Abraham Baldwin Agricultural College

# Human Subjects Research Procedures

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## Contents

# POLICY STATEMENT

It is Abraham Baldwin Agricultural College (ABAC) policy that no research involving human subjects may be undertaken until approval has been granted by the Institutional Review Board (IRB). This includes research conducted or involving ABAC faculty, staff, and students from all instructional sites. The procedures below hereby incorporate ABAC policy 13.2 by reference. ABAC adheres to the principles outlined in the Belmont Report, as well as with the federal regulations, outlined in 45 CFR 46 and 21 CFR 56, including their subparts, as applicable. In addition, the college complies with other ABAC and University System of Georgia policies and procedures concerning the use of human participants in research.

Procedures shall be reviewed every two years or as needed. Minor procedure changes, such as updated web links or forms, may be completed by the VP for Academic Affairs without prior authorization. Substantive changes and new procedures will be brought to the full IRB for their review and approval. If the Board determines it is warranted, further review by the Cabinet and President may be required.

# INSTITUTIONAL REGULATIONS

Abraham Baldwin Agricultural College's IRB is registered with the Office for Human Research Protections (OHRP) as IRB00007799 and holds a Federalwide Assurance (FWA) of compliance as FWA00028397.

# STATE, FEDERAL AND INTERNATIONAL REGULATIONS

## Georgia laws

Age of Consent: In Georgia, the basic age of consent for participation in research is 18 years, which is also the age at which Georgians may enter contracts or consent to medical services. Those under the age of 18 are considered "children." Parental permission must be provided for children to participate in research; exceptions to this requirement may only be granted by the IRB.

Emancipated Minors: Georgia law recognizes the concept of the emancipated minor. "Emancipation" means termination of the rights of the parents to the custody,

control, services, and earnings of a minor. "Minor" means a person who is at least 16 but less than 18 years of age.

Reporting Requirements: Georgia law requires certain individuals to report the abuse, neglect, or exploitation of children, disabled adults, and elderly persons (See OCGA § 19-7-5; OCGA § 30-5-4; OCGA § 31-8-82).

Lotteries, raffles and games of chance: The State of Georgia closely regulates the operation of lotteries, raffles, and other games of chance (collectively, “raffles” for purposes of these procedures). In Georgia, a raffle is defined as “any scheme or procedure whereby one or more prizes are distributed by chance among persons who have paid or promised consideration for a chance to win such prize.” O.C.G.A. § 16-12-22.1(b)(3), as it pertains to 501(c) nonprofit organizations or bona fide nonprofit organization approved by a sheriff. This definition is very broad and includes any procedure whereby a prize is given away, as long as the participant is required to provide something of value (i.e., “consideration”) in exchange for the chance to win. Consideration can include an individual buying a raffle ticket or giving up his/her time in order to participate in a research study. It is a misdemeanor of a high and aggravated nature, and in some instances a felony, to conduct a raffle (or aid in the operation of a raffle) without a license issued by a county sheriff in Georgia.

However, raffles may be conducted if persons are allowed to participate in the raffle without having to provide any consideration. For example, in the research context, any person should be able to participate in the raffle, even those persons not participating in the research study itself, for the raffle to satisfy state laws. Accordingly, in a rare circumstance where a raffle may be conducive to a research study, the ABAC Institutional Review Board must review and approve the procedures underlying the raffle, as well as the protocol generally. Due to concerns related to fairness and the potential for coercion and undue influence, the IRB generally discourages the use of raffle as a mechanism for participant compensation. However, ABAC’s IRB recognizes that such raffles may provide useful and meaningful participant engagement in certain specific research studies. Accordingly, the IRBs may consider protocols utilizing raffles as a means for participant compensation on a case-by-case basis, with appropriate justification provided by the Principal Investigator.

## Federal regulations and guidance

The Belmont Report:
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

45CFR46:
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

National Institutes of Health:
https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects

National Science Foundation:
https://new.nsf.gov/funding/research-involving-human-subjects

Food and Drug Administration:
https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fda-policy-protection-human-subjects

Food and Drug Administration 21 CFR 56:
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56

Health and Human Services on International protections:
https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

### International regulations and guidance

General Data Protection Regulation (European Union)
https://gdpr-info.eu/

Declaration of Helsinki
https://www.wma.net/policies-post/wma-declaration-of-helsinki/

Health and Human Services compilations
https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

## INFORMATION PRIVACY

### FERPA

The Family Educational Rights and Privacy Act ("FERPA") (20 U.S.C. § 1232g; 34 CFR Part 99) is a federal law that gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she

reaches the age of 18 or attends a school beyond the high school level ("Eligible Students"). The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education (ED), such as Title I. ABAC researchers are responsible for complying with FERPA, USG policy on Student Privacy and applicable ABAC policy.

FERPA requires written permission from parents or Eligible Students to be obtained before releasing any information from student Education Records, except in the case of specific exceptions set forth in 34 CFR § 99.31. While FERPA does not have a research exception to the written consent requirement *per se*, FERPA does allow educational agencies or institutions to share Personally Identifiable Information ("PII") from Education Records under certain circumstances.

Under FERPA, the educational institution is responsible for determining whether and what information may be accessed from an Education Record. The IRB does not have authority to require access to information from an Education Record. If an institution denies a researcher access to information in an Education Record, the IRB cannot overrule the decision.

FERPA regulations specify that a parent or Eligible Student must provide a signed and dated written consent in accordance with the requirements of 34 CFR § 99.30 before Personally Identifiable Information from Education Records is disclosed, unless the disclosure falls within one of the exceptions set forth in 34 CFR § 99.31. FERPA's consent provisions require specification of: 1) the records that may be disclosed; 2) the purpose of the disclosure; and 3) the identity of the party or class of parties to whom the records may be disclosed. The consent language may be included within an informed consent document.

FERPA allows schools to designate and disclose, without consent, certain items of information as Directory Information, such as a student's name, home town, major, class level, honors and awards, and dates of attendance. Each educational institution designates what information is considered directory information. (See definition for Georgia's list.) The researcher should contact each institution from which they propose to access student records and follow that institution's FERPA policy and procedures when accessing directory information.

For all studies that involve access to Education Records held by a school other than ABAC, a letter from such school indicating its willingness to participate in the study AND the manner under FERPA the Education Records will be accessed, e.g., researcher is obtaining student consent, researcher is accessing Directory Information, etc., must be included in the study application to the ABAC IRB.

