESEARCH AND OTHER SPONSORED PROGRAMS**

**I. BACKGROUND**

The University of North Alabama (UNA) realizes that actual or potential conflicts of interest may occur in the normal course of research and other sponsored activities. The University has developed this policy relating to conflicts of interest applicable to all UNA investigators and the policy applies to all Sponsored Programs, including federal, state and local government; industry; or not-for-profit sponsors. The policy also covers UNA intellectual property licensed to an entity in which a UNA investigator owns an interest or serves as an employee, officer, or member of the Board of Directors regardless of the source of funding. The policy is to be administered in conjunction with laws and policies setting forth standards of conduct including

Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F; Title 45 CFR Part 94; and the Ethics Act of the State of Alabama.

The Public Health Service (PHS) (which includes the National Institutes of Health) and the National Science Foundation (NSF) have regulations promoting objectivity in research by requiring that a university applying for grants or cooperative agreements for research insure that there is no reasonable expectation that the design, conduct, and reporting of the research to be funded pursuant to the application will be biased by any significant financial interest of the investigator or other personnel with decision making capacity working on the research and that the research environment is one that promotes faithful attention to high ethical standards. In further support of this expectation the federal government has issued an agency-wide requirement that policies and procedures regarding financial conflicts of interest be issued on

research and other sponsored programs federally funded. The University has adopted this Policy on Conflict of Interest to prevent or resolve, through management and/or mitigation, real or apparent conflicts that may exist in relation to research, instruction, and service activities undertaken by University investigators.

**II. POLICY STATEMENT RELATING TO CONFLICTS OF INTEREST**

It is the purpose of this policy to insure that no proposed, awarded or ongoing UNA research or sponsored programs (hereinafter referred to collectively as “research”) shall be biased by Significant Financial Interest, as defined below, or by a conflicting commitment of UNA investigators responsible for the design, conduct, or reporting of that research.

All UNA faculty or staff who serve as Principal Investigators, Co-Principal Investigators, Project Directors, Co-Project Directors or in a decision making capacity on a grant, contract, cooperative agreement or other sponsored agreement, who have a five percent (5%) or more ownership in a

company or receive $10,000 or more income from the company will disclose that ownership to allow a review of potential conflicts of interest, conflicts of commitment, conflicts regarding employment and/or use of graduate students in the company.

This policy also applies to any faculty, staff, student, fellow, trainee, or other individual who, under the aegis of UNA or pursuant to the review and approval of UNA’s Institutional Review Board for the Protection of Human Subjects (IRB), conducts research involving human subjects.

Prior to seeking UNA approvals for submission of any research or sponsored project proposal or application, each investigator, as defined under definitions below, must have submitted to UNA’s Office of Sponsored Programs a financial disclosure statement certifying they have no conflict of interest or if they believe they have a conflict of interest listing all Significant Financial Interests of the investigator and the investigator’s immediate family, as defined under definitions below. Each such financial disclosure statement must be updated during the course of the award either on an annual basis, or as new reportable Significant Financial Interests are obtained.

The Office of Sponsored Programs will maintain confidential records, identifiable by investigator, award and/or company, of all financial disclosures and all actions taken with respect to each Significant Financial Interest for at least three years beyond the termination or completion of the award, or until resolution of any action by a granting agency involving the records, whichever is longer. In the case of faculty or staff ownership of a company, all financial disclosures and all actions taken with respect to each Significant Financial Interest will be held for the life of the company.

This policy establishes guidelines for the appropriate structuring of relationships with industry and other outside ventures to prevent conflict with previously established responsibilities to UNA. Investigators are expected to make reasonable inquiry as to whether their relationships and activities fall within the provisions of this policy. It is not the intent of this policy to eliminate or prohibit all situations involving potential conflicts of interest. Rather, the policy is intended to enable investigators to recognize situations that may pose a conflict of interest, to provide processes for reporting these situations to UNA’s Office of Sponsored Programs and for working with the Office of Sponsored Programs to manage these situations. This policy is intended to maintain the professional autonomy of researchers inherent in the self-regulation of research and scholarship.

In the event that an investigator participates in research subject to this policy and the research is being simultaneously supported by an organization that has a commercial interest in the outcome of the research project, the research support by such organization must be provided through UNA. Any direct compensation or payment to the Investigator under that support must be disclosed, regardless of the amount. This policy will provide assurance to the investigators, UNA, and, most importantly, the public, that relationships with industry and for-profit entities have been examined and will be conducted in a manner consistent with UNA and public values.

