GEORGIA SOUTHERN UNIVERSITY
RESEARCH INTEGRITY

Institutional Review Board (IRB)

IRB Administrative Procedures

Table of Contents

Table of Contents 1
- **SOP H100: Functions & Responsibilities** 1
- **SOP H101: IRB Protocol Submission** 9
- **SOP H102: IRB Review & Approval** 9
- **SOP H103: IRB Informed Consent** 15
- **SOP H104: Continuing Review** 20
- **SOP H105: Holds; Suspensions; Terminations** 20
- **SOP H106: Sanctions and Noncompliance** 22
- **SOP H107: Reporting Responsibilities of the Investigator** 26
- **Definitions – Human Subjects Research** 30
- **Investigational New Devices** 31

SOP H100: Functions & Responsibilities

- Statement of Principles and Purpose
    - The Institutional Review Board (IRB) exists primarily to provide protection for human subjects who participate in research. The university has an obligation to ensure that all research involving human subjects meets regulations published in the United States Code of Federal Regulations (CFR), under Title 45, Part 46 and where applicable, 21, Part 50 and 56. It is not the intent of the university or the IRB to interfere in any manner with competent, ethical, and sound research involving human subjects. However, the university must ensure that its personnel act in compliance with federal, state, university system, as well as its own institutional regulations because the manner in which university researchers conduct research reflects upon our professional, personal, and community commitments to the ethical and scientific standards of conduct.
    - The main focus of the committee, when reviewing research protocols, is on identifying the risks which may exist for participants. However, one of the ethical justifications for research involving human participants is the social value of advancing scientific knowledge and promoting human welfare. If a research study is so methodologically flawed that little or no reliable information

will result, it is unethical to put participants at risk or even to inconvenience them through participation in such a study. To this extent, the IRB must also consider the soundness of the methodology that is proposed for a research study, so that it can determine whether "risks to subjects are reasonable in relation to … the importance of the knowledge that may reasonably be expected to result" [Federal Policy §46.111(a)(2)].

- IRB approval means that the IRB has determined that the potential risks to human subjects are, in its collective opinion, acceptable. Further, it means that the research may be conducted at the institution within the constraints set forth by federal and institutional requirements.
- The role of the IRB is dictated by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (otherwise known as The Belmont Report). https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- Persons conducting research involving human subjects have both an ethical and a professional obligation to ensure the safety, protection, and rights of participants. It is the intent of Georgia Southern University through the Institutional Review Board (IRB) to assist those engaged in research involving human subjects to conduct their research along ethical guidelines that reflect professional as well as community standards. Georgia Southern recognizes its duty and obligation to protect the rights and welfare of human beings who are subjects in research regardless of the source of funding.
- It is likely that all possible contingencies may not have been foreseen nor considered in the development of these guidelines and procedures. The IRB requires the cooperation of the university's research community in establishing the means to assure adequate protection of human subjects involved in research. Therefore, the IRB invites input from investigators and other interested parties regarding the revisions and updates to these guidelines and procedures.

- Federal Regulations Governing IRB Activities and Authority
  - The role of the IRB is further defined by federal statute, specifically the HHS Regulations for the Protection of Human Subjects at Title 45 Code of Federal Regulations Part 46 and where applicable, 21, Part 50 and 56. The HHS regulations are intended to implement the basic ethical principles governing the conduct of human subject research as set forth on The Belmont Report. The Food and Drug Administration (FDA) has a separate set of regulations governing human subjects research (21 CFR Part 56 — IRB's and 21 CFR Part 50 — Informed Consent). The basic requirements for IRB's and for informed consent are congruent between the HHS and FDA regulations.
    - HHS regulations include additional protections for vulnerable populations as subparts of 45 CFR Part 46:

        - Subpart B – Additional HHS Protections for Pregnant Women, Human Fetuses and Neonates involved in Research.
        - Subpart C – Additional HHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.
        - Subpart D – Additional HHS Protections for Children Involved as Subjects in Research.
    - Georgia Southern University IRB adopts and adheres to the HHS regulations as described above. These regulations may be found at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.
    - Where applicable, the University adheres to FDA regulations for covered research. https://www.fda.gov/science-research/good-clinical-practice-educational-materials/comparison-fda-and-hhs-human-subject-protection-regulations
        - According to 45 CFR 46.109:
            - An IRB must review all research activities covered by the HHS regulations, including proposed changes in previously approved human subjects research, and have the authority to approve, require modifications to secure approval, or disapprove any research activity.
            - An IRB must conduct continuing review of approved research at intervals appropriate to the degree of risk. Full board research requires continuing review at intervals not less than once per year. GS will evaluate the need for and conduct continuing review for expedited research as required by current regulation.
            - An IRB has the authority to suspend or terminate approved research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects.
            - Any suspension or termination of approval must include a statement of the reason for the IRB action and must be reported promptly to the investigator, appropriate institutional officials, and where required, HHS or FDA.`
        - Research approved by the IRB may be subject to further review and approval or disapproval by institutional officials. However, institutional officials may not approve the conduct of human subject research covered by HHS regulations that has not been approved by the IRB.
    - What activities does the IRB review?
        - The IRB reviews all research involving human subjects conducted by faculty, staff and/or students of Georgia Southern University. In addition, any research or related activity that involves the use of Georgia Southern University time, facilities, resources, and/or students is covered by these IRB policies.
        - Human subjects research sponsored by an outside agency that utilize Georgia Southern University resources are considered to be under the auspices of both Georgia Southern

University and the outside agency. In this case, approval (or in some cases cooperation) must be obtained from committees for the protection of human subjects of both Georgia Southern University and the outside agency unless a single IRB or IRB authorization agreement (reliance agreement) is in place.

- No data collection or any other aspect of human subject research may take place prior to IRB approval. Failure to comply with these restrictions may result in disallowance of the research, denial of publication rights, and may result in further disciplinary action by the University. In addition, researchers must comply with institutional policy governing human subjects data collection and resource allocation, (i.e., the GS survey distribution policy).

- Human Subjects Investigator Responsibilities
  - The IRB approves protocol content as presented to the Board. It is imperative that the investigator conduct the research in the approved manner.
    - Any deviation from the approved protocol may result in immediate termination by the IRB approval and may incur disciplinary or legal action by the University if subjects are determined to have been harmed by changes in the approved methodology.
    - Special Note on Student Research – Student-conducted research is deemed to be the responsibility of the supervising faculty member. As such, the IRB and the University hold the faculty member accountable for the conduct of the research and for the management and retention of all appropriate documentation relating to the study.
  - Investigators have the primary responsibilities for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of the GS institution's Assurance.
  - Investigators are expected to be knowledgeable about the requirements of the HHS regulations, applicable state law, the GS institution's Assurance, and institutional policies and procedures for the protection of human subjects. Maintaining current training will assist the researcher in remaining current.
  - Investigators are 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.

- Providing a copy of the IRB-approved informed consent document to each subject or the subject's legally authorized representative at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained for the longer of 3 years after the completion of the research or the life of the identifiable data unless a longer period is specified by University retention policy.
- Promptly reporting proposed changes in previously approved human subject research activities to the IRB. The proposed changes may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
- 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.
- Faculty and Student researchers maintain personal responsibility for research or related activities involving the use of human subjects that are conducted without the use of Georgia Southern time, resources and/or students and without the use of their Georgia Southern credential or affiliation.

