Section 3: Lines of Authority and Responsibilities

3.1. The Institutional Official

Policy

The University of Illinois at Chicago assigns responsibility for the protection of human subjects to an official with the appropriate authority to ensure the implementation and maintenance of a program of excellence.

Procedures

Selection

UIR's institutional authority for the protection of human subjects rests with the Chancellor of UIC, who has delegated this authority to the Vice Chancellor for Research (VCR). In turn, this authority has been delegated to the Regional Dean of the University of Illinois Rockford who serves as the Institutional Official (IO) and ensures the implementation and maintenance of a program of excellence.

Responsibilities

The responsibilities of the Institutional Official are as follows:

- Assuming, on behalf of the institution, the obligations of the Federal Assurance of Compliance for the protection of human subjects.
- Implementing the obligations of an institutional official within the scope of applicable regulations.
- Setting the tone for an institutional culture of respect for human subjects by effectively communicating the importance of human subject protections, and by demonstrating an ongoing basis a strong commitment to human subject protections at UIR.
- Possessing a thorough knowledge of the human subject regulations.
- Being involved in the allocation of resources to RSS.
- Supporting the implementation of RSS decisions.
- Ensuring effective, institution-wide communication of and access to human subject information.
- Encouraging participation in human subject educational activities.
- Assigning the role of the Human Protections Administrator (HPA).

3.2. Human Protections Administrator

Policy

The HPA is an individual capable, both in experience and available resources, of overseeing UIR's human research protection program. The HPA is selected by the IO and serves as the primary contact for OHRP regarding human subject's research protection issues for UIR.

Procedures

The HPA is the primary contact person for human subject's protection issues for OHRP and is responsible to:

- Maintain the FWA and ensure compliance with its terms, as well as UIR policies and procedures, federal regulations, and state and local laws relative to the conduct of human research studies.
- Provide guidance regarding the interpretation of regulations, laws, and policies to the UIR IRB, researchers, staff, and administrators.
- Develop and implement UIR policies and procedures for the protection of human subjects in research.
- Oversee and coordinate RSS activities.
- Complete all required CITI and HIPAA training.
- Ensure that human research protection training is available and completed by investigators, key personnel, the IO, and all UIR staff who participate in the HSPP.
- Oversee the quality assurance monitoring of RSS, including research protocols and investigation of matters of non-compliance. Ensure implementation of corrective action, as needed, in accordance with UIR policies and the UIR IRB policy and procedure manual.
- Maintain current knowledge of human subject's protection program guidance and regulations as they evolve.

3.3. IRB Chair: Selection and Responsibilities

Policy

The Institutional Official (IO) appoints the UIR IRB Chair. The IO may appoint an acting or interim chair during any period of vacancy.

Procedures

Selection and Appointment

During any period of temporary vacancy, the IO may appoint an interim or acting IRB Chair.

Other than to make a temporary or interim appointment, the IO may seek counsel from an advisory committee to solicit and review nominations from qualified physicians or researchers. The advisory committee shall consult with the IO, the Director of Healthcare Compliance & Risk

Management, and the Associate Dean for Academic Affairs. The advisory committee may make its own nominations.

Nominees shall be employees or agents of University of Illinois Rockford and be members in good standing, be proficient in research, and without conflicts of interest that would curtail their ability to serve objectively and according to the mission of UIR HSPP as defined in applicable laws, regulations, and policies.

The advisory committee shall recommend to the IO at least three candidates in order of desirability. The IO shall select from among the candidates recommended, or request additional candidates.

Responsibilities

In addition to IRB membership, the responsibilities of the Chair include the following:

- Holding primary responsibility for conducting IRB meetings.
- Ensuring a quorum is present at convened meetings.
- Ensuring operation of RSS within all applicable regulatory requirements.
- Advising and consulting with investigators regarding human subject protection issues and RSS requirements.
- Participating in non-compliance investigations.
- Contributing to the development of policies and procedures.
- Conducting exempt reviews or designate another reviewer.
- Serving as a liaison between RSS, the investigators, and the IO.
- Working with the Director of Healthcare Compliance & Risk Management and HPA to resolve administrative issues of concern.
- Offering guidance to all reviewers and RSS staff.