## HIPAA

In response to requirements in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act ("HITECH") and the Genetic Information Nondiscrimination Act ("GINA"), the Department of Health and Human Services has issued regulations that are commonly referred to as the HIPAA Privacy Rule and the HIPAA Security Rule. The Privacy Rule is a response to public concern over potential abuses of the privacy of health information. The Privacy Rule establishes a category of health information, referred to as Protected Health Information, or PHI, which may only be used or disclosed to others in certain circumstances or under certain conditions. PHI is a subset of what is termed Individually Identifiable Health Information. With certain exceptions, Individually Identifiable Health Information becomes PHI when it is created or received by a Covered Entity. Covered Entities are health plans, health care clearinghouses, and health care providers that transmit health information electronically in connection with certain defined HIPAA transactions, such as claims or eligibility inquiries.

ABAC is not primarily engaged in the activities that define a Covered Entity, but it does have units that perform functions that fit the "Covered Entity" definition. HIPAA allows a single legal entity whose business activities include both functions that are covered by the regulations and those that are not covered to designate itself as a "Hybrid Entity" regardless of whether those functions that are not covered are a primary part of the educational and research purposes or just a small percentage. Accordingly, ABAC designates itself a "Hybrid Entity" for HIPAA compliance purposes. As a Hybrid Entity, ABAC is required to document identification of those of its units that perform covered functions ("Covered Units").

ABAC has designated the Health Center in Tifton GA and the ABAC Counseling Services Center in Tifton GA as its health care components and Covered Units. While the Student Health Center is a Covered Unit, it does not hold PHI, as the patient population consists only of ABAC students; therefore, the records are considered "treatment records" under the Family Education Rights and Privacy Act ("FERPA"). The Counseling Services Center is required to comply with HIPAA's privacy rules and standards. More information about the policies and procedures of the clinic may be obtained by the practice manager of the Center.

The HIPAA Privacy Rule will impact ABAC research projects if the PHI is obtained from Covered Entities within or outside ABAC, such as a hospital or pharmacy. If

your research involves a Covered Unit, contact the Office of Sponsored Programs prior to submitting your application for research to the IRB.

Personal health information that is not obtained from a Covered Entity, that is self-disclosed by research participants, and that is kept only in the researcher's records is not subject to HIPAA but is regulated by human subjects protection regulations.

De-identified health information, as described in the Privacy Rule, is not PHI, and thus is not protected by the Privacy Rule.

PHI may be used and disclosed for research with an individual's written permission in the form of an Authorization. PHI may be used and disclosed for research without an Authorization in limited circumstances: under a waiver of the Authorization requirement; as a limited data set with a data use agreement; in a review preparatory to research; and for research on decedents' information.

The ABAC IRB has the authority to consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. Also, under the Privacy Rule, an Authorization may be combined with the informed consent document for research. If the informed consent document is combined with an Authorization meeting the Privacy Rule's requirements, Protection of Human Subjects Regulations (45 CFR part 46) would require IRB review of the combined document.

## ELECTRONIC DATA

Most human subjects research data is collected, stored and/or analyzed electronically. It is important to consider the risk of data breach in any project, doubly so with personal or sensitive information. Some general considerations are discussed below, but ultimately it is the responsibility of everyone on the research team to safeguard this important asset. Final and ultimate responsibility of protecting the safety and security of human subjects data lies with the Responsible Researcher. In all cases, the IRB will only grant permission to use software, systems, apps, etc. that conform to applicable federal, state, Board of Regents and ABAC information security policies.

When using email to collect and/or store project information, researchers must use ABAC systems. For students, the domain is stallons.abac.edu; for faculty and staff abac.edu. Any project correspondence taking place outside of these two domains must be disclosed in the IRB application and must be approved in advance by the IRB.

When using software systems to collect and/or store project information, these systems must be disclosed in the application. Examples include survey software such as Qualtrics, transcription services such as otter.ai, or analytical software such as SPSS or Nvivo. The use of these systems must receive advance approval. Researchers are strongly encouraged to use packages ABAC or the researcher maintains current subscriptions to and has working privacy agreements with, such as Qualtrics and Microsoft Forms. Other packages, such as Google Forms, Facebook or Survey Monkey may be acceptable in their higher-compliance subscriptions (that are HIPAA compliant) but will require a review of the package's suitability and privacy controls. When using software systems that are not maintained by ABAC, researchers must include information about those systems' handling of private and/or confidential information in their IRB application.

Generally, social media should be avoided in human subjects research data collection and/or storage unless the social media content is the research topic. The ABAC IRB does not allow researchers to use social media to collect data from human subjects or store such data. Examples of using social media for human subjects research data collection include using Facebook messenger to conduct interviews, using Twitter (now X), Whatsapp or LinkedIn polls to collect survey responses. Researchers may propose using these platforms to collect data where there is no interaction with the subjects, for instance, scraping data from a large number of customers to detect trends. Researchers may also propose using these platforms to research the interactions between users, for instance, as an observational study. In all allowable cases, no research data are stored within the social media platform.

The IRB also recognizes, however, that social media provide excellent venues for recruitment. Researchers may use these platforms for anonymous recruitment purposes, such as posting a QR code to an online survey which then directs researchers to an acceptable survey package. When using social media for recruitment purposes, research teams should note that anything posted to social media is no longer under their control or ownership, so they must take care in crafting their recruitment messaging. Anything posted to social media no longer belongs to the person posting. Instead, it belongs to the media company.

Artificial Intelligence (AI) is a rapidly evolving research area. Human subjects research data are always private and protected and so any AI systems used must ensure this. Generally, PII, PHI, medical records (even if de-identified), proprietary information, including research data and other intellectual property, may not be entered into any AI system. It may be acceptable to use certain AI systems to create

content for reports or publications but must be cited as such and shall not use ABAC human subjects research data. Since the nature of human-AI interactions and data sharing may be complex, applicants are required to discuss these as part of their application in any sections needed but at least within the research protocol, consent, privacy and risk areas. The IRB will treat these on a case-by-case basis.

Similarly, applications to and correspondence with the IRB should be the researcher's own work product and not generated by an artificial intelligence system. Any portions of applications or correspondence produced by an AI system must be disclosed and cited as a reference like any other non-original work. Meetings will not be recorded or transcribed by conventional, electronic or AI-based technology.