- IRB Committee Structure
    - Membership will be consistent with the CFR, Title 45, Part 46, Section 46.107.
        - The committee shall consist of at least five members with varying backgrounds.
        - Members are expected to have appropriate professional expertise, maturity, and experience to thoroughly review a variety of research activities conducted at Georgia Southern University. They should also be sensitive to relevant professional standards, community attitudes and diversity, applicable laws, and institutional requirements.
        - All appointments are 12 month appointments; including potential for reviews during summer months regardless of teaching status.
        - Each member, including the chair, will maintain current documentation of approved training in the protection of human research subjects as a condition of service.
        - Members of the committee are appointed by the Institutional Official named by the President of the University. The GS Institutional Official is the Provost and Vice President for Academic Affairs, who acts upon recommendations from the Director of the Office of Research Integrity in consultation discipline area Chairs and Deans.
        - The committee shall include a diverse mix of faculty from a similar mix of scholarship disciplines to the research reviewed by the Board. The committee shall include at least

one member whose primary concerns are in a non-scientific area and one member who is not affiliated with GS. These roles may be held by the same person.

- Georgia Southern faculty who serve on the IRB must be full-time tenure track faculty member. Preference will be given to faculty who have 3 or more years of service to Georgia Southern (including service under the name of Armstrong States University) or equivalent experience at a similar institution.
- The IRB Administrator will impanel and register individual boards as necessary to meet the needs of current research on GS campuses. Each board will review expedited research via email. Full board studies will be reviewed by a committee meeting on Statesboro Campus with remote access from Armstrong Campus.
- The committee structure includes a primary member and alternate member appointed from each represented discipline. The appointed board members may serve as a primary member, responsible for full board attendance and expedited reviews, or an alternate member, responsible for expedited reviews and full board attendance in the absence of the primary member. Members of each cohort may switch roles at the beginning of each semester by mutual agreement within the cohort and notification of the IRB administrator.
- Each committee shall have faculty leadership in the form of a committee Chair. Associate chairs and Assistant chairs may be appointed to fully support the committee structure. Chairs,Associate and Assistant chairs may be appointed to serve one or more committees simultaneously.
- Members are appointed for a continuing term of at least 3 years. The term of service may be renewed.
    - Committee service renewal will be based upon the need of the committee for the discipline represented by the faculty member in conjunction with annual committee member productivity reviews and new faculty integration needs.
    - Annual service letters will be provided to document service.
- The current structure consists of the following:
    - IRB-A: Social and Behavioral (00004564)
    - IRB-B: Social and Behavioral (00007863)
    - IRB-M: Medical (000101300)
- Should any IRB member, including the chair, conduct himself/herself in a manner that disrupts the work of the IRB, or calls into question his/her ethical or professional competence, or fails to conduct reviews and committee work in an equitably timely fashion, that member may be removed from the IRB by the Chair in consultation with the IRB administrator. The IRB administrator will seek recommendations for a replacement member from the chair of the needed discipline.

- The IRB Chair, Associate Chair and Assistant Chairs Function
    - The chair(s) and associate chair(s) of the Georgia Southern IRB will be appointed by the Provost upon the recommendation of the Office of Research Integrity. Preference in appointment will be given to full professors.
    - The chair must hold the doctoral degree, be a tenured member of the Georgia Southern faculty, and possess the professional competence necessary to review research activities, ascertain their acceptability in view of institutional commitments and regulations and applicable law as well as standards of professional conduct and practice. The committee chair will be responsible in adverse event and non-compliance investigations, and complaint inquiries with the support of the IRB administrator. The Chair will participate in IRB faculty training and IRB promotional events. Full professor status is preferred for this position.
    - The IRB Associate-chair will be a Georgia Southern faculty member who holds a doctoral degree and is tenured. This individual will have all associated responsibilities and obligations of the chair when the chair is unable to serve in that capacity or when the chair is an investigator on a research project being considered or reviewed by the IRB. The duties and responsibilities of the Associate-chair include participation in all investigation and faculty training responsibilities of the Chair upon request. The Associate chair will maintain the same as for any IRB member except when assuming an authorized role of the chair.
    - Assistant Chairs will be appointed from the board membership to serve as support for the Chair and Associate chair. Assistant chairs will be provided with additional training to support advancement to the Associate and Chair positions. The duties and responsibilities of the Assistant-chair are the same as for any IRB member except when acting in support of the Chair and Associate-chair.
- Institutional Official Function
    - The Institutional Official is the individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The GS Institutional Official is the Provost, and Vice President for Academic Affairs.
    - Administratively, the Institutional Official is responsible for:
        - Designating one or more IRB's that will review research covered by the institution's Federal-wide Assurance.
        - Providing sufficient resources, space, and staff to support the IRB's review and record keeping duties.
        - Providing training and educational opportunities for the IRB and investigators.
        - Setting the "tone" for an institutional culture of respect for human subjects;
        - Ensuring effective institution-wide communication and guidance on human subjects research;
        - Ensuring that investigators fulfill their responsibilities;

        - Providing support for enforcement of regulation, policy and procedure.
        - Encouraging all staff engaged in the conduct or oversight of human subject research participate in education activities;
        - Serving as a knowledgeable point of contact for OHRP, or delegating this responsibility to another appropriate individual.
    - The Institutional Official can review or disapprove research approved by the IRB for institutional purposes. However, institutional officials may not approve the conduct of human subject research that has not been approved by the IRB. The Institutional Official may not intervene in or have input into the review or approval of any study before the IRB.
- University Responsibilities
    - The University is responsible for:
        - Ensuring that all institutions and investigators engaged in its human subject research operate under an appropriate OHRP-approved Assurance for the protection of human subjects.
        - For all HHS-conducted or supported research, all of the requirements of the HHS Regulations at 45 CFR Part 46, Subpart A, as well as Subparts B through D, must be met.
        - For FDA covered or supported research, all the requirements of 21 CFR Part 50 and Part 56 must be met.
        - Developing policies and procedures for effective and efficient administration of a comprehensive Human Research Protections Program (HRPP).
        - Ensuring that Assurances are in place and certifications of IRB review are submitted to the appropriate authorities for all HHS-sponsored research, not only for themselves, but also for collaborating performance sites for which the institution has agreed to accept oversight responsibility.
        - Implementing appropriate oversight mechanisms to ensure compliance with HHS regulations and effective administration of the HRPP.
        - The Institution bears full responsibility for all research involving human subjects covered under its Assurance.
- IRB Committee Function
    - No member of the committee shall be involved in the initial review or any continuing review of an activity in which the member is a researcher, faculty adviser or a sponsor, except to provide information requested by the committee.
    - The committee may invite individuals with competence in special areas to serve as non-voting reviewers when dealing with complex issues. Consultants will be asked to agree to maintain research and board deliberation confidentiality prior to access to the research application.
    - A quorum shall consist of a majority of the committee's membership consisting of ½ of the voting primary plus 1 and will include a non-scientific member. The IRB will conduct official

business meetings only if a quorum is present. The IRB administrator and/or the community member serve as non-scientific members.
    - The community member shall not have a current formal association with the institution. Retirees and graduates must have a minimum of a 2 year separation prior to serving in this capacity.
    - Alternate members of the board may serve in the absence of a primary member and will be considered to have the cohort vote for that meeting.
    - Appropriate administrative assistance and support for IRB functions are provided by the University through the Office of Research Integrity.
- Member potential for Conflict of Interest (COI)
    - It is the responsibility of each IRB member, including alternate members, to disclose any conflict of interest in a study submitted to the IRB and recuse themselves from review of that protocol. No member may participate in the discussion or review decision for a protocol in which the member has a conflict of interest, except to provide information or answer questions from the IRB as requested. Recused members may not be present during a vote on that protocol.
    - Definition for conflict of interest: An IRB member is said to have a conflicting interest whenever that IRB member, or his/her spouse, domestic partner or first degree relative (e.g., child, sibling, or parent):
        - is an investigator or key personnel on the protocol under consideration;
        - acts as an officer or a director of the sponsor or an agent of the sponsor;
        - is involved in the research as a coordinator, protocol consultant and/or primary advisor;
        - has received any of the following from an entity whose financial interests would reasonably appear to be affected by the outcome of the research:
        - non-university salary or other payments for services (e.g., consulting fees or honoraria) exceeding $10,000 over a 12-month period;
        - equity interests (e.g., stocks, stock options or other ownership interests) exceeding $10,000 or 5% of the equity of the entity; or
        - intellectual property rights (e.g., patents, copyrights, royalties from such rights); or
        - has identified him/her self for any other reason as having a conflicting interest (e.g., having a close personal or professional association with the submitting investigator, serving as co-investigator and/or the primary mentor for a student or post doc investigator).

