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A. Introduction

The Shaw University Institutional Review Board (IRB) for the Protection of Human Subjects was established to ensure that the University complies with all federally mandated regulations which govern research involving human subjects’ protection. Shaw University’s policy is to protect the rights and welfare of all human volunteers who participate in research activities conducted under the auspices of the University.

B. Definitions

The IRB has adopted the definitions used by the U.S. Department of Health and Human Services, Office for Human Research Protections (OHRP) and the 45 CFR 46:

- **45 CFR 46** – Code of Federal Regulations: Title 45 Public Welfare, Part 46 Protection of Human Subjects is a federal policy that guides the conduct of research involving human subjects.

- **Federalwide Assurance (FWA)** – The FWA is documentation of an institutional commitment to comply with Federal regulations and maintain adequate programs and procedures for the protection of human subjects. It is the principal mechanism for compliance oversight by OHRP.

- **Human subject** – A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information.

- **Institutional Review Board (IRB)** – A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

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

- **Research** – Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

C. Institutional Responsibilities

1. **Federalwide Assurance (FWA)**

   The FWA is required for all Department of Health and Human Services (DHHS) funded research involving the use of human subjects. It is a formal commitment made by an institution to provide for the protection of human subjects. Any institution with a FWA agrees to and is responsible for protecting human subjects. A FWA is not required for research that has not received federal funding but an institution may make the decision to hold all research involving human subjects to the standards listed in the FWA. **Shaw University has agreed to hold all research to the federal standards.** The FWA became effective on March 11, 2003 and is renewable every 3 years.

   The FWA includes the following important components:
Shaw University assures that all research involving human subjects, regardless of funding source, will be guided by the ethical principles in The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, lays out the basic ethical principles and guidelines to consider when conducting research involving human subjects. The three ethical principles, as defined in the Belmont Report include:

- **Respect for Persons** - Individuals should be treated as autonomous agents or human beings. Persons with diminished autonomy are entitled to protection.
- **Beneficence** – Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. (do not harm; and maximize possible benefits and minimize possible harms)
- **Justice** - The ethical principle requiring that the burden and benefits of research shall be distributed equitably.

The University will be guided by these ethical principles and use them as a foundation for all research conducted with human subjects.

Shaw University assures that it will apply Title 45 Code of Federal Regulations Part 46 and all of its subparts (A, B – additional protections for pregnant women, human fetuses and neonates, C – additional protections for prisoners, and D – additional protections for children) to all human subject research. Whereas the Belmont Report discusses ethical principles, 45CFR46 discuss the federal rules for conducting research involving human subjects.

- The University’s FWA number is FWA00004331.
- The University’s IRB Registration number is – IRB00005060.

2. Institutional Oversight

Two additional sections of the FWA describe institutional oversight of the human protections program at Shaw University and list the individuals responsible for such oversight.

- The **Signatory Official**, according to OHRP, is responsible for “setting the tone for an institutional culture of respect for human subjects”. The designated Signatory Official is Clarence G. Newsome, Ph.D., President.

- The **Human Protections Administrator** is the primary contact for DHHS OHRP and has administrative responsibility for Shaw's Human Protections Administration that includes ensuring that human subjects involved in research are adequately protected and that Shaw remains in compliance with regulations. The Human Protections Administrator shall be the Director of the Office of Research and Sponsored Programs, Dr. Daniel L. Howard, or his designee.

D. Investigator’s Responsibilities

All research investigators and their key personnel must comply with the following guidelines:

- All investigators must obtain IRB approval for each research protocol involving human subjects prior to initiating the study.
• The principal investigator is required to prepare the “New Protocol Application Form” and provide the research proposal, informed consent form(s), study instruments, recruitment materials, focus group questions and any other relevant documentation to the IRB.

• The principal investigator and/or faculty advisor may request or may be asked to attend a full board meeting when his or her protocol is under review.

• The principal investigator and all key personnel working on the research project must complete the required human subjects’ protections educational training prior to beginning the research. Proof of training in the form of a certificate must be supplied to the IRB with the application. IRB applications from investigators who have not completed the required education will be returned without review.
  o Faculty advisors of student investigators must also complete the training.