**III. DEFINITIONS**

**A. Immediate Family.** Immediate family includes the investigator, his/her spouse, and dependent children.

**B. Investigator.** Investigator means UA faculty or staff members who are principal investigators or project directors, co-principal investigators, or other persons at the university responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

**C. Research Compliance Officer (RCO) aka Director, Office of Sponsored Programs.** The RCO will be the first point of contact for investigators on issues relating to conflict of interest and will perform the initial review of the Statement of Potential Conflict of Interest. The RCO will also coordinate the review of this statement with the University’s Institutional Review Board for the Protection of Human Subject. The RCO will process all paperwork related to conflict of interest disclosures and, if appropriate, conflict of interest management plans.

The Research Compliance Officer is responsible for keeping the appropriate external funding agency informed if UNA finds it is unable to satisfactorily manage an actual or potential conflict of interest for any activity in which that agency requires that it be notified in such an instance.

**D. Sponsored Research.** Sponsored Research means research, training and instructional projects involving funds, materials, or other compensation from external sources.

**E. Research**. Research means a systematic investigation designed to develop or contribute to knowledge.

**F. Responsible University Official (RUO ).** The Responsible University Official will be the Vice President for Academic Affairs.

**G. Significant Financial Interest.** Significant Financial Interest means anything of monetary value or potential monetary value including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stocks, stock options, or other ownership interests), and intellectual property rights (e.g. patents, copyrights,

licensing agreements, and royalties from such rights). The term does not include any of the following:

1) An equity interest that, when aggregated for an investigator and the investigator’s immediate family, meets both the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity. (NOTE: When

the proposed project requires the use of human subjects and approval from the Institutional Review Board, these monetary thresholds do not apply.

In such cases, the disclosure threshold is any amount above $0 and any equity percentage above 0%.)

2) Salary, royalties, or other payments that, when aggregated for an investigator and the investigator’s immediate family, are not expected to exceed $10,000 during the next twelve-month period.

3) Interest(s) held directly through funds such as mutual funds, pension funds, or other institutional investment funds in which the investigator or the investigator’s family does not control the selection of investments.

4) Salary or other remuneration received from UNA, including salary received from external sources through sponsored research agreements administered by UNA;

5) Standard royalties received for published scholarly work or other professional writings;

6) Income from seminars, lectures, or teaching engagements sponsored by public entities or non-profit entities; or

7) Income from services on advisory committees or review panels for governmental entities, public or non-profit entities.

**I. Use of Human Subjects in Research**. Human Subject means a living individual about whom an Investigator conducting research obtains data through intervention or interaction with the individual or obtains data through identifiable private information. If a potential conflict of interest exists, and human subjects are involved in the research, the investigator will need to obtain the approval of UNA’s Institutional Review Board for the Protection of Human Subjects.

**CONFLICTS OF INTEREST**

A potential or actual conflict of interest exists when an investigator or an investigator’s immediate family has a significant financial interest, as defined above, in an outside funding source which interest could directly and significantly affect decision making in the design, conduct, or reporting of externally funded instruction, research, or service activities performed on behalf of the University.

**V. PROCEDURES**

**A.** All Investigators must certify to the University’s Research Compliance Officer (RCO) knowledge of and compliance with UNA’s policy for promoting objectivity in research by managing, reducing, or eliminating conflicts of interest as outlined herein (the Statement of Potential Conflict of Interest). This certification and disclosure form also requires similar information about members of the investigator’s immediate family. Statements must include detailed supplemental information if an investigator marks any “yes” box.

**B**. Investigators must disclose to the RCO on an ad hoc basis new situations in which Significant Financial Interests are obtained and which may raise questions of conflicts of interest as soon as such situations develop.

**C.** The Research Compliance Officer (RCO) will review the certification and disclosure statement to determine whether a potential for a conflict of interest exists. A potential conflict of interest exists when the RCO reasonably determines that a Significant Financial Interest could affect the design, conduct, or reporting of the research or educational activities in question. If it is determined that no conflict exists, the RCO will sign the statement, seek and obtain the signature of the Responsible University Official (RUO), and notify the Office for Sponsored Programs. If the RCO determines that there may be a potential for conflict of interest covered by this policy, the RCO will forward this determination along with the submitted materials to the RUO.

**D.** Should the RUO agree that the situation represents potential for a conflict of interest, and recommend development of a conflict of interest management plan; the RCO shall work with the Investigator to develop the plan to manage, reduce, or eliminate the actual or potential conflict of interest. The plan will then be submitted to the RUO who then may recommend approval of the plan as developed or may recommend modification of the plan.

**E.** Examples of conditions or restrictions that might be part of the plan to manage, reduce, or eliminate actual or potential conflicts of interest include:

**1.** Public disclosure of Significant Financial Interests;

**2.** Monitoring of the research by independent reviewers;

**3.** Modification of the research plan;

**4.** Disqualification from participation in all or a portion of the research project in question;

**5.** Divestiture of Significant Financial Interests; and,

**6.** Severance of relationships that create actual or potential conflicts.

**F.**  Once a plan approved by the RUO is developed, the Research Compliance Officer (RCO) will work with the investigator on the implementation and management of the plan.