Identifiable human subjects research data should only be stored on password and malware protected systems in use by the institution. ABAC researchers should only store human subjects research data, including de-identified data, on "corporate" systems, e.g., work-issued computers, software packages or cloud services such as OneDrive or Sharepoint. Students and faculty should not collect or store human subjects research data on their own computers or cloud systems. Off-site researchers should use "corporate" systems similarly fitted with malware protection, hardware firewalls and licensed, current, comprehensive security packages. Details of these protections should be included in the application to the IRB. Off-site researchers may not use personal systems to store ABAC human subjects research data. Under no circumstances should identifiable data be stored or transported on open systems such as flash drives, removable drives, unencrypted devices, personal clouds or network attached storage systems. If necessary, secure USB devices may be employed for data transport with advance permission from the IRB. Anonymous data may be stored or transported on any system.

## DEFINITIONS

*ANONYMOUS DATA* is collected without use of any personal identifiers in the first instance. Given the data collected, it would be impossible to re-create the respondent's identity in part or whole.

*A CONFLICT OF INTEREST* is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

*DE-IDENTIFIED DATA* is collected using personal identifiers that are removed during the research process.

*DIRECTORY INFORMATION:* All institutions in the USG conform to a system-wide definition, available here: https://www.usg.edu/academic_affairs_handbook/section3/C678#:~:text=Definition%20of%20Directory%20Information,Hometown. Other institutions outside the USG may have different definitions.

*GENETIC MATERIAL* refers to substances contained within cells that indicate heredity within the organism. Examples include DNA (Deoxyribonucleic acid) and RNA (ribonucleic acid).

A *HUMAN SUBJECT* a living individual about whom an investigator conducting research 1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For these purposes, Test Subject, Participant and Research Subject are synonyms with Human Subject.

*An INSTITUTIONAL REVIEW BOARD* is charged with safeguarding human subjects research and uniformly applying applicable federal, state and ABAC policies.

*RESEARCH* refers to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The *RESPONSIBLE RESEARCHER* is the person who oversees a human subjects research project. They are responsible for applying to the IRB, conducting the project as listed in the application, overseeing participant privacy/confidentiality and reporting results.

*RISK* is the possibility of harm. Examples include physiological, physical, legal, social or financial harms.

A *SYSTEMATIC INVESTIGATION* is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

# FOR IRB MEMBERS

## Membership

The Institutional Review Board (IRB) is appointed by the Provost and Chaired by an employee appointed by the Provost. The Board shall : 1) have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects; 2) have at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas; 3) have at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; 4) not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. Membership will be reviewed by the Chair and Provost annually.

## Member Training

Voting IRB members shall maintain at least current “IRB Member Basic or Refresher” and “CITI Conflict of Interest” training certificates through Collaborative Institutional Training Initiative (CITI) and shall send electronic copies to the Chair for IRB records. Certain *ad hoc* members who may be called upon to assist in their areas of expertise may choose to take these courses of training, or others as appropriate.

## Membership Conflict of Interest

Members shall sign Conflict of Interest Certifications annually, copies of which will be kept with IRB records. Further, Members shall indemnify and hold the College and other IRB Members harmless against damages caused directly by their failure to disclose conflicts of interest. Members shall disclose immediately any conflict of interest to the Chair. These conflicts may be financial in nature, or may involve commitments to others, shared projects, involvement with a protocol under review, or some other. Failure to disclose a conflict may result in removal from the IRB and other disciplinary action per existing ABAC policy. Should a conflict exist, the Chair and Provost will be responsible for adjudicating and, if necessary, notifying appropriate agencies.

## Meetings

The IRB shall meet as a group at least once each month during the academic terms or eight times per academic year. Additional meetings may be required to address pressing needs and will be scheduled by the Chair. For voting purposes, a quorum shall be half of the voting membership plus one. The Chair or other officer as deemed necessary will circulate an agenda in advance of each meeting and will take minutes during meetings. Minutes will be revised as needed at the next meeting and will be maintained by the Chair with IRB records. Meetings will not be recorded or transcribed by conventional, electronic or AI-based technology.

## IRB Review Process

The Chair will receive all new applications via an email address set up for IRB correspondence. Within five business days, the Chair will conduct an initial administrative review of the application. Pursuant to that review, the Chair will correspond with the applicant as needed to resolve any issues with the application or supporting materials. When the application is complete and ready for review, the Chair will either review the protocol directly or will assign it to one or more members, as needed. Members will have five business days to review and revert their determinations to the Chair. All reviews will be documented by single review form to be used in all cases. Once reviews are complete, the Chair will correspond with the applicant. If revisions are needed, the Chair will collect adjusted materials and may revert to the original reviewers who will have five business days to conduct a follow-up review. This process will continue for one further round, if needed. Beyond this – one administrative review and two rounds of revisions – the application will be disqualified if not approved. Once approved, the Chair will send the applicant a letter reflecting the same, as well as any conditions the Board may impose on the research. The applicant will be asked to review and sign the letter, then return it to the Chair within five working days or one calendar week.

## Research Determination for Exempt, Expedited and Full Board Review

There are two main types or levels of IRB review, expedited and full board. In addition, some research projects do not need to be reviewed in a formal way. In all cases and for all research projects, the IRB – not the applicant – determines which applies to each research project, then conducts a review accordingly.

EXEMPT review refers to a group of research project types and circumstances that need not undergo a formal review by the IRB but do need to undergo a limited review to determine if an exemption applies per 45 CFR 46.104. One or more IRB member(s) may make this determination. If on review the IRB determines a project to be EXEMPT, no further review will be required unless the research circumstances change.

Research circumstances determined to pose no more than minimal risk to participants, or for minor changes to protocols, as described in 45 CFR 46.110, the IRB may use an EXPEDITED review procedure. The review may be carried out by the Chair of the IRB and one or more experienced reviewers designated by the Chair from among membership of the IRB. The reviewers may exercise all of the authorities of the IRB except that they may not disapprove a research project.