• Investigators must provide a copy of the IRB-approved and stamped informed consent form to each participant at the time of consent. All documentation must be stored as outlined in the IRB application in a secure location for a minimum of three years after the completion of the study.

• Principal investigators must promptly report proposed modifications to approved studies to the IRB using the “Modification to a Previously Approved Protocol Form”. No changes to the study should be initiated without prior IRB review and approval. Some modifications may require full IRB review.

• Principal investigators must inform their co-investigators from cooperating institutions that any change in a previously approved protocol must be submitted to the appropriate IRB and approved before implementing the change.

• If findings are developed during the course of the research that may have an effect on participant’s willingness to continue in the study, Principal investigators must report the findings to both the IRB and study participants.

• Principal investigators must report all adverse events and unanticipated problems that involve risks to study participants immediately to the IRB using the “Adverse Event Reporting Form”.

• The IRB will send a letter to the principal investigator 2 months before the expiration of a study as a reminder that the study will expire soon. Principal investigators are required to submit the “Continuation or Termination of an Approved Protocol Form” indicating if they will continue the study or terminate the study. In general, the IRB grants approvals for no more than one year. Some studies may be approved for a shorter time depending on the nature of the research. If an IRB approval has expired research activities must cease.

• Research activities involving institutions and agencies outside of Shaw University must receive written approval from the appropriate official within the agency. The written approval must be submitted with the IRB application.

E. The Institutional Review Board (IRB) for the Protection of Human Subjects

1. IRB Authority

   In accordance with federal guidelines, the IRB has the authority to approve, modify, or disapprove proposed human research studies; authority to modify or disapprove ongoing studies; no individual in the institution can approve a project that the IRB has disapproved.
An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRBs requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of reasons for the IRBs action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (45CFR46.113).

2. Composition

According to federal policy, 45CFR46.107, IRB committee membership shall consist of a minimum of five members of diverse backgrounds in regards to race, gender, cultural background, profession, and sensitivities to community issues. The membership should include at least one person who is not affiliated with the University or related to a person who is affiliated with the University. One member shall work in primarily the scientific arena while one should work primarily in the nonscientific arena. The goal is to have a diverse group of members to limit bias in regards to the approval or disapproval of research.

3. Member Appointment

IRB members are appointed by the Shaw University Director, Office of Human Subjects Protection (OHSP) based on consultation with department chairs and interest by perspective faculty and staff members. Appointments are for two-year terms.

An invitation letter from the Director of OHSP will be sent to interested parties whose department chairs agree to the appointment.

4. IRB Member Responsibilities

IRB members shall:

- serve under the Director of the Office of Human Subjects Protection. Members may be reappointed at the end of their 2 year term. Members may also be removed by the Director of OHSP at any time, given written notice, for due cause (e.g. failure to meet IRB responsibilities, chronic lack of attendance, failure to meet educational requirements for human participant research, ethical misconduct, disregard for federal regulations or University policies).

- keep updated with an understanding of the ethical principles of human participant research, federal regulations, applicable state laws, the University’s FWA and institutional policies and procedures for the protection of human participants.

- complete the required human subjects’ protections training before beginning their term and be recertified every two years.

- keep all information related to the discussions of specific research studies in strict confidence at all times.

- notify the IRB Administrator when he/she will not attend an upcoming IRB meeting.

- serve as primary reviewer for protocols when assigned and lead discussion of the assigned protocol during the IRB meeting.
• abstain from participating in the review, voting, or continuing review of a study when he/she has a conflict of interest. The IRB member may be required, however, to provide information to the IRB about such projects.

5. IRB Chairperson Responsibilities

The Chair ensures that University and federal rules and policies are being considered as the committee reviews the planned research proposals. Therefore, the Chair should be familiar with every protocol that comes before the committee and have a thorough knowledge of policy. The IRB Chairperson is also responsible for directing the IRB Committee meetings to ensure that the meetings proceed as planned in the agenda. The Chair may also independently review and approve research that can be identified within federal guidelines as “expedited”, because it involves “no more than minimal risk” to a person who may consent to participate or if there is a small change in a previously approved protocol. The IRB Chairperson is usually a well-respected member of the institution who will play a leading role in establishing and implementing IRB policy, representing the IRB in discussions with University officials, and in discussions with federal authorities. The Chair must be fair and impartial and be regarded highly by the administration and faculty.