**G.** If the management recommendation involves divestiture of financial interests or severance of relationships that create actual or potential conflicts, the RUO will confer with the President. The President has the authority to require the divestiture of significant financial interests and/or the severance of relationships that create actual or potential conflicts.

**VI. Appeals**

**Appeals of Recommendations made by RUO.** Should an Investigator wish to appeal a decision made by the RUO, he/she may present the appeal to the Responsible University Official (RUO). The RUO will confer with the President. In such cases, the President shall review all of the materials relating to the action in question, shall discuss the findings/decisions with the investigator, RCO, and RUO. After review, the President shall make a final decision as to the action.

All decisions of the President of an appeal under this policy are final.

**VII. INVESTIGATOR RESPONSIBILITIES**

A. **Responsibilities of Investigators.** UNA Investigators involved in research shall be responsible for:

**1.** Reading, understanding and following this policy;

**2.** Disclosing financial interests to the Research Compliance Officer by completing, signing, and submitting the Statement of Potential Conflict of Interest on or before a specified date or before submission of the grant/contract application;

**3.** Updating the statement with the Research Compliance Officer as changes occur, so that the statement on file is current and accurate at all times when an award is pending or in force;

**4.** To the extent possible, ensuring that funded research carried out through subgrantees, contractors, or collaborators complies with UNA’s Policy on Conflict of Interest or that these entities provide assurance of compliance with all federal regulations and state law;

**VIII. REPORTING**

**A.** For externally funded or sponsored activities, the University must report any conflicting interest to the funding source prior to expending any funds, and any interest identified as

conflicting subsequent to the initial report must be reported within 60 days of that identification. Further, the University agrees to make conflict of interest information available, upon request, to any external funding source potentially or actually affected by this information. If it is determined that an investigator has biased externally funded or sponsored activities, the University will promptly notify the funding source of the corrective action taken or to be taken. In the case where a project to evaluate a drug, medical device or treatment, and or equipment was conducted by an investigator with a conflict that was not disclosed or managed, the University will require the investigator to disclose the conflict in each public presentation of the results of the research.

**IX. ENFORCEMENT**

**A.** UNA anticipates that its investigators will comply fully and in a timely manner with this policy. Instances of deliberate breach, including: (i) failure to submit required statements or updates thereof; (ii) failure to provide additional information requested by the Research Compliance Officer (RCO), or the RUO; (iii) knowingly filing an incomplete, erroneous, or misleading statement; (iv) knowingly violating applicable laws, UNA policies or procedures; (v) or failure to comply with prescribed conditions or restrictions that have been imposed pursuant to this policy, may subject the investigator to disciplinary action under UNA policies or procedures. Such action could result in a formal reprimand, non-renewal of appointment, termination of appointment for good cause, or any other enforcement action mandated by a granting agency.

**XI. Use of Human Subjects**

**A. Use of Human Subjects.** Any faculty, or staff, student, fellow, trainee, administrator, volunteer, or other individual who, under the aegis of UNA or pursuant to the review and approval of UNA’s Institutional Review Board for the Protection of Human Subjects (IRB), conducts research involving human subjects must complete and submit a statement for review by the Research Compliance Officer (RCO). The statement must be updated as circumstances of the Investigator or his/her spouse or dependent children change.

**TO BE COMPLETED BY EACH PRINCIPAL INVESTIGATOR OR PROJECT DIRECTOR**

**THE UNIVERSITY OF NORTH ALABAMA STATEMENT OF POTENTIAL CONFLICT OF INTEREST**

**Certification of Compliance with the Policy for Promoting Objectivity in Research by Managing, Reducing or**

**Eliminating Financial Conflict of Interest**

Name:

Title:

Department(s)/Unit:

Campus Telephone Number:

E-Mail Address:

The following questions apply to your current situation. If there are any changes during the course of the proposed project, you must resubmit this form with the new information.  **If you answer yes to any of the questions below, provide an attached detailed and thorough written description and explanation.**

**1.** Do you or members of your immediate family (i.e., spouse or dependent children as defined by the Internal Revenue Service) have an equity interest (5% or more ownership and greater than $10,000 in fair market value) in a company, enterprise or entity?

Yes\_

(If yes, attach a detailed description and explanation of the level of equity for you and all immediate family

members involved) No

**2.** Do you currently conduct internally or externally sponsored research or are you supported by a grant or contract the outcome of which could affect the interests of a company, enterprise or entity in which you (or members of your immediate family) have an equity interest, have employment or consulting arrangements and/or other financial interests?