Except when an expedited review procedure is used, an IRB must review proposed research at a FULL BOARD convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

## Record Retention and Destruction of IRB records

It is the responsibility of the IRB Chair to maintain official records of the Board's actions and decisions per retention schedules set out by funding agencies, USG Board of Regents, and ABAC policies. All research records must be accessible for inspection and copying/reproduction by authorized representative (e.g. HHS, FDA, Sponsors, auditors) at reasonable times and in a reasonable manner. Once the specified retention period has expired, records – both paper and electronic – shall be destroyed or permanently deleted. NOTE: Retention schedules for Institutional Review Board records may vary from those required for researchers. For instance, the IRB may store a researcher's protocol with their application but would not store or have access to project data. The retention requirements for data and protocol application may differ. It is the researcher's responsibility to store project data.

# FOR APPLICANTS

## Research Determination and Retroactive Approval

Only the IRB may make the determination whether or not a project is human subjects research. ABAC's IRB has determined that research using specific publicly available data sets, class projects meeting specific criteria, some oral history projects, some sponsored project reporting, and some projects using readily available cell lines or cultures do not constitute human subjects research and do not require you to submit an application.

Determining what constitutes human research is often a difficult task, in part because the distinction between research, on one hand, and non-research evaluation, journalism, and other activities involving interactions with living individuals or use of their private information, on the other, may not be clear cut. The Institutional Review Board is responsible for making the determination of whether an activity is human subjects research.

The IRB considers the research use of certain publicly available data sets to not involve "human subjects" as defined by federal regulations. The data contained within these specific data sets are neither identifiable nor private and thus do not meet the federal definition of "human subject." Therefore, ABAC does not require these research projects to be reviewed and approved by the Institutional Review Board (IRB). Please contact the IRB if you have questions regarding the use of publicly available data.

Student work involving human subjects at ABAC generally falls into one of two categories: 1) Research practica and 2) research projects. ***Research practica*** - research activities, such as class projects, with the goal of providing research experience to the students; by definition, research practica are not intended to add to generalizable knowledge and thus do not meet the federal regulatory definition of research. That is, the product from the practicum will not be submitted for presentation or publication at the time of the activity or in the future.
Since they do not contribute to generalizable knowledge, research practica do not usually require IRB submission. However, the faculty of record bears the responsibility to ensure that students engaged in these practica behave according to the highest standards of professional ethics and in accordance with the policies and procedures of the setting in which the activity takes place. ***Research projects*** - faculty-directed or independent research activities (for example, some capstone, undergraduate research, honors or graduate theses) with the goal of adding to generalizable knowledge must be submitted to the IRB for review and subsequent

approval. The Institutional Review Board is responsible for making the determination of whether a student activity is human subjects research.

The purpose of oral histories is to preserve primary source information about the past to be used by others. Oral history is a method of gathering and preserving historical information that is authentic, useful, and reliable. It is done by recording interviews with subjects about people, places, or events in their lives in the form of recollections, reminiscences, and memories of the subject about their past as requested and recorded by an interviewer. Oral histories are primary sources recorded in the person's own words with no interpretation, analysis, or aggregation by another person.

A decision whether oral history or other activities solely consisting of open-ended qualitative type interviews are subject to the protection of human research subjects (45 CFR 46) is based on the prospective intent of the investigator *vis* "research" and "generalizable knowledge", as defined above. Oral history documents specific historical events through the individual perspective of the narrator, and thus in general is not designed to contribute to generalizable knowledge and should not be considered "human subjects research." However, if an historian collects answers from 200 people to the same questions on a Likert scale, then performs statistical analyses and presents at a regional meeting, it would be considered "human subjects research." The Institutional Review Board is responsible for making the determination of whether an oral history activity is human subjects research.

Journalistic work is generally not considered "human subjects research". If the intent of the work is to gather facts and circumstances then publish a summary, abstract or commentary on the same, even if those facts originate with live humans, the activity will generally fail the "systematic investigation" portion of the "research" definition. Data will not be collected using established measures, statistics will not be applied to the results, analyses will not follow the scientific method, and results will not be presented at a research symposium or peer reviewed journal. The work product does not purport validity through data collection methods and analyses, rather, the journalist will follow an idea, fact, or event as observed by one or more people, record their thoughts as they issue them, and present a story in a suitable media venue. For journalists, purported validity rests with the subjects and their retellings. The Institutional Review Board is responsible for making the determination of whether a journalistic activity is human subjects research.

Reporting progress of a sponsored project to a funding agency is generally not considered human subjects research because the purpose is for program improvement and not increasing generalizable knowledge. However, if the funding

agency or project staff wish to present project data involving human subjects at a conference or annual meeting, this meets the "generalizable" criteria and so would be considered human subjects research. Also, public-facing abstracts or web posts may meet the "generalizable" criteria and so would be considered human subjects research. The Institutional Review Board is responsible for making the determination of whether a project reporting activity is human subjects research.

Researchers in the situations above should bear in mind that retroactive approval may never be given by ABAC's IRB, or any other institution's IRB. That is, if a study is conducted for a non-research purpose, the researcher may not receive IRB approval to analyze the data collected in a different manner, perhaps a manner meeting the definition of "research," after the fact. As such, it is generally advisable for researchers to apply to and receive IRB clearance if the work or data may be used later.

*In vitro* research using cell lines that are already derived and established, from which the identity of the donor cannot readily be ascertained by the investigator, is not considered human subjects research and therefore is not governed by 45 CFR 46. IRB review is not required for such research.

Research involving cells that have already been derived and established, where the donor may be identified, including cells that retain links (such as a code) to identifying information, is human subjects research and therefore requires submission, review and approval by the IRB. The Institutional Review Board is responsible for making the determination of whether a cell line activity is human subjects research.

Literature reviews using only published data are not considered human subjects research. Literature reviews where additional unpublished data are obtained from the author or others for meta analyses and other activities may be considered human subjects research. The Institutional Review Board is responsible for making the determination of whether a literature review activity is human subjects research.

## Researcher Qualifications

Any ABAC employee may conduct human subjects research, provided the researcher:

- Has obtained the necessary human subjects research certification(s)
- Is not debarred or suspended by any agency, nor is currently under indictment for any crime, nor has been convicted of a crime which might preclude responsible conduct

- Is an adult, physically capable of carrying out the project
- Has the requisite licenses or certifications to carry out the project
- Has the requisite funding to carry out the project, if needed
- Has passed a state of GA background check within the past two years, if needed
- Has completed suitable ABAC mandatory reporter training, if working with minors
- Has suitable systems and devices available for storing research artifacts

Non-ABAC employees from other institutions, including graduate students, may conduct human subjects research using participant ABAC students or employees, provided they apply as any other and meet the qualifications above.