In addition to meeting the requirements of an IRB member, the IRB Chair will:

• ensure that the IRB fulfills its responsibilities and is fair and impartial in its decisions
• facilitate IRB meetings
• review and approve exempt and expedited protocols in a timely manner or appoint a designee to perform in his or her place
• review and approve or disapprove any resubmissions of protocols deemed “approval pending clarification/modification” by the full IRB only when the convened IRB has stipulated specific revisions requiring simple consensus by the investigator
• identify and assign lead reviewers for protocols to be reviewed by the full board

As stated above, the time requirement for the IRB Chairperson will be dependent on the volume of proposals received by the OHSP. The time commitment will increase as more research is granted funding.

The IRB Chairperson will be appointed by the Director of OHSP and will serve no more than two consecutive years as chair.

6. IRB Administrator Responsibilities

The IRB Administrator will work closely with the IRB Chairperson in matters of developing policy for IRB Committee meetings. The Shaw IRB Administrator will have a large role in the day-to-day management of the OHSP. The Administrator must have a thorough understanding of federal policy and must work daily to ensure that the University remains in compliance with all applicable federal regulations. A major responsibility is to triage the proposals received into the categories of IRB review (exempt, expedited, or full committee review). The IRB Administrator will also be responsible for taking minutes of all IRB meetings. The time requirement for the IRB Administrator will be dependent on the volume of proposals received by the OHSP. The time commitment will increase as more research is granted funding.

7. Alternate Members

From time to time, as needed, alternate members may be appointed for a regular voting member(s). The appointment of an alternate member shall be based on expertise similar to that of the regular voting member(s). An alternate member may vote only when the regular
voting member is absent.

8. IRB Meetings

The IRB will meet once a month, as needed, to review, discuss, and vote on submitted protocols. If there are no protocols to review in any given month, the IRB is not required to meet. From time to time, if there are no protocols to review, the IRB may decide to meet to keep updated on the expedited and exempt protocols that were received in the OHSP. One week prior to each meeting, members will receive submitted protocols for preliminary review. In addition, each IRB member will receive the location, time, and date of the meeting. The dates of each meeting will also be posted on the Shaw IRB website.

During a convened meeting, a majority of the members of the IRB must be present including at least one scientist and one nonscientist. If the required number of members is lost during a meeting, no further action may be taken until it is restored. In order for research to be approved, it must receive the approval of a majority of the voting members present at the meeting.

If necessary, an IRB meeting may be convened by telephone conference call, provided that each participating IRB member has received all pertinent material prior to the meeting and can actively and equally participate in the discussion of all protocols. Minutes of such meetings will document which members were present on the call.

The Director, OHSP and IRB chair may call the IRB into special meetings outside the published schedule of meetings. The IRB must have a majority present for such meetings to convene.

Minutes of IRB meetings will include attendance; actions taken by the IRB; vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

The IRB will make one of the following four determinations regarding an application:

- **Approved** without questions, concerns or requests for modifications.

- **Approval pending** clarification and/or modification of minor specific points or components of the application. The research activity may not be undertaken until the IRBs concerns are addressed and submitted to the designated IRB member for review and approval.

- **Deferred (tabled)**. This indicates approval by the IRB has been withheld as substantive concerns or significant requests for clarification have been raised and/or the proposed research does not meet University or Federal guidelines for the protection of human participants. The research activity may not be undertaken until the IRBs concerns are addressed and submitted to the full IRB for review and approval.

- **Disapproved**. The IRB may disapprove a proposed activity with serious and substantive problems and/or that fails to meet University or Federal guidelines for the protection of human participants.

