Human Research Participant Protection Plan

The Human Research Participant Protection Program is the University’s established program designed to support its commitment to the protection of human research participants. The HRPP is the umbrella entity that covers all aspects of human research participant protection, training, and community outreach. The IRBs are the part of the HRPP concerned with the regulatory and ethical review of research applications.

I. Mission Statement
The mission of the Human Research Participant Protection Program (HRPP) is to protect the rights, privacy, and welfare of all human participants in research conducted by UA faculty, staff, and students or by others under its oversight through adherence to ethics and federal and state regulations. The mechanisms for protection include development of the policies and procedures of the IRBs in keeping with best practices; education, guidance, and training for investigators, faculty research supervisors, students, and Research Compliance staff; development of a community outreach program to educate research participants and the non-University community about their rights as research participants; and development of a program of evaluation and quality improvement for the HRPP.

II. Goals of the Human Research Participant Protection Program (HRPP)
1. The HRPP will (a) uphold the UA Federalwide Assurance of Compliance (FWA) with the Department of Health and Human Services (DHHS) and the Office of Human Research Protection Program (OHRP), (b) improve the research infrastructure through effective leadership, (c) ensure an effective regulatory review system by providing excellent support services to the IRB members who review research, and (d) ensure that policies and procedures are maintained for the University’s adherence to regulatory requirements and ethical guidelines.

2. The HRPP will institute and maintain a rigorous education program for all users and staff of the HRPP/IRBs to ensure that all components of human research participant protection are compliant with the regulations and that investigators of all levels regard the protection of human research participants and their ethical treatment paramount interests.

3. The HRPP will evaluate itself periodically and use the findings to develop and maintain a quality improvement program to ensure proper protection of human participants, the effectiveness of its training and guidance for investigators and compliance staff, the quality of its reviews of research applications, and the effectiveness of its community outreach. It will identify measures that would strengthen the HRPP and initiate strategies for needed improvements.

III. Governing Principles
The UA IRBs are guided by the ethical principles applied to all research involving human participants, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical
and Behavioral Research (Ethical Principles and Guidelines for the Protection of Human Subjects of Research [The Belmont Report, Appendix K]:

1. **Respect for Persons:** Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information.

2. **Beneficence:** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

3. **Justice:** Justice may be viewed as the equitable distribution of benefits and burdens of research. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Justice demands that: 1. Selection of research subjects is directly related to the problem being studied and 2: Research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

**IV. Applicable Laws**

In the administration of these principles and in its oversight of the research process the University of Alabama will adhere to state and federal law and regulations, including:

- the U.S. Food and Drug Administration 21, CFR Parts 50, 54, 56, 312, and 812;
- the U.S. FDA Information Sheets for the “Guidance of Institutional Review Boards and Clinical Investigators; Alabama Law, and other pertinent regulations and applicable guidelines, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) at 45 CFR 160 and 164.

Legislation about student and parental rights and confidentiality of records (FERPA, “No Child Left Behind”) are relevant to many UA studies. Investigators must also observe special sponsor requirements such as those of the Department of Defense and the Department of Energy.

**V. Organizational Components, Structure, Roles, and Responsibilities**

The institutional Official (I.O.) for UA is the Vice President for Research, who reports to the University President and Provost and is the signatory authority for the OHRP FWAs. The I/O/Vice President for Research is ultimately responsible for the policies and procedures of the HRPP/IRB, ensuring its effectiveness in protecting human research participants through the Director of Research Compliance, and approving resources for the functioning of the HRPP/IRB.