Unaffiliated researchers (who do not have a home institution) may conduct human subjects research using participant ABAC students or employees, provided they apply as any other and meet the qualifications above. In addition, they must agree to abide by the ABAC IRB terms discussed in the Unaffiliated Investigator Agreement.

## Researcher Responsibilities

Researchers are collectively and separately responsible for:

- Conducting their research according to the IRB-approved protocol and complying with all IRB determinations
- Obtaining and documenting the informed consent of each subject or each subject's legally authorized representative, unless the IRB has waived one or more of these requirements
- Ensuring that each potential subject understands the nature of the research and participation
- Promptly reporting proposed changes in previously approved human subject research activities to the IRB.
- Reporting progress of approved research to the IRB as often as, and in the manner, prescribed by the IRB.
- Promptly reporting to the IRB any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with the HHS regulations or determination of the IRB

## Training Requirements

Everyone applying to the ABAC IRB must furnish proof of human subjects research training covering at least the following human subjects research topics:

- The Belmont Report and its principles
- History and Ethical principles
- Defining research with Human Subjects

- Federal regulations
- Assessing risk
- Informed consent
- Privacy and Confidentiality
- Internet-based research
- Populations requiring additional safeguards and/or protections

Additional training and certification may be required if the applicant intends to work with prisoners, HIPAA or FERPA data, minors, public school children, individuals outside the United States, vulnerable populations, or who may have potential conflicts of interest (commitment and/or financial). The IRB will make the final determination if and which additional training is needed.

ABAC maintains an institutional subscription to the Collaborative Institutional Training Initiative (CITI Program) that offers the necessary training and certifications free of charge to all ABAC researchers. The most basic level of human subjects research training is "Basic/Refresher" with offerings in Social and Behavioral Sciences or Biomedical Sciences tracks. This course covers the necessary topic for most applicants. Modules are available free of charge to all ABAC researchers for the additional training mentioned above. These are listed as "Elective Modules" within the CITRI environment.

Current CITI training from non-ABAC institutions may constitute sufficient human subjects research training but the IRB will make that determination. Applicants should furnish not only the current CITI completion Certificate for the outside institution but also the accompanying Completion Report showing the modules completed and scores. Non-CITI training generally will not be accepted, though exceptions may be granted for research-based institutions providing their own human subjects research curriculum.

The Responsible Researcher will ensure everyone who will collect, have access to, analyze, or store raw/identifiable data maintain current human subjects research training. CITI training is usually valid for three years. After that, researchers may take a "refresher" course to keep their certification current. ABAC offers these CITI courses free of charge to all of its employee and student researchers. ABAC does not offer training for off-site or unaffiliated investigators.

## Undergraduate student researchers

Undergraduate students must conduct human subjects research with a supervising faculty member. The student is responsible for identifying, recruiting and signing the faculty member while the faculty member is responsible for reviewing and approving the student's training credentials, protocol and application. The faculty

member should have and maintain CITI Human Subjects Research training certification. The student should be listed on the application as the Responsible Researcher, but in cases where risks to participants are more than minimal, the IRB may re-assign this role to the faculty member. Data sharing between faculty and student should be discussed in the application, along with data retention and destruction.

## Submitting and application

The IRB makes a form and instructions available for applicants. The latest should be posted amongst other documents on the IRB website available here:

https://www.abac.edu/academics/provost/institutional-review-board.html

The content of this form may change over time so be sure to check back for the latest. If for some reason this site does not contain what you need, please email IRB@stallions.abac.edu.

Although the form and instructions are largely self-explanatory, a few items need mentioning. Be sure to list everyone who will collect, have access to, analyze, or store raw/identifiable data, as well as anyone who will have an active part in the research project in Sections I and II. The IRB or FWA number requested in section II is only for researchers outside of ABAC. Everyone listed in these two sections should have completed at least basic human subjects research.

The questions in section III are designed to prompt certain review responses from the IRB and should be filled out as completely as possible. Once the IRB determines that you have a human subjects research project, the type of review your project needs, and the possibly exemptions from those reviews will be determined by the IRB, not the applicant.

Section III requires an attachment answering questions 10-18. The instructions provide guidance on these questions. Do not forget to attach your responses.

Review Section IV carefully in light of your project. The basic requirements everyone should take are listed first, then additional training requirements for special situations or vulnerable groups.

Section V requests certifications and signatures. Please read these carefully. The Responsible Researcher signs first, then any co-investigators listed in section II, then a “Supervising Faculty” if it is an undergraduate research project. Most signatures will suffice. Although the form is set up for Adobe electronic signatures,

and those are preferred because they are time-stamped, the state of Georgia requires only the *intent* to sign as legally binding. It is also acceptable for applicants to sign in ink, then scan the application for transmittal to the IRB.

Undergraduate research projects require an additional "Faculty Advisor Routing Sheet" which must be filled out and signed by the same person signing as "Supervising Faculty" on the application.

Investigators wishing to collect data or use study populations not affiliated with ABAC should enclose letters of permission from each location as signed by a Director-level administrator or researcher in a position to oversee human subjects research at that site or with that population.

External investigators affiliated with other institutions wishing to use ABAC's students, faculty or staff as test subjects should apply to the ABAC IRB normally but also enclose IRB clearance from their home institution and applicable human subjects research training certificate(s). Please be sure to list the home institution's FWA and IRB in Section II.

External investigators who have no institutional affiliation should also fill out, sign and enclose an "Unaffiliated Investigator" form with certain declarations and contact information.

The completed application form should be sent to IRB@stallions.abac.edu and the Chair of the IRB (currently scott.pierce@abac.edu) with co-investigators and/or faculty supervisors in copy. In addition to the application form, make sure to include along with it, the following in a single PDF file:

- Responses to questions 10-18
- Faculty Advisor Routing Sheet, if applicable
- Consent and Assent dialog, if applicable
- Recruiting materials/fliers and sample recruiting language
- The IRB needs to review everything participants will see or be asked to do so be sure to enclose materials to be distributed to respondents, e.g., survey questions, debriefing language, etc.
- Human Subjects Research training certification(s)
- Completion Reports for any additional modules
- Additional forms or letters, if applicable

# PROJECT DESIGN

The following are general guidelines and process requirements for social science research. ABAC does not undertake clinical trials for medications and so its IRB is not equipped to adjudicate such cases.