“Approval of the proposed research is usually granted for a period of one year commencing on the date of the convened meeting of the IRB at which the protocol was reviewed and approved. Based upon an assessment of the degree of risk to human participants, the IRB
may specify special conditions whereby the investigator has a shorter approval period or must report research progress at specific intervals. Continuation of projects past the approval period requires project continuation review and approval by the IRB chair or designee.

Investigators will be notified in writing of the IRBs decisions generally within seven days of the date of approval.

F. The IRB Review Process

1. Review Requirements

The IRB chair or his/her designee will determine whether a given study/protocol can be considered human participants’ research based on the federal definition of “research”.

The IRB Chair or his/her designee will also determine if certain categories of research involving minimal risk to participants meet one of the Federal categories for expedited review. In these cases the IRB chair or his/her designee will review the study through expedited review procedures and the entire board need not review the study.

The three basic ethical principles – Respect for Persons, Beneficence, and Justice – set forth in the Common Rule and The Belmont Report, shall guide the IRB in its review.

a. Respect for Persons

- Where appropriate, the IRB shall require adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

- In accordance with 45 CFR 46.111(b), when some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB shall determine whether additional safeguards have been included in the research to protect the rights and welfare of these participants.

- The investigator shall seek informed consent from each prospective participant or the participant’s legally authorized representative in accordance with and to the extent required by 45 CFR 46.116, and such consent shall be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 and retained as a matter of record.

- When research involves more than minimal risk or substantial stress or discomfort, such risk, stress or discomfort shall be carefully explained to the participant before his or her participation and justified by the expected benefits of the research.

- A participant shall have the right to withdraw from a research project at any time or to refuse to participate without loss of benefits to which the individual would otherwise be entitled. In addition, a participant shall have the right to appropriate professional care, to privacy and confidentiality in the use of personal information, and to freedom from undue embarrassment, discomfort, anxiety and harassment.

b. Beneficence

- Direct or potential benefits to the participant or the importance of knowledge to be gained shall not preclude consideration of the inherent risks to the individual.
• The IRB will consider the qualifications of the investigator, his or her professional development, and experience when assessing the degree of risk to participants in the research project. This assessment applies to research that may fall within all categories of IRB review.

• Research plans should make adequate provision for monitoring the data collected to ensure the safety of participants, where necessary.

• Risks to participants shall be minimized by using procedures that are consistent with sound research design.

• Risks to participants shall be reasonable in relation to anticipated benefits, if any, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits participants would receive even if they were not participating in the research). The IRB shall not consider the long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibilities.

c. Justice

• Selection of participants shall be equitable. When appropriate, every effort shall be made to include participants of diverse age, race, gender, and ethnicity.

• The IRB shall ensure that compensation or inducement offered for participation in a study is made appropriately, with participants fairly recruited and adequately informed rather than unduly influenced by promised compensation. Financial incentives should not be so great as to be coercive to potential participants and should constitute reasonable compensation for the inconvenience of participating. Information related to compensation shall be included in the informed consent form.

• No recruitment or involvement of human participants in research shall be permitted until the IRB has reviewed and approved the research application, and informed consent has been obtained. It is the principal investigator’s responsibility to obtain approval from the IRB prior to the initiation of any research, including pilot or pre-test studies, involving the use of human participants.

• The investigator should ensure that consent for participation is sought only under circumstances that minimize the possibility of coercion or undue influence. Student participation must be voluntary and the student should be able to withdraw from the study at any time without penalty.

2. Criteria for IRB Approval of Research

(45 CFR 46.111) (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

• Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits
that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

- Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

3. Levels of Review

a. Exempt from Review

The following research activities are considered exempt from federal regulations as stated in 45 CFR 46.101(b):

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

  - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifies linked to the subjects; and

  - Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
  - The human subjects are elected or appointed public officials or candidates for public office; or
  - Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic formation is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or level of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture. (45 CFR 46.101(b))

b. Expedited Review

Expedited review categories of research shall comply with “Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure”. 63 FR 60364-60367, November 9, 1998.

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

- Prospective collection of biological specimens for research purposes by noninvasive means.
• Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

• Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

• Collection of data from voice, video, digital, or image recordings made for research purposes.

• Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

• Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

• Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The IRB may use the expedited review procedures to review minor changes in previously approved research during the period for which approval is authorized.

The expedited review procedure is carried out by the IRB chair or his/her designee.

In reviewing the research, reviewers may exercise all of the authorities of the IRB except the reviewers may not disapprove the research. Disapproval of a research application requires the majority of the full IRB.

At a convened IRB meeting, members may request that certain protocols be approved by the IRB in accordance with full board review procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. A PI may also request that an application receive full board review.

The IRB chair shall review amendments for previously approved research which can be approved under an expedited review procedure.

c. Full Board Review

All proposed research deemed by the IRB chair to fit neither the exempt or expedited review must be reviewed by the full IRB. In addition, the IRB may require full review of
any research submitted or approved under expedited review and any research not approved by expedited review.

The primary criteria for full board review are the risk to participants during the procedures and interactions between participants and researchers.

Examples of research activities that must be reviewed by the full IRB include:

- Research in which potential participants may not be given sufficient information to make decisions about whether to participate and accept potential risks. This may include research in which outright deception or incomplete disclosure of the purpose of the study might reasonably affect a person’s decision to participate in the study.

- Research involving more than minimal risk, where defined as “the probability and magnitude of harm or discomfort are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examinations or tests”.

- Non-curricular, interactive research in primary and secondary schools.

- Research in which participation per se in the study constitutes a risk (e.g., identification as a participant in a drug-use survey). This would include research in which researchers have applied for a waiver of documentation of consent, which can be used as a method of reducing risks to participants who may be placed at risk simply by being involved in the study.

- Research on special populations, e.g., minors, prisoners, pregnant women and mentally incompetent persons.

- Research involving potential risks to participant's right to privacy and/or threats to confidentiality.

d. Continuing Review

The IRB is required to re-evaluate research projects at appropriate intervals not less than once a year. For research involving no more than minimal risk, the approval period is generally one year from the date of the convened meeting at which the protocol was reviewed and approved. For research involving greater than minimal risk, the IRB will determine the appropriate approval period.

Investigators are required to submit the Continuation or Termination of an Approved Protocol form to the IRB before the expiration date of the study.

An original protocol may have received an expedited review but the continuing review may go to the full IRB, as deemed necessary by the IRB Chair or a designee.

Continuing review is required for continued analysis of identifiable information but is not required if the data have been de-identified.

- For new analysis of previously collected identifiable data, a new IRB protocol is required.

- For a new analysis of previously collected de-identified data, no IRB review is required.
4. Informed Consent Process

Informed consent must be sought from each prospective participant or the participant’s legally authorized representative before research is begun. Consent is a continuing process and participants always retain the right to withdraw from participation in a research project. Federal policy requires that investigators inform participants of any important new information that might affect their willingness to continue participating in the research.

a. The basic elements of informed consent as stated in 45 CFR 46.116 are:

- A statement that the study involves research.
- An explanation of the purpose of the research.
- The expected duration of the subjects’ participation.
- A description of the procedures to be followed and, if appropriate, identification of any procedures that are experimental (e.g., therapies that are being tested).
- A description of any benefits to the participants or to others which may reasonably be expected from the research and how that will contribute to the field of study or may benefit others.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant, description of foreseeable risks or discomforts to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant is maintained. This includes the matter and place of data storage.
- For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available if injury occurs and what they consist of or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research-related injury. Shaw University consent forms should include the address, phone number and email addresses for the PI and the Shaw IRB.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

b. Additional requirements may include:

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable.
• Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant’s consent.

• Any additional costs to the participant that may result from participation in the research.

• The consequences of a participant’s decision to withdraw from the research and procedures for orderly closure of participation by the participant.

• A statement that significant new findings developed during the course of the research, which may relate to participants’ willingness to continue participation, will be provided to the participant.

• The approximate number of participants involved in the study.