The Director of Research Compliance (DRC) is leader of the Office for Research Compliance and reports to the Vice President for Research. The DRC bears day-to-day responsibility for UA adherence to federal, state, and university regulations regarding the conduct of research; fostering ethical integrity involving research; training HRPP staff, IRB members, investigators, and research staff in human participant protection, care, and safety; managing the IRBs, and staffing, budgeting, and performance of the HRPP/IRB. The DRC maintains channels through which individuals from the research or non-research communities can report complaints and concerns about research studies or investigators, directs that studies be monitored for areas of potential concern, and reports findings to the Vice President for Research and the Office of Legal Counsel. The DRC is a key member of committees or other efforts to
evaluate and improve the HRPP/IRB. The DRC interacts with other University administrators and departments as necessary to accomplish the business of Research Compliance, the IRBs, and the HRPP.

The DRC is assisted by the Executive Secretary (ES) who is responsible for maintaining the inflow log of document into the Office for Research Compliance. The ES is also responsible for (1) managing the training database which includes notifying investigators about deadlines for continuing review and training, (2) coordinating logistics and clerical support for a variety of meetings for the Director of Research Compliance; i.e. Clinical Trial meetings, IRB meeting, and staff meetings, and (3) the maintenance and oversight of all research compliance files. This includes performing yearly archiving duties.

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The DRC is assisted by four Research Compliance Specialists who interface most directly with investigators and the processes of research review. They maintain study records, assist investigators to compile complete applications, remind investigators of deadlines for initial or continuing review and training, send letters informing them of IRB decisions, and assist with compiling of reports.

The DRC is also assisted by a Manager of Research Compliance who monitors approved studies routinely or for cause. These reviews are designed to assess compliance with state and federal laws and IRB policies and procedures and to improve IRB education and operations. Routine monitoring is done in a spirit of quality improvement, and commendable practices will be noted. The results of compliance reviews are reported to the DRC and the IRB. A summary of study monitoring and the needs for education or revision of IRB policies suggested by the findings will be part of the evaluation of the effectiveness of the HRPP/IRB. In addition, the Manager of Research Compliance (1) develops, implements and maintains educational and training materials and programs for the Office for Research Compliance, (2) develops and coordinates effective training and education workshops and modules, (3) creates written materials and lead educational programming for both instructor-led and web-based programming, (4) develops and maintains training manuals, materials and related documentation, and (5) develops, implements and maintains a research compliance participant outreach program. This includes development of training modules, non-compliance hotline standard procedures and program policies to increase awareness of research compliance community initiatives and outreach program. This program is essential to Research Compliance's contribution to the University mission and strategic goals related to research, service and scholarship.

The DRC is assisted by the HRPP Coordinator/ HRPP Accreditation Leader who is responsible for serving as the front line AAHRPP contact and for planning and coordinating the Human research protection program accreditation. The HRPP coordinator keeps the DRC and the Vice President for Research informed of issues of considerable significance that bear on the operations, planning, development, and administration of the accreditation process.

VI. The Institutional Review Boards
The University of Alabama currently has two IRBs designated “Medical” and “Non-Medical” that are authorized by the University to review biomedical and behavioral research involving human participants. Although the IRBs function independently of each other, their reviews can be coordinated with the requirements of other University offices and committees, such as those for Sponsored Programs or
scientific misconduct. In addition to reviews, the IRBs are responsible for reporting unanticipated problems involving risks to participants or others, investigating serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRBs, and suspension or termination of IRB approval. (NOTE: Although the IRB can suspend or terminate a study, only the Vice President for Research can remove a UA investigator’s research privileges.) The decisions of the IRBs about research applications are final and cannot be overruled by any university official.

The IRBs are responsible for reviewing and approving all studies involving humans as participants before the research, including recruitment and screening activities, is initiated. The IRBs are responsible for documenting their findings concerning ethical issues, scientific and scholarly merit, and adherence to University policies and federal or state regulations. A lawyer from University Legal Counsel shall be an ex officio member of each IRB.

VII. The Office for Sponsored Programs
The Office for Sponsored Programs (OSP) is a central resource to faculty for all pre- and post-award administrative aspects for sponsored research, training, and service activities. As some of these administrative aspects (reporting of IRB approvals to sponsor, reports of study problems, sharing and disseminating information, etc.) overlap with IRB concerns, the DRC and the Director of Sponsored Programs will communicate to ensure that human research participants are adequately protected.