SOP H101: IRB Protocol Submission

IRB Meeting Dates & Deadlines – Research Integrity - Georgia Southern University

SOP H102: IRB Review & Approval

- Criteria for Approval of Research:
    - In order to approve research, the IRB must determine that all of the following requirements are satisfied:
        - Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk;
        - Whenever appropriate, risks to subjects are minimized by using procedures already being performed on the subjects for educational, diagnostic or treatment (etc.) purposes.
        - Assuring risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result.
        - The IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies, activities or procedures subjects would receive or participate in even if not participating in the research).
        - The IRB should not consider possible long-range effects of applying knowledge gained from the research (for example, the possible effects of the research in public policy or social development) as among those research risks that fall within the purview of its responsibility.
        - While it is not the responsibility of the IRB to evaluate the scientific, social, or political worthiness of any research project, issues of project design are appropriate for IRB review as the risk to participants increases.
            - Design of the research becomes a determining factor for project approval when the design either directly or indirectly places the participant at undue risk.
            - The IRB will consider the level of risk involved when the design of the research is not expected to yield meaningful results.
            - If the protocol introduces an element of risk that is not outweighed by the direct benefit to participants, the IRB may consider design when arriving at its decision to approve, request modification or reject the project.
        - Guiding principles:
            - Respect for Persons is observed to allow participants autonomy of decision. Extra care must be provided for individuals who have reduced capacity to make decisions.
            - Beneficence is observed to assure there is an appropriate balance between research participation risk and benefit.
                - Risk will exist in all research participation. Greater risk studies will require a greater benefit to the participant or society for approval.

        - Risk to participants should be reduced as much as possible while still allowing for acquisition of the necessary data to answer the research question.
        - Confidentiality and privacy should be maintained to the greatest extent possible within the bounds of the study needs. Adequate information to allow an informed choice about participation must be provided to participants.
    - Justice is observed to assure fair distribution of risk and benefit among potential or possible subject pools.
        - Recruitment must be fair and transparent
        - Recruitment should include as broad a segment of the population as possible to provide equal access to research outcomes. (e.g., pregnant women or children should not be excluded based upon their population where the study outcome benefit is important to their health and welfare.)
        - The subject pool chosen for each study should be based upon the purpose of the study – not convenience.
        - It is recognized that some studies may be conducted for the primary purpose of educating future researchers in research techniques and practice.
- Possible Areas of Risk:
    - The following descriptions provide additional information about some possible kinds of risks that may occur in research studies:
        - Physical Harm: Pain, injury or impairment.
            - For example, if you ask your participant to exert themselves beyond their resting state and/or there is a possibility for injury as the result of participating in the study, this risk should be described in the consent form and information should be provided as to what care the participant has access to should they become injured. For some studies it may be necessary to exclude participants whose health conditions increase the likelihood of injury.
        - Psychological Harm: Stress, worry (warranted or unwarranted), feeling upset or depressed, embarrassed, shameful or guilty, and/or result in the loss of self-confidence or peace of mind.
            - An example of psychological harm would be stress or feelings of guilt or embarrassment from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual orientation, selfishness, or violence. These feelings may be aroused from being interviewed or from filling out a questionnaire.

        - Another kind of risk would be invasion of privacy, for example, from covert observation (even in a public place) of behavior that participants would likely consider private.
        - Still another risk of psychological harm occurs when there is inadequate protection for the confidentiality of data that has been given voluntarily (e.g., by retaining audiotapes or videotapes longer than is necessary to analyze the relevant information).
- Social and Economic Harm: Reputation, belonging, standing in the community
    - For example, if you are studying HIV patients and a participant has not disclosed their HIV status to the community, it is important that you keep that individual's participation confidential and private, even to the level that your meeting together is done privately. In your protocol it is important that you demonstrate sensitivity to the social needs of your participants and that you describe how you will act with discretion to preserve the privacy and confidentiality of your participants.
- Economic Harm: Costs associated with participation, effect of participation on employment or employ-ability
    - Researchers should consider any costs participants would have to bear in order to participate in the study such as travel, child care, food, etc.
    - Participants should be made aware of the amount of time it will take to participate in a study, particularly if it is time that they would spend away from their employment.
    - Participation in a drug use study may affect participants ability to obtain employment or insurance if confidential information is breached.
- Legal Harm: Illegal behaviors, slander
    - Researchers cannot protect their participants' confidences in a court of law. Where information is collected that could be subpoenaed in the USA, a Certificate of Confidentiality should be sought through the NIH.
    - There may be certain circumstances in which you are obligated to breach confidentiality and report illegal behaviors and activities. If a participant describes an immediate threat to hurt another individual, you may be legally or ethically required to report this information. If you learn of child abuse, you may be legally or morally obligated to report it.
- Inadequate Protection for the Confidentiality of Research Data:
    - Where identifiers of individual participants are not required by the design of the research study, none should be recorded.

- If identifiers are recorded, they should be separated, if possible, from the data; stored securely, with linkage restored only when necessary to conduct the research; and destroyed when they are no longer needed.
- More elaborate procedures may be needed in some studies, either to give participants the confidence they need to answer questions truthfully (e.g., promising to submit course grades before analyzing data from one's own students) or to enable the researcher to offer honest assurances of confidentiality.
- Even when participants are otherwise anonymous, there may be a danger of deducing the identity of individual participants by combining specific pieces of information collected during the research about the participants. Additional precautions may be needed to deal with these circumstances.

- Application Categories
  - Full Board Review
  - Medical Board Review
  - Expedited Review Review
  - Exempt Review Review
  - International Research
  - Continuing Review
  - Non-Human Subjects Research

Any application may be escalated to a higher level of review by the reviewing member.

- Application Procedures
  - Applications must be submitted to the Office of Research Integrity IRB Office.
    - Preferred submission method: Single pdf file emailed to irb@georgiasouthern.edu
    - Alternate Submission Method: Via mail to the Georgia Southern University Office of Research Integrity, PO Box 8005, Statesboro, GA 30460.
    - Applications can be found on the Office of Research Integrity forms page at the Current Guidance and Access to Forms page.
  - The application must be signed by the investigator and the researchers supervisor
    - If the investigator is a student, the students must sign the cover page, and the protocol must be reviewed and signed by the faculty adviser to provide evidence of the faculty adviser's approval for the research.
    - Faculty investigators must obtain their department chairs signature to provide evidence of review of scientific merit within the discipline.