## Research Subject Recruitment and Participation

Applicants must describe in detail how research subjects are to be recruited into their project and the extent they will be involved. This must include the method(s) and instrument(s) to be used, as well as materials and communications the researchers wish to use. These materials should specify the number and age of the subjects, their locations, their reasons for being suitable for the project, and what risks they may encounter if they participate in the project. Further, applicants must estimate the time subjects will spend on the project in a timeframe that suits, e.g., 15 minutes to complete a survey or one hour per week for one month in interviews. If participants are expected to devote more than their time, this should be discussed in detail.

## Gift cards and incentives to participate

Certain nominal incentives for participation may be allowed provided the amount is reasonable for the subject population and that the source of the funds will not cause any financial conflict of interest. Incentives must be disclosed in the application and the terms explained to participants during recruitment. In no case will ABAC's IRB be responsible for the distribution or allocation of research incentives and will bear no culpability for their use or absence. Applicants should take care to review the above sections of these Procedures detailing Games of Chance in the state of Georgia. Further, applicants should take care to make incentives appropriate for participant norms. For example, if the participant population is adult college students aged 18-23, a gift card of $20 for all completing two @ one hour interviews might be appropriate, but a gift card of $1000 for the same work would not be. Generally, gifts and incentives for vulnerable populations should be avoided.

## Informed consent, assent, and other participant permissions

With rare exception, test subjects should give affirmative consent before participation in a research project. The nature of that consent and how it is administered may vary considerably between project types but must always include: The names and contact information of the Responsible Researcher, the institution providing human subjects research protections, along with an appropriate officer's contact information, the title, bracket dates and funding agency (if any) of the project, a brief statement of project scope and performance locations, what the participant is asked to do and when, what the participant stands to gain, incentive, if

any, the risks of participation and methods for mitigating the same, a statement indicating participation is voluntary and that consent may be revoked by the participant at any time, a method of recording consent and the date of consent. In cases where deception is necessary (where the success of the project hinges on the Test Subject not knowing they are participating), consent may be obtained after the fact but must be secured before data are analyzed.

Please be sure to review the Georgia laws regarding minors above. Anyone less than 18 years of age is considered a minor child in Georgia, unless they have been emancipated by a suitable court. As such, unemancipated minors are considered a vulnerable population and can give their assent but cannot give their consent. When minor children are Test Subjects in a research study, parental consent is required. Parental consent documents may follow the same guidelines as above, but minor child assent must use age-appropriate language and terminology. Applicants should solicit assent to participate from minor children as soon as the child is likely to understand the nature of the project and their role in it. Additionally, researchers should review 45CFR46 Section D carefully. Use of these participants will trigger an automatic full board review.

Other vulnerable populations must be described in detail in the application. Particular attention should be paid to the process researchers will use to assent these participants and consent their responsible caretakers. Additionally, researchers should review 45CFR6 Sections B and C. Use of these participants will trigger an automatic full board review and will require periodic progress reporting. ABAC's Human Subjects Research training through CITI has applicable modules on this topic which should be taken by anyone using vulnerable populations for their research.

## External Researchers

As mentioned above, graduate students, community members and other researchers may use ABAC faculty, staff or students as test subjects for their projects but must first apply to the ABAC IRB for permission to do so. This application takes the same form as any other, regardless of the originating institution's permissions granted. In most cases, if an institution with a valid FWA determines a project is EXEMPT or has passed an EXPEDITED review, ABAC will cede human subjects protections to the originating institution after an administrative review. However, given the complex nature of vulnerabilities within populations, this is not guaranteed.

The reverse is also true, as mentioned above: ABAC faculty, staff or students may use community members, affiliates of other institutions or off-site locations to

recruit and engage test subjects. In these cases, ABAC's IRB will control the research project and will rely on its FWA. When applying to ABAC's IRB for permission to conduct the study, researchers should include letters of consent from institutions, locations or populations wherein data collection will occur. If off-site organizations have their own IRB and will not grant permission to use their facilities or populations before ABAC IRB clearance is obtained, a letter agreeing to review once internal clearance is granted should be included.

## Reliance Agreements

At the outset of a research project, ABAC and other institutions' IRBs may cooperate and agree to rely on one of the group's Boards. In this instance, a Reliance Agreement must be agreed to and signed by all applicable parties before data collection begins. The terms of that agreement must contain information about the various parties, training requirements, the research project, unintended consequences, data sharing, use and storage, agreement duration, reporting requirements and dissolution.

## International Research

Researchers regularly conduct human subjects research projects in multiple locations, some located outside the United States. When applying for such a project to ABAC's IRB it is important to indicate the rationale for the added complexity of an international project and an understanding of the regulations regarding human subjects in the foreign research sites. A detailed discussion of these regulations, as well as the norms and customs for each research site or population outside the United States must be provided. A detailed discussion of data sharing and privacy protections must be provided. Written consent from appropriate agencies in research site countries/locations must be provided in the application. International research participants will trigger an automatic full board review.

## Internet-Based Research

Many research tools, software packages and data storage vehicles are hosted in locations not known to the researcher. As discussed above under *ELECTRONIC DATA*, most internet-based projects at ABAC involve researchers using traceable (non-anonymous) means for recruiting that links to a software platform ABAC has data use agreements with such as Microsoft Forms or Qualtrics. These are straightforward use cases and are routinely approved.

Other use cases may require closer examination. If a research project involves only anonymous data scraping public sources, it is not considered human subjects research and does not require IRB approval. Recording the behavior of avatars or "Non-Person Characters" may be traceable to a living human and so therefore may

be human subjects research triggering an IRB review. Applicants must disclose any and all internet-based tools and methods in the application. It is the researcher's responsibility to use these tools appropriately and with the necessary safeguards to privacy. This is especially important given new AI tools available to link seemingly de-identified data to living humans, a process referred to as re-identification. It is also important to consider where and how research data will be stored. Are servers in the United States? Where? Do we have data sharing and privacy protection agreements with those countries or systems? Finally, the risk of breach of confidentiality is very difficult to mitigate in an internet-based environment and should be considered carefully. ABAC's Human Subjects Research training through CITI has a module on this topic which should be taken by anyone using the internet for their research.