Yes\_ No

(If yes, attach a detailed description and explanation)

**3**. Do you currently have internally or externally sponsored research or are you supported by a grant or contract where you (or members of your immediate family) have: (check all that apply)

employment or consulting arrangements with the sponsor of the research significant financial interest with or in the sponsor of the research

significant financial interest with or in a subcontractor/subawardee to the grant

If your checked any statement above, please attach a detailed description and explanation) No

**4.** Do you currently have gifts, cash, or property which directly support your teaching or research activities from a company, enterprise or entity in which you (or members of your immediate family) have an equity interest, employment or consulting arrangement and/or other financial interests?

Yes\_ No

(If yes, attach a detailed description and explanation)

**5.** Does the University currently have a technology licensing arrangement with a company, enterprise or entity for which you (or your immediate family members) have equity interest, employment or consulting arrangements and/or other financial interests?

Yes\_

(If yes, attach a detailed description and explanation or attach your UNA Conflict of Interest Management Plan

(STTR/SBIR and/or Standard) No

**6.** If you answered yes to any question above, please describe in an attachment the involvement, if any, of human subjects in your research.

**Certification**

In submitting this Statement, I certify that the above information is true to the best of my knowledge and that I have read and understand the University of North Alabama’s Conflict of Interest Policy, Ethics Policy, and Faculty or Staff Outside Employment Policy. I certify that I have disclosed all potential financial interests as required by all UNA policies, including these policies. I agree to comply with provisions of UNA policies to immediately report changes in my financial interests. Furthermore, I agree to comply with conditions or restrictions imposed by UNA to manage, reduce or eliminate actual or potential conflicts of interest.

Signature:

Investigator

Date:

Signature:

Department Chairperson

Date:

Signature:

Dean

Date:

Completed Statement must be submitted to the University’s Research Compliance Officer.

Signature:

Research Compliance Officer

Date:

Signature:

Vice President for Academic Affairs

Date:

**Upon completion, please submit to the Office of Sponsored Programs, UNA POB 5041, Florence, AL 35632**

**Please address any questions concerning this Statement to the Office of Sponsored Programs.**

**III. DEFINITIONS**

**A. Immediate Family.** Immediate family includes the investigator, his/her spouse, and dependent children.

**B. Investigator.** Investigator means UNA faculty or staff members who are principal investigators or project directors, co-principal investigators, or other persons at the university responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor.

**C. Sponsored Research.** Sponsored Research means research, training and instructional projects involving funds, materials, or other compensation from external sources.

**D. Research**. Research means a systematic investigation designed to develop or contribute to knowledge.

**E. Significant Financial Interest.** Significant Financial Interest means anything of monetary value or potential monetary value including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stocks, stock options, or other ownership interests), and intellectual property rights (e.g. patents, copyrights, licensing agreements, and royalties from such rights). The term does not include any of the following**:**

1) An equity interest that, when aggregated for an investigator and the investigator’s immediate family, meets both the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity. (NOTE: When the proposed project requires the use of human subjects and approval from the Institutional Review Board, these monetary thresholds do not apply. In such cases, the disclosure

threshold is any amount above $0 and any equity percentage above 0%.

2) Salary, royalties, or other payments that, when aggregated for an investigator and the investigator’s immediate family, are not expected to exceed $10,000 during the next twelve-month period.

3) Interest(s) held directly through funds such as mutual funds, pension funds, or other institutional investment

funds in which the investigator or the investigator’s family does not control the selection of investments.

4) Salary or other remuneration received from UNA; including salary received from external sources through sponsored research agreements administered by UNA;

5) Standard royalties received for published scholarly work or other professional writings;

6) Income from seminars, lectures, or teaching engagements sponsored by public entities or non-profit entities; or

7) Income from services on advisory committees or review panels for governmental entities, public or non-profit entities.

**UNA EXPORT CONTROL POLICY**

**(LIMITING DISTRIBUTION AND SHARING OF INFORMATION, TECHNOLOGY AND COMMODITIES BOTH INTERNATIONALLY AND DOMESTICALLY)**

**Policy Statement**

It is the policy of the University of North Alabama that, absent extraordinary circumstances, teaching, research, and service will be accomplished openly and without prohibitions or restrictions on the publication and dissemination of the results of academic and research activities. Certain federal regulations however, may require the University to obtain permission from the Department of State, the Department of Commerce, or the Office of Foreign Assets Control before allowing foreign nationals to participate in research involving specific technologies or before sharing research information with persons who are not citizens of the United States or permanent resident aliens.

It is also the policy of the University to comply with U.S. export control laws. Export control laws restrict certain types of information, technologies, and commodities that can be transmitted overseas to individuals, including U.S. citizens, or made available to foreign nationals on U.S. soil. These export control regulations have the potential to limit the research opportunities of University researchers and their students, affect publication rights, and prevent international collaboration in certain research areas. In addition, violations of these export control regulations can result in the loss of research contracts, monetary fines, or incarceration of individuals. The regulations do not apply, however, to information that is in the public domain or to information that is the result of fundamental research activities. Therefore, it is the policy of UNA to pursue its mission in teaching, research, and service in a manner that is consistent with the applicable export control regulations while making reasonable efforts to maximize the situations in which the University may claim the benefit of the public domain or fundamental research exemptions to the regulations.