- All new protocol submissions must include the most current version of the IRB application as posted on the Office of Research Integrity forms page at https://ww2.georgiasouthern.edu/research/researchintegrity/institutional-review-board-forms/.
- All personnel involved in the research who will have access to the subjects or subject data (Principal Investigator, Co-Investigator, Faculty Adviser, and data collectors/analyzers), including exempt review projects, must complete the applicable CITI training and provide the certificate of completion with the IRB application. Training is valid for three years from the date of completion. Visit the ORI training page for further information. research.georgiasouthern.edu/researchintegrity/training/
- All applications must include applicable supporting materials:
  - a copy of the appropriate consent documents for research participants. Please see the informed consent procedures for more information on content.
  - Any written instruments and/or questions to be used.
  - Any recruitment materials (flyers, emails, social media posts, oral recruiting script, etc.)
  - Letter(s) of cooperation

- Reviewer Criteria
  - Review category is determined by administrative review upon application submission. The assigned reviewer(s) may at their desegregation move any protocol to a higher level of review.
  - Individual reviewers may approve, request clarification or modification to protect subjects, or send a protocol to the fullboard for review. Individual members may make suggestions for the improvement of the research. Items in the suggestion category are not required to be addressed by the applicant prior to approval.
  - Applicants must respond to all reviewer comments. Responses may correct, clarify or justify research methods.
    - Full Board Review – Review by a quorum of qualified IRB members in a called and minuted meeting.
    - Medical Board Review – Review by a quorum of qualified IRB members in a called and minuted meeting. Expedited review may be used through this board.
    - Expedited Review Review – Review by 2 IRB members.
    - Exempt Review Review – Review by 1 IRB member or IRB administrator based upon current regulatory standards and definitions. Researchers are reminded that the IRB must grant exemption status, the researcher may not make that determination.
    - International Research – Review by a quorum of qualified IRB members in a called and minuted meeting.
    - Continuing Review – Review by 1 IRB member or IRB administrator.
    - Non-Human Subjects Research – Review by 1 IRB member or IRB administrator
    - External IRB

        - Required for non-observational clinical trials or industry sponsored clinical research, or as deemed necessary by the GS IRB.
    - Quorum consists of 50% plus 1 of the voting membership of the board. A quorum is required for a protocol disposition vote to occur. Where quorum can not be achieved, the protocol may be remanded to another board or held over for the next meeting.
- IRB Determination Options
    - Approval – When an acceptable risk/benefit ratio exists and the criteria required for approval are deemed acceptable, protocol is approved as submitted or corrected.
    - Conditional/Withheld Approval (Pending Changes) – The IRB determines that the protocol will meet the regulatory criteria for approval provided the investigator agrees to make specific changes to the IRB application including the informed consent document. Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB Executive Chair, Chair or another designated IRB member subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure. Research may not be initiated until a letter of IRB approval is received and other applicable committee reviews are satisfied.
    - Tabled/Re-submission – The IRB requires substantive changes that are directly relevant to the determinations required by the IRB under federal regulations at §_.111, the IRB will table the approval of the protocol or remand the protocol for re-submission pending subsequent review by the convened IRB of the responsive material.
    - Disapproved – The IRB determines that the research does not meet the regulatory criteria for approval and cannot provide modifications that may allow the protocol to be approved.
- IRB review appeals process
    - Any applicant may appeal the review of their project by the following methods:
        - Fullboard appeal – protocol will be sent the an alternate board for re-evaluation.
        - Expedited appeal – protocol will be sent to the next available fullboard.
        - Exempt appeal – protocol will be sent to the next available fullboard or may, at the IRB administrator's discretion be sent to a chair or IRB member for expedited review.
    - Review category is determined by administrative review upon application submission. The assigned reviewer(s) may at their desegregation move any protocol to a higher level of review.

SOP H103: IRB Informed Consent

- Informed Consent Procedure
    - Informed consent is not a single event or just a form to be signed. Rather, it is an ongoing process that takes place between the investigator and the subject. Informed consent is a basic tenet of ethical research with human subjects.
    - The basic concepts of the consent process include:

        - full disclosure of the nature of the research and the subject's participation,
        - adequate comprehension on the part of the potential subject, and
        - the subject's voluntary choice to participate.
    - The Informed Consent Form must be on GS letterhead or maintain the letterhead elements and include the required Common Rule elements. (See the sample and/or checklist below.)
    - Informed Consent Sample
    - Informed Consent Checklist
- General Requirements for Consent
    - Informed consent must be prospectively obtained from the subject or a legally authorized representative of the subject unless all or some element is specifically waived by your IRB approval.
    - Information must be conveyed in language that is understandable to the subject and/or the subject's legally authorized representative.
    - The subject must be given sufficient opportunity to consider whether or not to participate.
    - Consent must be sought only under circumstances that minimize the possibility of coercion or undue influence.
    - Informed consent may not include any exculpatory language. For example, subjects must not be made to give up legal rights or be given the impression that they are being asked to do so.
    - The format and language used for Informed Consent documents should be tailored to the subjects needs and level of comprehension.
- Comprehension
    - Even though the IRB has approved a consent procedure, it is the investigator's responsibility to ensure that each potential subject understands the information and to take the appropriate steps necessary to gain that comprehension. This may require multiple forms of delivery for your information.
    - Individuals may not be involved as research subjects unless
        - they understand the information that has been provided and informed consent has been obtained, or
        - the IRB has approved a waiver for informed consent of the subject.
- Factors involved in consent
    - Ability to Provide Consent
        - Informed consent assures that prospective participants understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.
        - It is a continuing process, not just a piece of paper; especially in a lengthy study, it may be necessary to obtain consent on more than one occasion or by more than one approach.
        - It protects both the participant and the investigator, who otherwise faces legal hazards.

        - Investigators may seek consent only under circumstances that provide prospective participants or their representatives sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
        - Furthermore, the information must be written/provided in language that is understandable to the participants.
            - If the prospective participants include persons who are unlikely to be familiar with specific technical terms, persons with limited verbal or cognitive skills, or persons whose primary language is not English, special care must be taken to ensure that both oral presentations and written consent forms are comprehensible to all participants.
            - When participants may include members of a vulnerable population (such as children, elderly persons, prisoners, or economically or educationally disadvantaged persons), additional safeguards are needed to protect the rights and welfare of those subjects.
- Assent from Children and/or Adolescents
    - When children and/or adolescents are participants in a research study, the investigator must solicit both the assent of the children and the permission of their parents or guardians. (There are limited exceptions for situations in which the parents' interests may not adequately reflect the child's interests.)
    - In certain circumstances, older adolescents may have the legal authority to give their consent even though they are not yet legally considered adults (i.e., are under the age of 18).
    - Also, the Buckley Amendment (FERPA) requires parental consent for release of records or identifiable information about children in public schools, and instructional materials to be used in connection with research must be available for inspection by parents or guardians.
- Recruitment
    - To minimize the possibility of coercion or undue influence, it is generally preferred that participants be recruited by open, written invitation rather than by personal solicitation.
    - For similar reasons, it is also preferred that professors not solicit their own students as participants and that supervisors not include their own employees in research.
    - If advertising will be used to recruit participants, the IRB needs to review that advertising to be sure that the information will not be misleading to potential participants.
    - Similarly, if participants are to be paid for their time, the IRB needs to review the amount of the payment and provisions for full, partial, or no payment (for example, if a participant withdraws part way through the research) to assure that participants will not be unduly influenced by the payment.
- The Consent Form