3.4. UIR IRB: Selection

Policy

UIR maintains an Institutional Review Board (IRB) that includes members with the appropriate expertise to review the wide variety of research protocols commonly conducted by investigators of UIR, as well as members who fairly represent the interests of the community.

The IRB members will be knowledgeable about regulatory requirements, and will review individual research protocols objectively and impartially.

Procedures

Appointment

Members for the IRB will be recruited based on an assessment of need. Committee members may submit names to the Chair who will then review the qualifications and talk with the potential member. When the Chair has reached a decision, that potential member's name will be shared with RSS and the RSS Specialist will contact the individual to initiate training.

Membership is established in compliance with the existing regulations of the Department of Health and Human Services (45 CFR 46.107), the Food and Drug Administration, and the State.

Composition

Members are selected to assure continual diversity and experience on the IRB, and are to include both males and females of various backgrounds and professions to promote complete and adequate review of research activities commonly conducted by the institution. Members of the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in subjects considered to be in vulnerable categories, such as children, prisoners, pregnant women, or handicapped and/or mentally disabled persons. Also:

- The IRB shall include at least one member whose primary concern is in scientific areas and at least one member whose primary concern is in non-scientific areas.
- The IRB shall include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- The IRB may not have a member participate in the IRB's initial or continuing review of any project in which a member has a conflict of interest, except to provide information requested by the IRB.
- The IRB in its discretion may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- IRB members are assigned to serve as either primary or secondary reviewers for new protocols, continuing review, amendments/revisions, adverse event reports, and other administrative and ethical issues pertinent to human subject protections. All members are expected to read all protocols before a meeting, and to participate in meeting discussions.
- RSS staff assigns reviewers based on the member's knowledge and expertise, and is responsible for ensuring that at least one member attending the meeting has the necessary knowledge and expertise to review the protocol. When the agenda includes protocols that involve vulnerable populations, RSS staff is responsible for ensuring that at least one member attending the meeting has knowledge and experience in working with the study population.
- If an IRB member is unable to attend a meeting, he or she is to inform RSS staff.

Compensation

UIR IRB members serve as volunteers with their honorable service to the Rockford campus to ensure the protection of human subjects in research. They do not receive any monetary compensation, but are greatly appreciated and highly regarded for their generous donation of time, effort, and dedication.

3.5. Evaluation of Chair, IRB, and RSS

Policy

IRB members may be asked on a periodic basis to complete an anonymous survey/self assessment to provide feedback about how the committee functions and what can be done to improve the operations of the committee and RSS.

Procedures

IRB members may be asked on a periodic basis to complete an anonymous survey/self assessment that includes questions regarding evaluation of the IRB chair. Members will be questioned about leadership, time management at meetings, allowing members to express concerns, and representing the IRB's interest and concerns to investigators and the institution. In addition, the survey will contain questions regarding how the Committee functions, perceived areas for improvement and needs for additional training. This will also provide feedback to the Chair regarding committee operations and changes he or she may want to implement as he or she leads the committee. Results from this survey will be provided to the IO.

On an annual basis, the IO reviews the membership of the UIR IRB to determine if the membership includes individuals with varying backgrounds and the experience and expertise needed to review the scope of biomedical and social and behavioral research conducted at UIR. In addition, the IO will provide a written evaluation to all members, which includes the number of meetings they have attended during the year, whether their reviewer worksheets are completed and turned in, timeliness to review responses to reviews, and whether they contribute to the regulatory and ethical discussion of protocols at the meeting. Also, if there are specific concerns about any member, the IRB Chair will confidentially speak with the individual member.

Survey results will be aggregated and shared with the full committee so that any necessary discussions and improvements can be made. This information will also be shared with the Institutional Official.

3.6. Consultants, Observers, and Guests

Policy

UIR is committed to establishing an Institutional Review Board (IRB) that has the appropriate expertise to review biomedical and social and behavioral research protocols and to take into

consideration the medical, emotional, social, and psychological needs of the subjects that participate in research. As necessary, the UIR IRB may seek the services of consultants in order to provide appropriate review. These individuals may be either internal or external to the institution. A consultant may be selected to assist in the review of an individual protocol or may be asked to attend a meeting and provide education on an issue or topic of general interest to the committee. Consultants do not count as part of a quorum or vote. A consultant may not have any conflict as defined for IRB members and will be asked if they have any conflict prior to serving that role.