VIII. Investigators
Investigators perform their work under the supervision of deans or department chairs who report to the Provost & Executive Vice President for Academic Affairs. They are responsible for creating an ethical climate for research, providing adequate resources for the study and training for research staff, conducting research in a manner that guards the safety of participants and is compliant with all applicable regulations and policies, for reporting study problems to IRB as described in IRB policies and guidance for reporting, and for cooperating with the IRB in its monitoring activities.

IX. Interactions of Organizational Components
The successful fulfillment of the University’s organizational components to protect participants requires open communication among those components. Therefore, regular reports, meetings, and other forms of communication are used both vertically and horizontally within the administrative units and internal groups or individuals involved in the HRPP/IRB. The topic of needed resources for the HRPP/IRB or other units of the Office for Research will be included within those meetings. An open door policy also applies for accommodation of issues that arise in intervals between regularly scheduled meetings.

Employees or agents of the organization may also communicate concerns or suggestions directly to the Institutional Official.

X. Commencement of Research
Research shall not begin until it has been reviewed and approved by the IRB. The IRB withholds the study approval letter until all applicable documentation has been received and any applicable agreements with industry sponsors have been signed. Investigator failure to observe this requirement will be considered serious noncompliance and will be investigated in keeping with the IRB policy on noncompliance.

XI. “Engagement in Research” and “Agents of the University”
The University becomes engaged in human participant research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes (45 CFR 46.102 (d)(f)).

An agent is a person who performs institutionally-designated activities or exercises institutionally-delegated authority or responsibility. The University is automatically considered “engaged” in human participant research when it receives a direct HHS award to support such research.

All research involving human participants, including research in which the only involvement of humans is in one or more categories exempted or waived under 45 CFR 46 101(b)(1-6) or 101(i), and all other activities which involve such research even in part, regardless of sponsorship, are subject to IRB review if one or more of the following apply:

1. The research is sponsored by the University;
2. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University in connection with his/her institutional responsibilities; and/or
3. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University using any of its properties or facilities;
4. The research involves the use of the University’s non-public information to identify or contact human research participants or prospective participants; and/or
5. The research is conducted by or under the direction of an individual employed by any affiliated sites and who is performing the research at that site.

XII. When Research is Subject to HRPP/IRB

All research involving human participants as defined in 45 CFR 46 102(f), even if exempt per 45 CFR 46, 101(b)(1-6) or 101(i) must be reviewed by an IRB or its designee before research begins, to ensure that participants or their interests are adequately protected.

According to federal regulations the activities that require IRB review include those involving the collection of data through intervention or interaction with a living individual or involving identifiable private information about a living individual. These activities include, but are not limited to:

1. An experiment involving a test article and one or more human subjects and that (1) meet the requirements for prior submission to the FDA, under relevant investigational drug or device provisions of the Food, Drug, and Cosmetic Act, or (2) are experiments that need not meet the requirements for prior submission to the FDA but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit;
2. A patient’s care or assignment to intervention is altered in any way for research purposes;
3. A diagnostic procedure for research purposes that is added to a standard treatment;
4. Systematic investigation involving innovative procedures or treatments compared to standard treatments;
5. Emergency use of an investigational drug or medical device. The patient in such case is a research subject as defined by FDA, and FDA requires that data generated from the care be used in reports to FDA. However, to meet the FDA exemption from prior IRB review, the activity cannot be a prospectively planned systematic investigation designed to develop or contribute to generalizable knowledge;
6. Human cell or tissue (genetic tissue) research collection, storage, and distribution of human tissue materials for research purposes when that activity meets the definition of human
participants research per 45 CFR 46 102(f) and the glossary. IRB review is not required if the activity does not meet the definition of human participants research.