**Reason for Policy/Purpose**

The export of certain items, technologies, software and services is regulated for reasons of national security, foreign policy, prevention of the spread of weapons of mass destruction and for competitive trade reasons. Prior written authorization (a “license”) from one or more U.S. government agencies will be required to carry out certain sponsored research or other educational activities involving specified technologies or certain countries, if an exemption or exclusion is not available.

Export control laws restrict the shipment, transmission or transfer of certain items, software, technology and services from the U.S. to foreign countries, as well as “deemed exports,” which are releases of controlled technology and software source code to foreign nationals located in the U.S.

Although many of the University’s activities are exempt from export control laws, some activities may be restricted. Failure to comply with these laws exposes both the employee and the University to severe criminal and civil penalties (fines and prison sentences) as well as administrative sanctions (loss of research funding and export privileges).

In cases where the President, Vice President of Academic Affairs, the Office of Sponsored Programs or the Principal Investigator(s) believe that a sponsored research effort or software, technologies, data, equipment, intellectual capital acquired and or developed using sponsored research funds may be subject to US export regulations then the any of the aforementioned parties can require a legal review of the research to determine applicability and compliance to export control regulations.

If a legal review of the research to determine applicability and compliance to export control regulations is required then the review will proceed as follows:

1. The Office of Sponsored Programs (OSP) will review the terms of the contract or grant for provisions that restrict access to or publication of research and technical data, that limit the participation of foreign nationals in the research effort, or otherwise render the exemptions from the export control regulations inapplicable.
2. In conjunction with the PI, the OSP will complete *Export Control Review*, (see Appendix A). If the results of the review indicate that an exemption from the export control regulations may not be available, the OSP will submit the checklist and supporting documentation to UNA’s legal counsel to confirm the review.
3. If UNA’s legal counsel confirms the review, then the PI, UNA’s legal counsel, and the OSP will determine if the research falls into one of the categories of technology designated by the Department of State or the Department of Commerce as export controlled, or if the restrictions imposed by the Office of Foreign Assets Control apply. If the research contract or grant falls under the terms of any of these regulations, UNA’s Legal Counsel, acting on behalf of UNA will contact the research sponsor to attempt to negotiate the removal or modification of the provisions in the contract or grant that impact the University’s exemption from export control regulations. If such negotiation does not result in the removal or modification of the identified clauses, the matter will be referred to the Vice President of Academic Affairs to determine whether the University will apply for an export control license, conduct the research under the export control restrictions, or abandon the research effort due to the possible burdens or restrictions associated with compliance with the regulations.
4. If the Vice President for Academic Affairs determines that the University will apply for an export control license, UNA’s Legal Counsel will proceed to make application for the appropriate license. No work under a contract or grant, or sponsored contract or grant, can begin until this process has been completed and any required export control license has been issued.

**Federal Regulations, Resources, and Penalties: Overview**

The Department of State, through its International Traffic in Arms Regulations (ITAR) of the Directorate of Defense Trade Controls (DDTC), and the Department of Commerce, through its Export Administration Regulations (EAR) of the Bureau of Industry and Security (BIS), have implemented regulations governing export of certain technologies, information, and software. The U.S. export controls also apply to “re-exports” of items, software and technology subject to U.S. law from one foreign country to another. In addition, the Department of Treasury, through its Office of Foreign Assets Control (OFAC), maintains targeted economic sanctions programs that restrict or prohibit a wide range of export and other transactions which may include educational services involving designated countries, entities and individuals.

**Penalties:**

Individual liability for the disclosure of controlled technical data to unauthorized foreign persons under the ITAR can reach up to $1 million per violation and 10 years imprisonment for willful violations, and civil fines up to $500,000 per violation. A university found to be in violation of ITAR regulations can be debarred from contracting with the government and could lose its export privileges. Liabilities under the EAR may involve fines greater of $1 million for each willful violation. Individuals can be fined up to $1 million and imprisoned for 20 years, or both. Civil penalties can reach up to $250,000 or 2 times the value of the transaction, whichever is greater, per violation. The university itself and individual faculty, staff and researchers can also lose their privilege to export and may be debarred from contracting with the federal government.