## Genetic Materials

In almost all cases, Test Subjects or patients must give their consent for their genetic material to be taken and tested. Samples may be collected via blood draw, cheek swab or sampling of the home or workplace. Consent discussions must include anticipated findings, limits of testing, possible harms associated with revealing certain traits or genes, implications for families and other loved ones, future research uses of the samples, possible commercial uses of the samples, what will be disclosed to the Test Subject and implications for whole genome sequencing. Since a vast number of genetic samples may be contained in very small volumes, the variety of information obtained from one test may provide information relevant to many other tests. For example, if a cheek swab was collected for the purposes of lineage determination, but then stored for future commercial use, those samples may be sold later to insurance companies for the purposes of hereditary disease screening, with implications for insurance rates. When considering genetic materials, it is vital to understand what the patient consented to when the sample was collected, and under what circumstances. If either of those have changed, the patient must be re-consented to include the new tests, risks, benefits, etc. Particular treatment of risk should be addressed to those closely associated with the Test Subject, especially if serious diseases are the test areas. ABAC's Human Subjects Research training through CITI has a module on this topic which should be taken by anyone using genetic materials for their research.

## Risk/Benefits

The Board must determine whether the risk a Research Subject faces is exceeded by the rewards they are likely to accrue, or the risk/benefit balance. Examples of human subjects risk include: Breach of confidentiality through data loss or hacking, physical injury while participating, lost business or employment as a result of leaked information about participants, or undue stress or adverse reactions to topics or

questions. In many cases at ABAC, risks are minimal and do not exceed what a Research Subject would encounter in daily life. The applicant must be sure to discuss all applicable risks and suggest methods or processes to mitigate. Similarly, the risk and mitigation strategies identified must be communicated to the prospective Research Subject via the consent process.

Any human subjects research project carrying risk must carry benefits to participants for if risk is present and benefits absent, the rational person would always choose not to participate. Examples of benefits include monetary or other direct incentive, contributing indirectly to the knowledge base of a topic the Participant cares about, learning about the research process, having access to the results of the research and/or the Participant's own data, increasing the Participant's knowledge base on a topic of interest and improved health. The applicant must be sure to discuss all applicable benefits in the application.

# REPORTING and REVIEW

## Amendments and Changes to Approved Protocols

If substantive changes are needed while the research project is running, the Responsible Researcher must request a formal change. Permission must be granted by the IRB prior to making these changes and prior to data collection based on the adjusted protocol. This applies to all review categories. A suitable form may be found on the IRB website. It should be filled out completely and returned to IRB@stallions.abac.edu with the subject line: Amendment/Change Request for ABAC IRB protocol xyz. Substantive changes include adding or subtracting personnel to the protocol, change of venue or cooperating partner, change of privacy protections/coding, change in consent procedure or change in study population. End date changes should be accomplished via the Continuing Review process, below.

## Continuing Review

For projects reviewed and approved as "expedited" or "full board", and for which more than one year is required for completion, a Continuing Review must be requested. A suitable form may be found on the IRB website. It should be filled out completely and returned to IRB@stallions.abac.edu with the subject line: Continuing Review request for ABAC IRB protocol xyz. Projects reviewed in these categories, not requesting continuing review before the end date issued on their letter, will be terminated and data collection must stop.

## Project Closure

For projects reviewed and approved as “expedited” or “full board”, a final report must be submitted within 120 days of the project’s end. Please email IRB@stallions.abac.edu for a suitable report format and instructions. When a Responsible Researcher terminates employment or other association with ABAC, he or she is obligated to submit a study closure report to the IRB or formally transfer the protocol to another Responsible Researcher via an Amendment Request which is reviewed and approved by the IRB.

## Unanticipated Problems

An unanticipated problem is any problem, event, occurrence or new information related to the research project that was not described in the research protocol and that places subjects or others at increased risk of Harm (including physical, psychological, economic or social harm) than was previously known or recognized. An unanticipated problem is one that is unforeseen in terms of nature, severity or frequency of occurrence as documented in the research or other materials approved by the IRB.

Responsible Researchers are required to disclose a summary of each instance to the IRB using the IRB Unanticipated Problem form on the website and mailed to IRB@stallions.abac.edu using the subject line “UNANTICIPATED PROBLEM REPORT for ABAC protocol xyz” within seven (7) business days. Problems that are determined to be unanticipated require prompt reporting to the sponsor. In many situations, an unanticipated problem will prompt a change in the consent form (e.g., listing an additional side-effect). In such cases, a revised consent form must be submitted by an amendment. An unanticipated event may be, but is not limited to, any of the following:

- An actual unforeseen harmful or unfavorable occurrence to participants or others that relates to the research protocol (injuries, side effects, deaths);
- An unforeseen development that potentially increases the likelihood of harm to participants or others in the future;
- A problem involving data collection, data storage, privacy, or confidentiality;
- A participant complaint about IRB approved research procedures;
- New information about a research study (e.g., a publication in the literature, interim findings, safety information released by the sponsor or regulatory agency, or safety monitoring report) that indicates a possible increase in the risks of the research;
- Changes in approved research initiated without IRB review and approval to eliminate apparent immediate hazards to the participant.

Upon receipt of an Unanticipated Problem report, the Chair of the IRB will convene a meeting of the Board or a suitable subset of at least three voting members within a further seven (7) days to determine if the problem was unanticipated and to determine what sponsor reporting and disclosure may be required. All board members will have access to the Unanticipated Problem and the submission file. The meeting group will make a recommendation to the full Board, for example:

- No action necessary
- Notifying, and re-consenting, current participants when information about the unanticipated problem might affect their willingness to continue to take part in the research
- Alter the continuing review schedule
- Peer review monitoring
- Approve with explicit changes:
    - Notification of previous subjects;
    - Modification of consent and/or protocol;
- Suspension of some or all research activities;
- Approve the study for a shorter period of time (e.g. 6 months versus 12 months);
- Terminate the study for cause.

The Board will consider and take suitable action.

## Suspension or Termination

The ABAC Institutional Review Board (IRB) may order a suspension or termination of research projects when, in the judgment of a majority of the convened (full) board membership, research is not being conducted in accordance with IRB requirements, federal, state or local requirements, or has been associated with unexpected serious harm to research participants. This applies to research projects that have received IRB approval and to those that have not. If the ABAC IRB determines a research project falls under ABAC's FWA purview but did not receive prior approval, it has the authority to suspend or terminate the project.