    - In most cases, federal regulations require that participants sign a written consent form [45 CFR 46.117], although the written consent document is not a substitute for discussion of the relevant information with prospective participants.
    - Participants must be given a clear and fair explanation of the research procedures, their risks and benefits, and provisions for confidentiality in the research.
    - Each participant must provide informed consent prior to participation. The person who signed the consent form must be given a copy as a reference and reminder of the information conveyed
- Oral Consent
    - A "short form" may sometimes be approved for the consent [45 CFR 46.117 (b)(2)]. This means that the information is presented orally to prospective participants without a written version of it in the consent document.
    - The IRB must review and approve a written summary of what will be presented orally.
    - The participant must sign the short consent form (stating that the information has been provided orally), and a third person must witness the oral presentation and must sign both the short consent form and a copy of the written summary of the oral presentation. The investigator obtaining the consent must also sign the written summary.
    - A copy of the written summary must be provided to the participants even though they are not asked to sign the written summary.
- Waiver of Written Consent
    - Waiver of written consent or use of an alternate method of documenting consent may only be considered if
        - (1) the research involves no more than minimal risk,
        - (2) the waiver or alteration will not adversely affect the rights and welfare of the participants,
        - (3) the research could not reasonably be carried out without the waiver or alteration, and
        - (4) whenever appropriate, participants are provided with additional pertinent information in a debriefing after their participation [Federal Policy §46.116(d)].
    - Furthermore, especially in studies which involve the collection of sensitive information (e.g., sexual or criminal activity), a request to waive written consent may be considered only if
        - (1) the only record linking the participant to the research would be the consent document and the main risk in the research would be the potential harm from a breach of confidentiality (in this case, participants must be asked whether they want documentation of their consent, and they may elect to sign a consent form or not), or
        - (2) the research is no more than minimal risk and involves no procedures for which written consent would normally be required outside of the research context [Federal Policy §46.117(c)].

        - The IRB may still require that a written statement of pertinent information be provided to participants who do not sign a consent form.
    - It may be appropriate to waive written consent (but not informed consent) for fieldwork studies where the nature of the continuing interactions with the researcher is not easily reduced to a consent form.
    - For some observational studies of people who are not aware that they are being observed or who are unaware that their behavior is being recorded for research purposes, it may be appropriate to completely waive the consent requirement if the knowledge to be gained is important, but such research can also raise serious ethical concerns about protecting the privacy of the unwitting participants.
    - Similarly, it may be appropriate to waive the consent requirement for studies of pre-existing records if the information contained in the files is not particularly sensitive, the investigator has devised procedures to protect the confidentiality of the information to be collected, and the study could not practicably be carried out if consent were required.
- Deception
    - Sometimes investigators plan to withhold information about the real purpose of the research, or even to give participants false information about some aspect of the research. This means that the participant's consent may not be fully informed.
    - The degree to which this is acceptable depends on whether the information to be withheld would influence the decision of prospective subjects about participating in the research.
    - When subjects have unwittingly participated in research or have knowingly participated in research that involved some form of deception, they should be debriefed afterward with pertinent information about the study whenever this can be done in a way that reduces rather than produces pain, stress, or anxiety.
    - Additional resource information should be provided in case your subjects need someone to talk to after they leave you. This may be access to a counseling center, hotline or similar resource.
- Special Conditions – Potential Injury or Personal Harm
    - Although institutions are not required to provide care or payment for research injuries, the IRB generally expects investigators to provide a way for participants to obtain at little or no cost any services necessitated by research injuries. This information needs to be provided in the consent form if possible.
    - In any case, the consent process must not involve the use of any exculpatory language through which the participant is made to waive or to appear to waive any of his or her legal rights, or releases or appears to release the investigator, sponsor, institution, or their agents from liability for negligence [Federal Policy §46.116].
- Special Conditions – Psychological Harm – Potential and Minor

    - The IRB strongly suggests that researchers consider the possibility of psychological distress which may result from discussion of disturbing events, reading or listening to possibly disturbing information, etc.
    - Researchers should advise participants of psychological and/or counseling resources available to them, should psychological or emotional distress occur.
- Special Conditions – Incentives
    - Researchers are advised to consider the impact of incentives (if provided) will exert of potential participants.
    - You must provide an explanation of compensation and an explanation of any additional costs the participant may incur are to be included in the Informed Consent Form. [45 CFR 46.116 (a)(6) & (b)(3)]
    - You also must include conditions under which the participant may receive full payment, partial payment or no payment.
    - Any payment that is provided from University or Grant funds must follow the procedures outlined in the GS Human Subjects Incentive Payment Policy.
    - If compensation is to be given to participants, it must be reasonable and non-coercive. Keep in mind the economy of your subjects.
        - g., $20 gift card will have a different value to small child versus an adult.
        - g., A study occurring over a time period of several weeks with participants receiving payment of a $100 at the end of the study. In case participants need to terminate their participation (e.g., illness, family emergency, etc.) prior to their completing the study, prorating payment to the participant needs to be addressed in order to avoid coercion.
        - g., If participants are Georgia Southern University students and extra credit points are being offered as compensation, a comparable alternate means of earning the extra credit points needs to be offered in order to avoid coercion.

SOP H104: Continuing Review

Continuing Review & Terminations – Research Integrity - Georgia Southern University

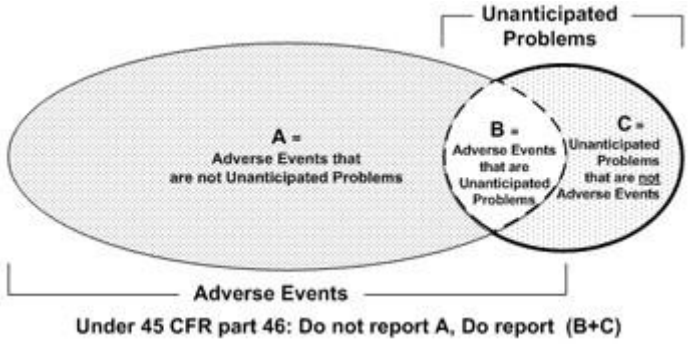
SOP H105: Holds; Suspensions; Terminations

- Authority – Who can suspend a protocol?
    - The convened IRB, an IRB Chair/Vice-Chair, IRB administrator or the Institutional Official (IO) or his/her designee has the authority to suspend or terminate approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a

statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and to the applicable department or agency head as required by 45 CFR 46.103(b)(5)(ii) and 113, and 21 CFR 56.108(b)(3) and .113.

- The Principal Investigator can place any protocol on hold by emailing the IRB or terminate the study by completing the termination form. A receipt of termination will be returned by email.
- An automatic hold will be placed on any study where there is an unanticipated event until the cause and any corrective action necessary are identified.

- When does a study suspension get reported to the federal agencies?
  - Where there is a finding of noncompliance or a serious adverse event that is related to the federally funded research, an incident notification report will be submitted to the OHRP (Office for Human Research Protections, HHS.gov) within a few weeks depending on the seriousness of the incident in alignment with the OHRP Guidance on Reporting Incidents. https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html A report will also be made to the funding agency where research is federally funded.
- Unanticipated Events are defined here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q1



Under 45 CFR part 46: Do not report A, Do report (B+C)

- What are the ways my study may be stopped?
  - Administrative Hold: A voluntary action by a PI or sponsor to temporarily or permanently stop some or all approved research activities in response to a finding of concern that does not adversely affect the safety, rights and welfare of research subjects. An administrative hold is not a suspension or termination. A hold is reversible and may be placed on a study by sending an email to the IRB.
  - Expiration of IRB Approval: If a PI has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the expiration date specified by the IRB, such a research study has expired. Once a protocol has expired, the investigator must reapply as a new project. The Investigator and student adviser/faculty department chair will be notified of the expiration
  - Study Completion – Closure: Once any study that has active IRB approval is completed and/or stopped voluntarily by the PI the study must be closed or terminated. This includes studies that

never enrolled subjects. This process is most often initiated by the PI, but can be initiated by actions of other involved parties, including study sponsors or the IRB. There is a form for this purpose on the IRB forms list.