7. Investigator-initiated research where an investigator both initiates and conduct, alone or with others, a clinical trial. In investigator-initiated research it is the investigator’s responsibility to keep IRB informed of unanticipated non-serious research-related events and unanticipated serious adverse events and other unexpected findings that affect the risk/benefit assessment of the research, even if the event occurred at a location for which the University is not the IRB of record. The UA IRBs recommend that an independent data safety monitoring board (DSMB) review all reportable adverse events and forward them to the IRB, in addition to individual reports.

8. Student research that meets the definition of research with human participants and is conducted as a degree requirement must be reviewed by the IRB. This includes pilot studies, honors theses, master’s theses, and doctoral dissertations, conducted with the intent to publish or otherwise disseminate findings and any research involving greater than minimum risk to participants.

9. More than one case study (n = 2 or greater) conducted with the intent to publish or disseminate findings is considered research at UA and must be reviewed by the IRB. A case study of a single individual that includes a procedure that is outside the standard of care also qualifies as research and must be reviewed by the IRB.

10. Research that is not medically invasive, not clinical, and not health-related but does involve human participants is also required to go through IRB review. The definition of research with human participants is “A systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge that involves a living individual about whom an investigator (whether professional or student) obtains data through an interaction with the individual or obtains identifiable private information. The intention to contribute to knowledge is key to the definition, whether or not the completed research actually does make such a contribution or is accepted for publication. Activities that may meet this definition include pilot studies (research development), interview procedures, surveys, observational studies, case studies, oral histories, and analyses of existing data such as chart reviews.

11. Socio-behavioral research that involves direct/indirect participant observation, questionnaires or surveys, interviewing, audiotaping, videotaping, photography, or review and analysis of existing data must be reviewed by the IRB. The IRB will consider study methods, storage, and destruction of data.

XII. Consultation
The HRPP/IRB may seek consultation about any issue about which additional guidance is needed, including proposal review, evaluation of HRPP, and quality improvement.

XIII. Investigation
The HRPP/IRB will investigate all complaints about investigators or other individuals associated with human subjects’ research. Findings will be reported to the Vice President for Research, other university personnel, sponsors, or OHRP as necessary.

XIV. Research Not Conducted at UA
UA does not conduct planned emergency research.
Current Characteristics of UA Research, February 2011

The following characteristics of UA research are the context for the HRPP Plan efforts:

1. Approximately 90% of UA research is non-medical, although the proportion that is medical is increasing. (This fact led to the creation of a separate Medical IRB in 2005.)

2. Our medical school provides rural health experience for family practice students from the University of Alabama at Birmingham. The nature of family practice means that medical research at UA does not generally involve research with high risks for participants.

3. Clinical trials are relatively new to UA; as yet no medical clinical trials have been initiated by a UA investigator.

4. School-based intervention research, longitudinal surveys of youth, research involving prisoners, research involving autistic children, research using cognitive-behavioral therapy, and research on exercise are major foci of UA investigators’ research.

5. Community-based research, community partnerships, and research on racial/ethnic populations are increasing.

6. Qualitative research, analysis of existing data sets, and studies using Protected Health Information are quite common in UA IRBs.

7. UA IRBs see many proposals from students.

8. There is a need to increase investigators’ familiarity with the regulations, particularly those involving vulnerable populations and waivers and alteration of consent.

9. The results of routine post-approval monitoring and monitoring for cause should be included in the quality improvement process.

10. Awareness of research rights and protections is not high among University students or the non-UA community. Therefore, an outreach effort is very much needed.

11. Historically, bulky handbooks for UA IRB reviewers and investigators have not seen much use. Current plans are to develop (1) single-focus policies and procedures (with policy and procedure combined in the same document). Policies will also direct investigators’ attention to related topics to consider; (2) Forms, to facilitate compliance with IRB policies and regulations and submission of complete applications, and (3) Guidance documents, which provide helpful suggestions, templates, or actual examples of items like consent forms.