

Data Security Policy Involving Research Data in Human Subject Research

This guidance discusses the protection of research information at the University of North Alabama. The Office of Sponsored Programs, working with Information Technology Services and the Human Subject Committee (HSC) has established guidelines for the protection of human subject data. While the responsibility for protecting confidential data ultimately rests with researchers, the UNA provides the following guidance and support.

Information Technology Services is available to review and approve researchers' information security arrangements. In the case of human subjects research, the HSC reviews study data security plans to ensure the protection of confidential information of research participants.

In the case of human subject research, the following groups have specific responsibilities under the research security policies:

1. Investigators are responsible for: disclosing the nature of the confidential data they collect so the HSC can assess the data security risk; preparing study data security plans and procedures and for implementing and monitoring the data security plans and procedures over the course of their projects.
2. The HSC is responsible for ensuring the adequacy of Investigators' provisions to maintain the confidentiality of data in human subject research. The HSC fulfills its responsibility by obtaining the assurance of the investigator that the proposed data security requirements will be followed. The HSC may seek the advice and recommendations of Information Technology Services in assessing the adequacy of provisions to maintain confidentiality of data and in recommending an appropriate data security process.
3. Information Technology Services will be responsible for assisting investigators to implement the appropriate security requirements for their studies.

1.0 Research Information from non-UNA Sources

Some research information in use at UNA comes from non-UNA sources or is the result of research by UNA personnel in non-UNA facilities.

Research information from non-UNA sources is often accompanied by a use agreement (such as a data use or business agreement) that defines use limitations and/or protection requirements for the information. UNA personnel working with such research information must, at a minimum, comply with the use limits and protection requirements in the use agreement. If confidential information is subject to security requirements specified in an information use agreement, grant, or contract, those requirements must be met. If a UNA researcher will obtain information about human subjects, see 2.0 below. HSC review and approval is required.

UNA personnel using non-UNA facilities, such as hospitals, are usually subject to the security policies in force at such facilities, as is the research information collected using such facilities. Note that the research may be covered by the policies of both UNA and the non-UNA facility. In the event that the non-UNA facility lacks an applicable policy, the research information should be protected under UNA policies.

Note that individual researchers do not have the authority to sign an information use agreement on behalf of UNA. Only offices that have been specifically authorized may sign such

agreements, even when the agreements do not include any transfers of funds. Authorized offices are Vice President for Academic Affairs and UNA President.

2.0 Research Information from UNA Sources

Research. Federal regulation 45 CFR 46 defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Human Subjects. Federal regulation 45 CFR 46 defines a human subject as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Under these regulations and UNA policy, all "human subjects research" at UNA must be reviewed by the HSC before any related research activities are conducted. Personally identifiable information collected for, used in, or resulting from research involving human subjects must be protected from inadvertent or inappropriate disclosure. The HSC will review and approve the researcher’s data security protocol and insure that security requirements are satisfied. In conducting its review, the HSC may rely on the attestation of the researcher, may request confirmation that there has been a satisfactory information security review, or may take other actions as appropriate to the sensitivity of the information.

Other Sensitive Research. UNA researchers may deal with sensitive information that does not relate to human subjects. This information can include proprietary information subject to confidentiality requirements, and information with national security implications. In such cases, the investigator is required to contact the Office of Sponsored Programs for further guidance.

3.0 Legal Requests for Research Information

A researcher may receive a subpoena, national security request or court order demanding disclosure of information in their possession. Should this occur, the researcher must tell the person making the request to contact the Office of the President and UNA’s General Counsel. Only the President or his authorized representative has the authority to respond to these types of requests.

To guard against the compelled disclosure of research data containing individually identifiable information, researchers should consider obtaining applicable government-provided protections for the data. For example, research may qualify, upon application, for a Certificate of Confidentiality. A Certificate of Confidentiality will allow a researcher to refuse to disclose personally identifiable information concerning research subjects in civil, criminal, administrative, legislative or other proceedings. Such subjects can be protected if the research information could damage their financial standing, employability, insurability or reputation. Certificates of Confidentiality can be obtained from the National Institutes of Health (NIH) for NIH-funded research. (See <http://grants2.nih.gov/grants/policy/coc/> for more information.) The Department of Justice also may grant similar protections, upon application, for research involving criminal records. Research funded by the Agency for Health Care Policy and Research enjoys a form of automatic protection. Investigators should consult the Office of Sponsored Programs or HSC for further information on obtaining these protections.