A suspension is an action by the IRB or IRB Chair to stop, temporarily or permanently, some or all human subjects research activities short of permanently stopping all research activities. Suspended protocols are not closed and require continuing review. A termination is an action by a convened (full) IRB review to stop permanently all activities of a research protocol. Terminated protocols are closed protocols, and they no longer require continuing review. The IRB may suspend or terminate research based on information received during its continuing review, findings from post approval monitoring, or from complaints made to the IRB. Common reasons for suspending or terminating a research protocol or research activities include but are not limited to the following:

- Research is not being conducted in accordance with IRB requirements (researcher non-compliance).
- Research continuation was not requested or granted.
- Research is associated with subject injuries or other Harms.
- Research is associated with or has led to an unexpected increase in risk of Harm to subjects.

The Responsible Researcher is ultimately accountable for the conduct of the study, and as such, should always be aware of safety and welfare of subjects involved. The Responsible Researcher should not hesitate to suspend or terminate his/her own study in order to eliminate imminent hazards to subjects. If the hazard cannot be removed or corrected by modifying certain aspects of the study (e.g. inclusion, exclusion criteria, study design) then the study should be terminated. The Responsible Researcher should develop a plan for notifying and safely withdrawing subjects from the study, and any follow-up that may be needed to assure their ongoing safety. All unanticipated or adverse events and outcomes of such events must be reported to the IRB. The Responsible Researcher must notify the IRB if he/she voluntarily suspends or terminates a study. Any proposed modifications must be reviewed and approved by an IRB prior to restarting the study.

Until a review can take place by a convened IRB, the Chair, in his/her authority, may independently suspend or terminate a research activity. The protection for rights and welfare of currently enrolled subjects must be considered. Therefore, if there is sufficient evidence of non-compliance by the research team that results in increased risk to the subjects, an IRB Chair can suspend or terminate the research activity. The Responsible Researcher will be notified of the decision immediately and be required to submit a response to the IRB Chair's concerns. At the next convened (full) meeting of the IRB, the Chair will report the suspension/termination, and discuss the rationale for the decision, review the PI's response to the suspension/termination and lead the IRB discussion of events and actions items to take place.

The IRB may request a review from an independent source with expertise in the type of research being conducted. A course of action and a timeline, which may include but is not limited to additional training, a plan for oversight, and internal audits will be developed and conveyed to the Responsible Researcher.

The IRB policy owner may suspend a research activity or study per the terms above.

If immediate action is required, the Responsible Researcher may be notified verbally, followed by written notification. Letters (written notification) to the

Responsible Researcher will be sent within five (5) business days of the effective date of suspension or termination. Contents of the letter include, but are not limited to the following:

- The reason for the suspension or termination.
- The effective date of the suspension or termination.
- If the notification was initially provided verbally, the letter will reference the date of the verbal notification.
- Aspects of the research activity that must cease (e.g. recruitment, enrollment, intervention, follow-up).
- Any corrective action or clarification that must take place.
- If applicable, instructions on how currently enrolled subjects should be managed.
- The date that a response is to be received from the PI, and to whom the response should be addressed.

When study approval is suspended or terminated, the ABAC IRB or an IRB Chair considers whether procedures for withdrawal of enrolled participants takes into account their rights and welfare (e.g., making arrangements for medical care outside of a research study, transfer to another researcher, and continuation in the research under independent monitoring), considers informing current participants of the termination or suspension, and has any adverse events or outcomes reported to the IRB.

To reinstate a project that has been suspended, the Responsible Researcher must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after one year, the study will be terminated. The IRB will send written notification to the Responsible Researcher when the suspension is lifted. The letter will be prepared by the Chair. The Chair will also send a copy of the letter lifting the suspension to all entities who received a copy of the notification of suspension.
To reinstate a project that has been terminated, the Responsible Researcher must submit the project to the IRB as a new IRB application and past issues must be resolved to the satisfaction of the IRB.

## Sponsor Notification and/or website posting

Upon determination of reports of unanticipated problems involving risks to subjects and/or others, incidents of serious and/or continuing non-compliance, or a suspension or termination of research activities has occurred, the Policy Owner and IRB Chair will review the findings and forward (or return it to the Office of Sponsored Programs for forwarding) it as appropriate to the regulatory agency or agencies. The maximum time between the determination of a reportable event and the time that a determination must be reported to fulfill the reporting requirements is thirty (30)

days. These reports may be sent via email to the Responsible Researcher, the funding agency and other organizational offices, as required.

The report should contain the following information:

- Name of the institution conducting the research
- Name of the Responsible Researcher
- Title of the research protocol and/or title of the grant proposal
- Nature of the event (unanticipated problem or event involving risks to subjects and/or others, suspension or termination of research activities)
- A detailed description of findings and rationale for the IRB's determination
- Action plan developed to address the problem (revised protocol, revised informed consent, increased monitoring, inform subjects, suspend enrollment, etc.)

If required by the sponsoring agency, the IRB Chair or Policy Owner shall post the report, findings and other required documents on the public ABAC IRB website.

# IRB ASSESSMENT AND COMMUNICATION

## Website

The IRB shall maintain a public-facing website with pertinent details including, at a minimum:

- Human subjects research training instructions and links
- Information specific to applicant category such as student, faculty and external researchers
- These procedures
- Links to suitable forms for applications, conflict of interest, review, amendments, etc.
- Templates for consent of various types
- Links to governing documents and policies
- IRB members
- Contact information
- Adverse event reporting, as required by law and agency policy

The IRB website should be reviewed at least every two years by IRB members, the Chair and the Policy Owner.

Separately, the IRB policy shall be posted within the ABAC Policy Manual and shall be accessible publicly (with no login requirement).

## Periodic IRB Audit and Review

At least every five years, the IRB will undergo an internal audit by no less than three personnel the Policy Owner may appoint, provided they have all served on IRBs for at least one year and have current CITI human subjects research training certificates. The audit will include the following areas:

- Policy and Procedures
- Website accuracy and completeness
- A sampling of approved protocols
- A sampling of communications with applicants
- A sampling of correspondence with Responsible Researchers
- Adverse events and/or unanticipated problems

The audit team will issue a brief (2-5 page) report to the Policy Owner at the end of the audit, and will include findings and recommended changs. Serious beaches of policy or protocol may need to be reported to other offices as deemed appropriate by the Policy Owner.