The IRB may waive written documentation of informed consent if: (i) the research represents no more than minimal risk of harm to participants, (ii) the waiver or alteration will not adversely affect the rights and welfare of the participant, (iii) the research could not be carried out without the waiver or alteration, and, (iv) where informed consent constitutes the only threat to anonymity, and (v) whenever appropriate, the participant will be debriefed. When consent is waived, the IRB may require the investigator to offer participants written information about the study. [45 CFR 46.116(c); 45 CFR 46.116(d)]

Consent forms should avoid jargon and should be written in the second person (e.g., If you agree to the research….) in a language and at a level that is understandable to the participant. Informed consent will not be accomplished unless the requirement is met that the participant understands the components of the consent form.

The person who signs the consent form must be given a copy as a reference and reminder of the information conveyed by the researcher. Non-written methods of administering consent are also possible.

The IRB will maintain a sample informed consent template on its web site. PIs should use the format of this template and its language whenever possible.

c. Informed Consent for Minors

*Children (minors)* are defined as persons who have not attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In North Carolina, residents under 18 years of age are considered minors unless they are “emancipated” by court order or marriage.

*Assent* is the child’s affirmative agreement to participate in research. A child’s legal guardian or parent must sign an informed consent form in order for a child to participate in a research study. Where appropriate, the child should assent to participate in the research. Both consent and assent forms must be submitted to the IRB for approval. If assent will not be used, an explanation for not including this component should be included in the application.

d. Informed Consent for Non-English Speaking Subjects

DHHS regulations for the protection of human participants require that informed consent information be presented “in language understandable to the subject” and, in most situations, that informed consent be documented in writing.
The written consent document should embody, in language understandable to the participant, all the elements necessary for legally effective informed consent. Participants who do not speak English should be presented with a consent document written in a language they understand. The IRB must receive a copy of the document.

The PI may ask the IRB to waive the written consent process if it constitutes a culturally unacceptable or insensitive procedure.

5. Modifications

All modifications/amendments to currently approved research must be reviewed and approved by the IRB before implementation. The PI must submit a Modification to a Previously Approved Protocol form. Changes that do not increase the risk to research participants may receive an expedited review. Modifications to approved research projects that are more than minimal risk and do not qualify for expedited review must be forwarded to the full IRB for review and, if appropriate, to those participating in the study by way of a revised informed consent.

The PI shall incorporate each approved modification to a research protocol or consent document into the approved protocol to ensure that there is only one complete protocol, with the revision dates noted. The PI will send a copy to the IRB.

6. Adverse Events and Serious Adverse Events

Adverse events and serious adverse events involving risks to participants or others are events or problems that are undesirable, unintended, and are harmful or detrimental to the welfare of study participants or other individuals involved with a research study. Reportable events are not limited to physical injury, but include psychological, social, and emotional harm or injury.

All adverse events and unanticipated problems involving risks to participants and others must be reported by the investigator immediately using the Adverse Event Reporting form. In addition, the investigator is responsible for reporting the event as required by Federal regulation, grant requirements, or contract.

The IRB is responsible for reviewing reports of any adverse events or unanticipated problems involving risks to subjects or others. Upon the receipt of the report, the IRB will determine whether the study should be modified to reduce the level of risk to participants, or whether the consent form should be modified to include a description of the event.

7. Closure of Approved Research

If an investigator terminates the study, the investigator shall notify the IRB by submitting the Continuation or Termination of an Approved Protocol form.

Once the PI has terminated the research and so notified the IRB, he or she may not recruit or enroll human research participants. There can be no intervention, interaction or follow-up with enrolled human participants, nor any continued collection of data or analysis of data previously collected as part of the research protocol.

8. Noncompliance

The IRB shall be responsible for reviewing and determining all issues of serious or continuing noncompliance with 45 CFR 46, IRB requirements, or University requirements. Any serious or continuing noncompliance will be reported to the Human Protections Administrator and the
IRB chair who together will investigate all credible reports of alleged noncompliance and inappropriate involvement of human participants in research.

Noncompliance includes: Conducting research without IRB review, not obtaining consent; using the wrong consent form, failing to report adverse events or serious adverse events or other problems, failure to maintain adequate records, failure to follow the IRB approved protocol, modifying an approved protocol without IRB approval, inadequate supervision, or inadequate training.