**Resources:**

For information on the EAR, visit the Bureau of Industry and Security at: [http://www.bis.doc.gov/.](http://www.bis.doc.gov/) For information on ITAR, visit the Directorate of Defense Trade Controls at:

[http://www.pmddtc.state.gov/regulations\_laws/itar\_official.html.](http://www.pmddtc.state.gov/regulations_laws/itar_official.html)

For information about the Office of Foreign Assets Control, visit: [http://www.treasury.gov/offices/enforcement/ofac/.](http://www.treasury.gov/offices/enforcement/ofac/)

For information on the SDN list and U.S. economic sanctions, visit [http://www.treas.gov/offices/enforcement/ofac/sdn/index.shtml.](http://www.treas.gov/offices/enforcement/ofac/sdn/index.shtml)

**Appendix A**

**Export Control Review**

**PROJECT INFORMATON**



**PROJECT INFORMATION**

**Project Title**

**Project/Contract/Proposal #**

**Sponsor**

**Principal Investigator**

**Campus Address**

**School Department/Division**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **SECTION I. PROJECT ANALYSIS** | | | | |
|  | **Sanctioned Countries, Entities and Persons** | | **YES** | **NO** |
| **1.** | Does the project in any way involve either of the following: | |  |  |
| a. | a country subject to US economic sanctions |  |  |  |
| b. | a person or entity designated by the US Government as a Specially Designated National or a  Blocked Person (SDN) | |  |  |
| *For the current list of sanctioned countries, please visit:* [*http://www.treasury.gov/offices/enforcement/ofac/programs/index.shtml.*](http://www.treasury.gov/offices/enforcement/ofac/programs/index.shtml)  *The Specially Designated National or a Blocked Person (SDN) can be viewed at:*  [*http://www.treasury.gov/offices/enforcement/ofac/sdn/index.shtml.*](http://www.treasury.gov/offices/enforcement/ofac/sdn/index.shtml)  If you answered “**YES**” to questions **1(a)** or **1(b)**, please contact the Office of Sponsored Programs before proceeding with the activity.  If the answer is “**NO**” to both of these questions, please proceed to the next question. | | | | |
|  |  | **Public Domain** | **YES** | **NO** |
| **2.** | Does the project  **solely** involve information or technologies that are in the ‘public domain’, (e.g., published, patented, or generally accessible to the public)? | |  |  |
| If the answer is “**YES**,” please skip to question #**4** and then question #**8** below. In summary, if no encryption software is involved and the activity does not involve a boycott-related request, then you must contact the Office of Sponsored Programs only if you know or have any reason to believe that the public domain item, technical data, or software to be shipped, transmitted or transferred will be used to support design, development, production, stockpiling or use of nuclear, chemical or biological weapons or missiles.  If you answered “**NO**” to question #2, please proceed to the next question. | | | | |
|  | **Fundamental Research** | | **YES** | **NO** |
| **3.** | Do the terms of the proposal, application or award, or the terms of the contract or research agreement, contain **any** of the following: | |  |  |
| a. | Restrictions on publication (e.g., sponsor approval rights or prepublication review) beyond a brief review for patent protection and/or inadvertent release of confidential/proprietary information? | |  |  |
| b. | Restrictions on the participation of foreign persons (e.g., sponsor approval required for participation of non-U.S. persons, explicit restrictions on participation by persons or entities based on their country of nationality, prohibitions on access by non-US persons to project information, or prohibition on hiring non-US persons)? | |  |  |
| c. | Requirement to keep information confidential (e.g., requires the PI to sign a non-disclosure or a confidentiality agreement, or otherwise addresses the use of proprietary information or security concerns) | |  |  |
| d. | Permission for the sponsor to claim resulting research information as proprietary or trade secret (i.e., sponsor’s intent to retain proprietary interest over the results)? | |  |  |
| e. | “Export controlled,” “ITAR controlled” or similar marks anywhere on the documents (e.g., RFP, SOW) or any other references to US export control regulations? | |  |  |
| If you answered “**NO**” to ALL of the questions (a)-(e), the “fundamental research” exclusion will apply to information resulting from the research.  *It is important to note that this exemption:*  • *does allow for the release of such information to a foreign person*  ***in*** *the United States; but*  • *does not authorize transmission or transfer of items, software or technical data outside the United States.*  *If the project contemplates or involves such export activity, or if you anticipate that the activities of this project will involve foreign persons who may need to use controlled equipment or software in the United States, completing the remainder of the questionnaire will assist you in determining whether a license is required for such export or whether the transfer of “use” technology is involved.*  If you answered **“YES”** to any of the questions (a) – (e) the Fundamental Research exclusion does not apply. In addition, if you answered “**NO**” to question #**2** above, you should contact the Office of Sponsored Programs in: (i) properly classifying the information or technology involved, (ii) determining the scope of applicable restrictions under US export controls and (iii) defining your obligations in conducting the research. You may be asked to complete questions **4**-**7** below as well as the Certification on the Handling of Export Controlled Information (also referred to as Appendix B of the Export Control Policy). | | | | |
| **SECTION II. TRANSFERS, CONTROLS, AND LICENSING** | | | | |