- Suspension: An action by the convened IRB, an IRB Chair/Vice-Chair, IRB administrator or the IO or his/her designee to stop, temporarily or permanently, some or all previously approved research activities short of permanently stopping all research activities. Suspended protocols are not closed with the IRB and require continuing review by the IRB. This will be done by the IRB Chair and approved at the next convened IRB meeting. Suspended protocols may be terminated.
- Termination: An action by the convened IRB to stop permanently all activities of a previously approved research protocol. Terminated protocols are closed protocols, and they no longer require continuing review.

- What protects currently enrolled subjects of a study?
  - Before an administrative hold, suspension or termination is put into effect, the convened IRB, or if time does not permit, an IRB Chair/Vice-Chair, considers whether any additional procedures are needed to protect the safety, rights and welfare of current subjects. Such procedures might include:
    - Transferring subjects to another PI
    - Making arrangements for clinical care outside of the research for a clinical study or continuation of the research benefit if warranted
    - Allowing continuation of some research activities under the supervision of an independent monitor
    - Notification of current subjects
    - Notification of former subjects
    - For terminated studies:
      • Requiring or permitting follow-up of subjects for safety reasons
      • Requiring adverse events or outcomes to be reported to the IRB and the sponsor.

SOP H106: Sanctions and Noncompliance

- Purpose
  - Noncompliance occurs when research involving human participants is conducted in a manner that disregards or violates federal regulations, the policies or procedures of the Institutional Review Board (IRB), or institutional policies governing human research. Noncompliance with respect to human research participant protection violates the University Federalwide Assurance Registration (FWA). Even in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk.
  - This policy sets forth the definition and examples of noncompliance; the procedures for reporting an allegation of noncompliance to the IRB; and the procedures for the IRB's management of such allegations, and if appropriate, of confirmed noncompliance.

- The purpose of sanctions initiated by the IRB against human subjects researchers:
    - The use of sanctions is intended to promote compliance with federal and state laws and regulations, and with University System of Georgia and Georgia Southern University (GS) policies. Actions based upon non-compliance by the IRB are not intended as punishment against any individual or group of human subjects researchers.
- Authority
    - The IRB has final authority and responsibility for approval of activities directly related to research conducted with human subjects by GS faculty, staff, and students.
    - The IRB has authority to enact operational sanctions. (i.e., restrict research approvals, sequester data and mandate training.)
    - The IRB has no authority to enact administrative sanctions but may make such recommendations to the Institutional Official. (i.e, sanction of professional status or pay.)
- Terms
    - Allegation: An assertion in the form of a complaint, concern or inquiry made by a party which has not yet been proven or supported by evidence.
    - Confirmed Noncompliance: An allegation of noncompliance that has been verified as a result of an investigation and/or a for-cause audit.\
    - Continuing Noncompliance: A repeated pattern or un-rectified instance of noncompliance by an individual investigator or research staff member either on a single protocol or multiple protocols.
    - Noncompliance: Failure to comply with federal regulations; the policies or procedures of the IRB; or institutional policies governing human research.
        - Examples of noncompliance include:
            - (1) conducting human participant research without IRB approval (e.g., before approval; after expiration of approval and in the absence of a continuation application submitted to the IRB; during a suspension of IRB approval; after termination of IRB approval);
            - (2) disregarding or otherwise violating IRB-approved informed consent procedures (e.g., failing to obtain consent/assent, using unapproved or outdated consent, assent, and information sheets, missing signatures, failing to document consent process);
            - (3) deviating from the protocol approved by the IRB;
            - (4) modifying an approved protocol without IRB consent;
            - (5) failing to report or late reporting unanticipated problems;
            - (6) failing to maintain adequate records;
            - (7) failing to train research team members in the proper procedures; and
            - (8) failing to follow recommendations by the IRB to ensure the safety of research participants.

- Serious Noncompliance:
    - Noncompliance involving one or more of the following:
        - (1) bringing harm to research participants;
        - (2) exposing research participants to a significant risk of substantive harm;
        - (3) compromising the privacy and confidentiality of research participants;
        - (4) causing damage to scientific integrity of the research data that has been collected;
        - (5) engaging in willful or knowing noncompliance;
        - (6) impacting ethical principles adversely.

- Addressing Allegations of Noncompliance
    - The IRB administrator the Office of Research Integrity (ORI) may become aware of an allegation of noncompliance or of circumstances indicating potential noncompliance upon the receipt of a complaint or concern from a participant, researcher, GS employee, committee member or member of the public; or from the interpretation of information received during a Continuation, Amendment, Unanticipated Problems Review; or from the findings of a random or for-cause audit, other quality control activities or review of public or social media.
    - Once it has received an allegation of noncompliance, ORI will conduct an initial interview to obtain the basic conditions of the concern and if appropriate complete and adverse event reporting form.
    - ORI will meet with the IRB Chair to make the following initial determinations:
        - (a) whether noncompliance is alleged; and
        - (b) whether the allegation indicates that an immediate action such as suspension by the IRB is warranted.
        - If it is determined that immediate action by the IRB is warranted (e.g., suspension), then the IRB Chair will initiate suspension proceedings. (See Suspensions)
    - ORI and the IRB Chair will initiate an investigation of the circumstances alleged in the noncompliance report.
    - Where funded, ORI will make the appropriate report to the Office of Human Subjects Protections (OHRP) and Sponsor where required.
        - ORI may elect to investigate informally by reading relevant documents and communicating
          with the affected parties.
        - If ORI and the IRB Chair determine that the allegation is not credible or is unsubstantiated, then the inquiry ends. ORI will document this finding in a written report;

place the report in the study file; and notify the IRB of the finding on the agenda of the next available meeting.

- If the inquiry yields evidence that noncompliance that is neither serious or continuing has occurred, then the IRB Chair and ORI may identify and will devise an appropriate corrective plan or if additional expertise is required, identify a subcommittee of IRB members to identify the harm and appropriate solutions. In all cases, a report will be made to the full IRB at the next available meeting.
- If it is determined that the noncompliance is serious or continuing, a forcause audit of the protocol will be conducted. If noncompliance creates a potential risk to participants, the protocol will be immediately suspended and contact made with the researchers chair and/or dean.
    - ➢ Protocol PI may decide voluntarily to suspend or terminate some or all of the research activities that may be under current review or investigation.
- The IRB Chair with the support of the IRB administrator, will report the results of the forcause audit to the Protocol PI, members of the IRB and if appropriate, the Institutional Official and/or appropriate Dean and/or Chair of the Protocol PI's Department. The IRB committee will consider
    - ➢ Whether the audit report and any other available information sufficiently supports a determination of non-compliance
    - ➢ Whether the audit report and any other available information supports suspension or termination of research in order to protect human participants or others
    - ➢ Additional actions to protect the rights and welfare of currently enrolled participants
    - ➢ Whether procedures for withdrawal of enrolled participants account for their rights and welfare
    - ➢ Whether participants should be informed of the noncompliance and/or any of the corrective actions
    - ➢ Construct an appropriate corrective action plan.
- ORI will follow up with the implementation of the Protocol PI's corrective action plan and report completion back to the IRB Chair and Committee as appropriate.
- While the IRB has the authority to take appropriate action concerning a research protocol, neither the IRB nor ORI has the authority to take disciplinary action against any individual

  relating to a finding of confirmed noncompliance. Instead, disciplinary action shall be the responsibility of the institution. The IRB administrator shall report any termination of research

to the appropriate institutional officials,and if requested, assist in any disciplinary action process taken by the appropriate academic unit.