When a report of alleged noncompliance is received by the IRB or OHSP, a preliminary investigation will be undertaken and a determination will be made as to whether participants are at risk or can be allowed to continue in the research while the investigation continues. If subjects are deemed to be at risk the IRB Chair or OHSP Director may ask the PI to temporarily stop the study.

The IRB shall send a letter to the PI citing the alleged areas of noncompliance and the associated federal regulations and asking the PI to respond to the allegation and provide a corrective action plan within a specified timeframe and/or ask the PI to attend a meeting with the IRB Chair, OHSP Director, and any other University administrator that is deemed necessary.

Actions the IRB may take:

- The IRB may determine that the research study is in compliance with federal regulations and IRB policy and no further action is necessary.

- The IRB may decide that the PI found in noncompliance should not be allowed to process new protocols or renew current projects until all concerns have been addressed.

- The IRB may determine the research study under review is substantially in compliance with federal regulations and IRB policy but may make specific recommendations to improve or enhance the protections for the study’s human participants or increase oversight of the project.

9. Suspension or Termination of Research

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRBs requirements or that has been associated with unexpected harm to participants. (45 CFR 46.113)

The PI will receive a written notice with the reasons for terminating/suspending his/her study.

The IRB has the authority to re-open terminated projects if it deems this action is necessary and in the best interests of the participants.

10. Appealing an IRB Decision

If the IRB makes a decision that an investigator believes to be unfair or unsubstantiated about his or her proposed research, the investigator should first discuss the matter with the IRB chair. The investigator should be prepared to present reasons that he or she believes that the proposed research is in compliance with University policy and Federal regulations for the protection of human participants.
If the issue cannot be resolved satisfactorily by negotiation, the PI may appeal the decision, in writing, to the full IRB. The results of any negotiations that require approval by the full IRB will be taken to the next convened meeting for decision and vote.

The investigator may appear before the IRB to present his or her appeal and any supportive material or documentation obtained through consultation, but the investigator cannot be present during the vote on the IRBs final recommendation.

G. Special Categories

1. Cooperative Research

Shaw University will ensure that any of its collaborating entities also possesses mechanisms to protect human participants that are at least equivalent to those procedures provided for in the ethical principles to which Shaw University is committed.

The University may enter into a joint review arrangement called an IRB Authorization Agreement, where it relies upon the review of another qualified IRB with similar standards of human participants’ protection, or make similar arrangements to meet IRB review requirements and eliminate duplication of effort. Such arrangements must be (a) in writing, (b) approved and signed by the Institutional Official (or designee) of the University, and (c) approved and signed by correlative officials of the cooperating institutions. These arrangements may be entered into on a case-by-case basis.

2. International Research

To be added...

3. Internet Research

Internet research can include: recruiting participants over the internet and gathering data over the internet.

- Recruiting over the web. Unsolicited email messages to multiple users are prohibited by the University without prior approval. The IRB must review the text of the recruitment script to be presented to participants and the context in which the recruitment takes place. If the IRB approves the script, the investigator must seek approval of the script from the Shaw University Public Relations Office and give the IRB proof of such approval.

- Gathering Data. This type of research involves having participants submit data (e.g., survey data) over the internet and presents the most serious human participants concerns (e.g., obtaining consent, particularly assent from minors) due to the potential limits to confidentiality. The investigator must inform the IRB of how he/she intends to obtain consent.

4. Incomplete Disclosure and Deception in Research

To be added...

5. Privacy Protection

The National Institutes of Health has made the following determinations in regards to protections privacy: “Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose
identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants. The OHSP can help with this application process.

Examples of research that can be considered sensitive include:

- Information relating to sexual attitudes, preferences, or practices.
- Information relating to the use of alcohol, drugs, or other addictive products.
- Information pertaining to illegal conduct.
- Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation.
- Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
- Information obtaining to an individual's psychological well-being or mental health.
- Genetic information.

Portions of this manual have been adapted with permission from the Wake Forest University Reynolda Campus “Policy Manual for Research Involving Human Participants”. Portions have also been adapted from the University of Albany “Policy Manual for Research Activities Involving Human Participants”.