| **Encryption Items** | | | **YES** | **NO** |
| **4.** | Does the project involve shipping, transmitting or otherwise transferring encryption software (in source code or object code)? | |  |  |
|  | If the answer is **“NO”**, please proceed to the next question.  If the answer is **“YES”**, please contact the Office of Resource Management, Operations and  Emergency Preparedness before proceeding with the activity. | |  |  |
|  | **Transfers or Exports** | | **YES** | **NO** |
| **5.** | Does the project involve shipment, transmission, or transfer of any item, information, or non- encryption software outside the US? | |  |  |
| If the answer is **“NO”**, please skip to question **#8**.  If the answer is **“YES”**, please proceed to the next question. | | | | |
|  | **ITAR / USML** | | **YES** | **NO** |
| **6.** | Is the item, software or information being shipped, transmitted or transferred subject to the International Traffic in Arms Regulations (ITAR) as a Defense Article or Technical Data listed on the U.S. Munitions List (USML) or otherwise specifically designed, developed, configured, adapted or modified for a military application? | |  |  |
| *The U.S. Munitions List (USML) is located at:*  [*http://www.pmddtc.state.gov/regulations\_laws/documents/official\_itar/ITAR\_Part\_121.pdf*](http://www.pmddtc.state.gov/regulations_laws/documents/official_itar/ITAR_Part_121.pdf) *.*  If you answered “**YES**,” it is likely a license will be required to ship, transmit or otherwise transfer the item, software or technical data outside the United States. You should contact the Office of Sponsored Programs before proceeding.  If the answer is **“NO”**, please proceed to the next question. | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Commerce Control List and EAR99** | | | |
| The Bureau of Industry and Security (BIS) maintain the Commerce Control List (CCL) which includes items (i.e., commodities, software, and technology) subject to the export licensing authority of BIS. In order to complete the next question, you must review the CCL to determine the category in which the item(s) used in this project will be classified. | | | |
| *The CCL is available at* [*http://www.access.gpo.gov/bis/ear/ear\_data.html#ccl,*](http://www.access.gpo.gov/bis/ear/ear_data.html#ccl) *Part 774, Cat. 0-9.* | | **CCL** | **EAR99** |
| **7.** | Is the item, software or information being shipped, transmitted or transferred listed on the Commerce Control List (CCL) of the Export Administration Regulations (EAR) or is it classified in the “basket” category EAR99? |  |  |
| If you have determined that the item, software or information being shipped, transmitted or transferred is classified in the basket category “EAR99”, please skip the next question and refer to the guidance information in the shaded text box below. | | | |
| **Transfer of Use** | | **YES** | **NO** |
| a. | If you are dealing with the CCL-listed information or software, has it been published, patented or generally accessible to the public in any form? |  |  |
| If your answer is **“YES”** the CCL-listed information or software is exempt from the EAR restrictions as “publicly available” information or software (with the exception of certain encryption software, which remains subject to the EAR and is covered by question 4 above).  If your answer is **“NO”** and you are dealing with the CCL-listed information or software that is  **not** publicly available and/or you are dealing with a CCL-listed item, the following must be determined:  1) the level of EAR controls applicable to that item, information or software (by determining the proper Export Control  Classification Number (ECCN) on the CCL);  2) the country of destination for such item, software or information and/or the nationality/citizenship of a foreign person who will receive such information or software in a third country; and  3) whether a license under the EAR is required,  4) or whether a license exception may apply.  You should contact the Office Sponsored Programs if you need assistance in making these determinations.  **EAR99** items generally consist of low-technology consumer goods and do not require a license in many situations. However, if your proposed export of an EAR99 item is to a country subject to US economic sanctions, to an end-user on a U.S. Government Restricted Party List, or in support of a prohibited end-use, you may be required to obtain a license.  ***Important note:***  *You will also need to advise UNA of the following information prior to engagement:*  • *whether you know or have any reason to believe that the item, technical data, or software to be shipped, transmitted or transferred will be used to support design, development, production, stockpiling or use of nuclear, chemical or biological weapons or missiles;*  • *any “red flags” are present (for a list of EAR red flags, please review* [*http://www.bis.doc.gov/enforcement/redflags.htm);*](http://www.bis.doc.gov/enforcement/redflags.htm)%3B) *or*  • *any of the parties to the contemplated transaction appear on any U.S. Government*  *“restricted party” lists*  *The lists are available at:*  [*http://www.bis.doc.gov/ComplianceAndEnforcement/ListsToCheck.htm*](http://www.bis.doc.gov/ComplianceAndEnforcement/ListsToCheck.htm)*)* | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Boycotts** | | **YES** | **NO** |
| **8.** | Does the project, or the contemplated activity, involve a boycott-related request? |  |  |
| For more information on anti-boycott compliance requirements, please review <http://www.bis.doc.gov/ComplianceAndEnforcement/AnitboycottCompliance.htm>  If the answer is **“YES”**, please contact the Office Sponsored Programs before proceeding (you should not provide any response to such request without obtaining prior legal guidance). | | | |