- Corrective Actions
    - The actions taken to correct noncompliance vary and depend on the nature and seriousness of the noncompliance. The IRB Chair, in consultation with the IRB Administrator, may take any combination of the following actions:
        - Take no action
        - Request a protocol and/or consent form modification
        - Require that all participants be re-consented
        - Require previous participants to be informed of any changes to the protocol and/or consent procedures
        - Require observation of consent procedures
        - Require more frequent review of the conduct of the research
        - Require additional training for the research team
        - Require follow-up audit(s)
        - Suspend the research
        - Terminate the research
        - Nullification of collected data
        - Refer issues to other institutional entities (e.g., Institutional Official, Dean, Legal Counsel)
        - Any other action deemed appropriate by the IRB to protect the rights and welfare of current or future research participants.

SOP H107: Reporting Responsibilities of the Investigator

- Purpose
    - Noncompliance occurs when research involving human participants is conducted in a manner that disregards or *violates federal regulations, the policies or procedures of the Institutional Review Board (IRB), or institutional policies governing human research. Noncompliance with respect to human research participant protection violates the University Federalwide Assurance Registration (FWA). Even in the absence of intent, an unapproved or otherwise noncompliant research activity may place a research participant at unnecessary risk. This policy sets forth the definition and examples of noncompliance; the procedures for reporting an allegation of noncompliance to the IRB; and the procedures for the IRB's management of such allegations, and if appropriate, of confirmed noncompliance. The purpose of sanctions initiated by the IRB against human subjects researchers:*

- The use of sanctions is intended to promote compliance with federal and state laws and regulations, and with University System of Georgia and Georgia Southern University (GS) policies. Actions based upon non-compliance by the IRB are not intended as punishment against any individual or group of human subjects researchers.

- Authority
  - *The IRB has final authority and responsibility for approval of activities directly related to research conducted with human subjects by GS faculty, staff, and students.*
  - *The IRB has authority to enact operational sanctions. (i.e., restrict research approvals, sequester data and mandate training.)*
  - *The IRB has no authority to enact administrative sanctions but may make such recommendations to the Institutional Official. (i.e, sanction of professional status or pay.)*
- Terms
  - **Adverse Events**:
    - Any untoward or unfavorable medical occurrence in a human subject; including any abnormal sign, symptom or disease that is temporally related to the research, whether or not it is related to the subject's participation in the research. Examples of AEs include:
      - (1) conducting human participant research without IRB approval (e.g., before approval; after expiration of approval and in the absence of a continuation application submitted to the IRB; during a suspension of IRB approval; after termination of IRB approval);
      - (2) disregarding or otherwise violating IRB-approved informed consent procedures (e.g., failing to obtain consent/assent, using unapproved or outdated consent, assent, and information sheets, missing signatures, failing to document consent process);
      - (3) deviating from the protocol approved by the IRB;
      - (4) modifying an approved protocol without IRB consent;
      - (5) failing to report or late reporting unanticipated problems;
      - (6) failing to maintain adequate records;
      - (7) failing to train research team members in the proper procedures; and
      - (8) failing to follow recommendations by the IRB to ensure the safety of research participants.
  - **Serious Adverse Events**
    - Events that are serious, not anticipated and related to the research activity
  - **Unexpected Problem**
    - Any subject related incident, experience or outcome that is:
      - unexpected (in the nature, severity or frequency) given the description of the likely harms in the protocol, the consent form and related materials (as presented to the IRB);
      - related to the subject's participation in the research; and

        - places research subjects, researchers or others at greater risk of any recognizable harm (e.g., physical, psychological, economic or social) than was previously anticipated or recognized by the protocol.
    - **Confirmed Noncompliance**
    - **Continuing Noncompliance**
    - **Serious Noncompliance**
        - Noncompliance involving one or more of the following:
            - (1) bringing harm to research participants;
            - (2) exposing research participants to a significant risk of substantive harm;
            - (3) compromising the privacy and confidentiality of research participants;
            - (4) causing damage to scientific integrity of the research data that has been collected;
            - (5) engaging in willful or knowing noncompliance;
            - (6) impacting ethical principles adversely.
- Addressing Allegations of Noncompliance
    - The IRB administrator the Office of Research Integrity (ORI) may become aware of an allegation of noncompliance or of circumstances indicating potential noncompliance upon the receipt of a complaint or concern from a participant, researcher, GS employee, committee member or member of the public; or from the interpretation of information received during a Continuation, Amendment, Unanticipated Problems Review; or from the findings of a random or for-cause audit, other quality control activities or review of public or social media.
    - Once it has received an allegation of noncompliance, ORI will conduct an initial interview to obtain the basic conditions of the concern and if appropriate complete and adverse event reporting form.
    - ORI will meet with the IRB Chair to make the following initial determinations:
        - (a) whether noncompliance is alleged; and
        - (b) whether the allegation indicates that an immediate action such as suspension by the IRB is warranted.
        - If it is determined that immediate action by the IRB is warranted (e.g., suspension), then the IRB Chair will initiate suspension proceedings. (See Suspensions)
    - ORI and the IRB Chair will initiate an investigation of the circumstances alleged in the noncompliance report.
    - Where funded, ORI will make the appropriate report to the Office of Human Subjects Protections (OHRP) and Sponsor where required.
        - ORI may elect to investigate informally by reading relevant documents and communicating with the affected parties.
        - If ORI and the IRB Chair determine that the allegation is not credible or is unsubstantiated, then the inquiry ends. ORI will document this finding in a written report;

place the report in the study file; and notify the IRB of the finding on the agenda of the next available meeting.

- If the inquiry yields evidence that noncompliance that is neither serious or continuing has occurred, then the IRB Chair and ORI may identify and will devise an appropriate corrective plan or if additional expertise is required, identify a subcommittee of IRB members to identify the harm and appropriate solutions. In all cases, a report will be made to the full IRB at the next available meeting.
- If it is determined that the noncompliance is serious or continuing, a forcause audit of the protocol will be conducted. If noncompliance creates a potential risk to participants, the protocol will be immediately suspended and contact made with the researchers chair and/or dean.
    - Protocol PI may decide voluntarily to suspend or terminate some or all of the research activities that may be under current review or investigation.
- The IRB Chair with the support of the IRB administrator, will report the results of the forcause audit to the Protocol PI, members of the IRB and if appropriate, the Institutional Official and/or appropriate Dean and/or Chair of the Protocol PI's Department. The IRB committee will consider
    - Whether the audit report and any other available information sufficiently supports a determination of non-compliance
    - Whether the audit report and any other available information supports suspension or termination of research in order to protect human participants or others
    - Additional actions to protect the rights and welfare of currently enrolled participants
    - Whether procedures for withdrawal of enrolled participants account for their rights and welfare
    - Whether participants should be informed of the noncompliance and/or any of the corrective actions
    - Construct an appropriate corrective action plan.
- ORI will follow up with the implementation of the Protocol PI's corrective action plan and report completion back to the IRB Chair and Committee as appropriate.
- While the IRB has the authority to take appropriate action concerning a research protocol, neither the IRB nor ORI has the authority to take disciplinary action against any individual relating to a finding of confirmed noncompliance. Instead, disciplinary action shall be the responsibility of the institution. The IRB administrator shall report any termination of research to the appropriate institutional officials,and if requested, assist in any disciplinary action process taken by the appropriate academic unit.