**Signature Date**

**APPENDIX B**

**CERTIFICATION ON THE HANDLING OF EXPORT CONTROLLED INFORMATION Overview**

The activity/project identified below will involve the receipt and/or use of technical data that is controlled under U.S. export control laws: the Export Administration Regulations (“EAR”), enforced by the

Commerce Department’s Bureau of Industry and Security, or the International Traffic in Arms Regulations (“ITAR”), enforced by the State Department’s Directorate of Defense Trade Controls (DDTC).

**EAR**

EAR controls the export and re-export of equipment, software and technical data that serve commercial or “dual use” purposes. The prohibition on the export or “deemed export” (i.e., disclosure to a foreign person in the United States) of technical data controlled under the EAR is determined on a country-by-

country basis, depending on the country of destination (or the foreign person’s country of citizenship/nationality) and the level of controls imposed by the EAR on particular equipment, software

or technical data. As a result, it is unlawful to export technical data from the US to a foreign country or to disclose technical data in or outside the US to foreign persons who are nationals/citizens of countries for

which an export license is required as a condition of making such exports and disclosures.

**ITAR**

ITAR controls the export and re-export of equipment, software, and technical data, and the provision of services, that are primarily military in nature (i.e., specifically designed, developed or modified for a

military application). It is unlawful to send ITAR controlled technical data to *any* foreign persons outside the United States or to disclose – in written, oral or visual form - ITAR-controlled technical data to  *any* foreign persons *in* or *outside* the United States unless one of several exclusions applies or the State

Department has issued a license authorizing the disclosure or export of the technical data to specific foreign persons.

**Obligations**

Recipients of export controlled technical data may be held personally liable for disclosures to

unauthorized foreign persons. As a result, members of the University community must take reasonable measures to prevent the disclosure to and use and access of export controlled technical data by unauthorized, unlicensed foreign persons. What qualifies as reasonable depends on the circumstances.

**Safeguards**

Examples of measures that members of the University community should consider adopting include clearly marking “controlled” technical data that is controlled, identifying personnel who may lawfully

access the technical data, storing hard copies of controlled technical data in locked cabinets or desks, securing access to electronic copies of and communications containing controlled technical data by

passwords, user ids, or other controls; storing technical data in a single location; making only that number of copies of technical data as is necessary, and requiring all persons with lawful access to controlled technical data to sign this certification.

**Penalty**

Individual liability for the disclosure of controlled technical data to unauthorized foreign persons under

the ITAR can reach up to $1 million per violation and 10 years imprisonment for willful violations, and civil fines up to $500,000 per violation. A university found to be in violation of ITAR regulations can be debarred from contracting with the government and could lose its export privileges.

Liabilities under the EAR may involve fines greater of $1 million for each willful violation. Individuals can be fined up to $1 million and imprisoned for 20 years, or both. Civil penalties can reach up to

$250,000 or 2 times the value of the transaction, whichever is greater, per violation. The university itself

and individual faculty, staff and researchers can also lose their privilege to export and may be debarred from contracting with the federal government.

**Certification on the Handling of Export-Controlled Information**

I certify that I am familiar with the University of North Alabama’s Export Control Policy and the export control issues summarized above, and I have read and understand this certification.

I understand that I could be held personally liable if I unlawfully disclose export controlled technical data to foreign persons and I agree to take reasonable measures to prevent unauthorized foreign persons from having access to or using any export controlled technical data I may receive under the contract identified below.

I agree to take appropriate security measures and to contact The Office of Sponsored Programs before making any type of disclosure of controlled technical data to any foreign person.

Signature of Member/Researcher: Date

Printed Name of Member/Researcher: Division / Department:

Research Project Title: \_\_\_\_\_\_\_\_\_\_ Proposal ID or Contract # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sponsor:

**Please attach a copy of the Export Control Review to this document and return to: Office of Sponsored Programs, Bibb Graves Room 208.**

1. [OMB Circular A-21](http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html) requires that indirect costs be allocated on the basis of modified total direct costs (MTDC). For sponsored agreements using federally-negotiated rates, indirect costs are not assessed on direct expenditures identified as MTDC exclusions. [↑](#footnote-ref-1)
2. \* Use this form for work on grant performed by non-UNA business entity. [↑](#footnote-ref-2)
3. \* See Grant Application Form for evaluation criteria used by the Research Committee regarding specific content and organization for the narrative. [↑](#footnote-ref-3)
4. \* See *Guidelines for Final Research Grant or Contract Report* for final report format. [↑](#footnote-ref-4)