- Corrective Actions

- The actions taken to correct noncompliance vary and depend on the nature and seriousness of the noncompliance. The IRB Chair, in consultation with the IRB Administrator, may take any combination of the following actions:
    - Take no action
    - Request a protocol and/or consent form modification
    - Require that all participants be re-consented
    - Require previous participants to be informed of any changes to the protocol and/or consent procedures
    - Require observation of consent procedures
    - Require more frequent review of the conduct of the research
    - Require additional training for the research team
    - Require follow-up audit(s)
    - Suspend the research
    - Terminate the research
    - Nullification of collected data
    - Refer issues to other institutional entities (e.g., Institutional Official, Dean, Legal Counsel)
    - Any other action deemed appropriate by the IRB to protect the rights and welfare of current or future research participants.

Definitions – Human Subjects Research

- Research
    - DHHS Definitions:
        - **Research** is as a *systematic investigation*, including research development, testing and evaluation, designed to *develop or contribute to generalizable knowledge*.
        - 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.
        - Examples of systematic investigations include:
            - surveys and questionnaires
            - interviews
            - focus groups
            - photovoice studies
            - analyses of existing data or biological specimens
            - epidemiological studies
            - evaluations of social or educational programs

        - cognitive and perceptual experiments
        - evaluation of business process effectiveness
        - medical chart review studies
    - Investigations designed to **develop or contribute to generalizable knowledge** are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program (like a class assignment).
    - Research results do not have to be published or presented to qualify the experiment or data gathering as research. The intent to contribute to "generalizable (scholarly) knowledge" makes an experiment or data collection research, regardless of publication. Research that never is published is still research. Participants in research studies deserve protection whether or not the research is published.
    - Examples of activities that typically are not generalizable include:
        - biographies
        - oral histories that are designed solely to create a record of specific historical events
        - service or course evaluations used only for the purpose of improving the service by the collector without presentation of application to outside entities.
        - classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices
        - quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the GS community.
- Human Subjects
    - DHHS definitions:
        - A **human subject** is as a living individual or a biospecimen about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.
            - **Intervention** includes both physical procedures by which data are gathered (e.g., blood draw) and manipulations of the subject or the subject's environment that are performed for research purposes.
            - **Interaction** includes communication or interpersonal contact between investigator and subject.
            - **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record or opinion poll).

- Investigators conducting human subjects research must satisfy DHHS (OHRP) regulations [45 CFR Part 46] known as the Common Rule and FDA regulations [21 CFR Part 50 and 56] regarding the protection of human subjects research, as applicable. Find a comparison of FDA and DHHS regulations at https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112910.htm

Investigational New Devices

- What is an Investigational Medical Device?
    - A medical device is considered investigational if (1.) the device is not approved for marketing in the U.S. or (2.) the device is approved for marketing but is being clinically evaluated for a new indication.
    - The Food and Drug Administration (FDA) regulates research involving medical devices, as well as all aspects of device manufacturing, marketing and distribution (*Code of Federal Regulations* Title 21, parts 800-1299). The FDA website contains several sets of useful and readable guidance documents about investigational devices, including mobile devices.
- Do I need an IDE (FDA Investigational Device Exemption)?
    - There are two types of clinical studies involving medical devices that require than an Investigational Device Exemption (IDE) be obtained from the FDA in addition to IRB approval before a research study may commence.
        - A clinical study involving an unapproved device that poses significant risk to subjects
            - The majority of IDE studies are conducted to collect safety and effectiveness data used to support Premarket Approval (PMA) applications submitted to the FDA.
        - A clinical study involving an approved (legally marketed) device being tested for a new indication
    - This includes both new devices as well as FDA approved devices being used or tested in a new way that significantly increases the risks associated with the device.
- How do I begin to get approval to conduct a study involving an investigational medical device?
    - You will need to have a determination of significant risk or non-significant risk (or exemption) from the sponsor supplying the investigational medical device for study. If you are the inventor – you become the sponsor and must take on all of the sponsors responsibilities as well as the investigator responsibilities.
            - Significant Risk
            - Nonsignificant Risk
            - Exempt
        - FDA guide on Determining Significant Risk and Nonsignificant Risk Medical Device Studies.
        - FDA guide to the IDE process – including definitions, risk determination and investigator requirements.

        - FDA FAQ about Medical Devices
        - FDA IDE Responsibilities (sponsor, researcher, etc.)
    - Once you have a determination, you may apply to the IRB.
        - Clinical trials and device studies that are conducted through a commercial sponsor will be reviewed by an commercial external IRB. Your sponsorship budget should account for direct charges from the IRB.
        - Clinical studies conducted on federal grants or University funded may be reviewed by the GS IRB or referred to commercial external review at the discretion of the IRB administration. Decisions will be based upon the ability of the board to adequately evaluate the risks associated with the study using available expertise. The cost of external review is the responsibility of the project PI and should be anticipated in planning of the study.
- What are the IRB procedures for determining significant or non-significant risk level?
    - The investigator will provide the IRB with the significant risk level determination from either the sponsor or if available, the FDA. (21 CFR 812.2(b)(1)(ii)). *(If the investigator is also the inventor, the investigator becomes the sponsor and must take on all of the sponsors responsibilities as well as the investigator responsibilities.)*
    - The IRB will review that determination with the supporting documentation.
        - The IRB may also use information from the application, protocol, the investigator's brochure, package insert, FDA Information Sheets, reports of prior investigations conducted with the device, description of subject selection criteria, monitoring procedures, proposed use of the device, potential harms and other evaluations presented by the sponsor to categorize the device as "SR" or "NSR" or other criteria at its discretion.
    - If the IRB disagrees with a sponsor's classification of a device as NSR," the investigator must file an IDE application with the FDA to obtain a determination. The IRB will abide by the FDA's determination.
        - If an IDE application is or has been submitted to FDA, but final approval has not been granted, the IRB can proceed with the review of the study, but final approval will not be granted until documentation of the FDA approval is submitted.
        - Once the IDE is obtained, the investigator may submit the IDE# and FDA letter to the IRB for The study will be reviewed by the IRB at the next convened meeting.
    - The investigation cannot proceed until the FDA IDE application approval is complete or NSR determination affirmed and the IRB has approved the study under the regulations for the protection of human subjects.
    - Once approved, the investigator is responsible for following FDA requirements for recordkeeping and reporting.

- Amendments or corrections of deficiencies required by FDA during the IDE process must be submitted for review and approval of the IRB.
- Reporting:
    - The IRB will record its determination of SR/NSR status in the minutes of the The minutes will describe the IRB's reasons for its SR or NSR determination and may also include the documents used to establish the IDE status for the study. For an SR determination, such documentation may include a copy of the IDE approval or conditional approval letter from FDA. For an NSR determination, the documentation may include FDA's NSR classification if the agency has made such a determination.
    - The IRB will review reports of unanticipated device effects. Investigators are required to report these events to the IRB within 10 working days of their receipt of the information. Should the IRB determine that the information gained in these reports changes the risk assessment; the IRB can reconsider any NSR decision at any time during the study and/or require the modification of the informed consent to contain the new information.