Procedures

Consultants

The determination that a consultant is required may be made under certain circumstances during the review process. Such circumstances are as follows:

- The IRB chair or RSS staff determines upon pre-review that a consultant is required, **or**
- Members of the IRB committee may request at any time during the review process to add a consultant to the review process.

This determination will be based upon the topic of the protocol and the expertise of the voting members.

- The consultant will be selected by the Chair. The Chair may consult with the principal investigator, Department Chair, or any other individual deemed appropriate to determine a suitable consultant. A consultant may:
  - Be an individual who is either internal or external to University of Illinois Rockford.
  - Be asked to review a protocol or provide education on a topic of specific concern to the IRB.
  - Be asked to provide information to the IRB committee by written report, attending a meeting(s), or both.
  - Participate in all discussions; however, he or she is not authorized to vote on the study.

Use of consultants will be documented in the protocol file and minutes.

- All individuals who are asked to serve as consultants will be:
  - Asked to sign a conflict of interest form to show that no conflict of interest exists prior to their work with the UIR IRB committee. If there is any conflict of interest, the individual will not be allowed to consult, and another consultant will be selected;
  - Advised that all discussions at the meeting are considered confidential; and
  - Asked for a written report which will be filed in the protocol.

Observers and Guests

Observers and guests may attend the IRB meetings at the discretion of the Chair. Guests and observers are individuals with a particular interest in the IRB and do not attend regularly. Neither guests nor observers count as part of the quorum. All observers and guests are advised that the deliberations of the IRB committee are confidential, and are not permitted to participate in discussion and voting.

3.7. Principal Investigator Responsibilities

Policy

Principal investigators (PI) at UIR must understand and accept their responsibilities.

Procedures

Ethical Standards

1. Research investigators are to acknowledge and accept their responsibility for protecting the rights and welfare of human subjects, and for complying with all applicable provisions of UIR assurance of compliance with the Office of Human Research Protections; with federal regulations; and with all UIR policies.
2. Research investigators are responsible for performing research with sufficient resources to ensure appropriate care, oversight, and safety of the research subjects during the course of research
3. Research investigators are to conduct research only with resources that are appropriate to ensuring research subject safety.
4. Research investigators who intend to use human subjects are required to obtain review and approval of the UIR IRB prior to initiation of the research.
5. Research investigators are responsible for ensuring that the research is conducted in accordance with UIR IRB approved protocols, and any conditions that are set in order to receive final approval.
6. Research investigators are responsible for having current training while conducting research.

Informed Consent

1. Research investigators are responsible for obtaining and documenting *informed consent* in accordance with the regulatory requirements unless otherwise authorized by the UIR IRB. Investigators are permitted to delegate to appropriate individuals the authority to obtain consent on their behalf; however, they are ultimately responsible.
2. Research investigators have an ethical responsibility to ensure that subjects and families understand, through the informed consent process, the nature of the research, the requirements of participation, the associated risk and benefits, and any alternative testing

or therapies (if applicable). Research investigators must take whatever steps are necessary to ensure this understanding and to facilitate implementation of valid informed consent process.

3. Research investigators are responsible for providing a signed copy of the UIR IRB approved informed consent to each subject at the time of consent, unless the UIR IRB has specifically waived the requirement. All informed consent documents are to be maintained in a manner approved by the UIR IRB.

Reporting

1. Research investigators are responsible for promptly reporting to the UIR IRB any proposed changes to previously approved human subject protocols. These changes are not to be initiated without UIR IRB review and approval, except when required to avoid apparent immediate harm to the subjects.
2. Research investigators are responsible for reporting the progress of the approved research to the UIR IRB, in the manner and frequency prescribed by the UIR IRB (based upon the risk to subjects), but not less than once per year.
3. Research investigators are responsible to promptly report to the UIR IRB any unanticipated and serious events, or other unanticipated problems, that involve risks to the subjects or others.
4. Research investigators are responsible for reporting to the UIR IRB all actions or processes that deviate from the protocol procedures approved by the UIR IRB.
5. Research investigators are responsible for submitting to the UIR IRB copies of all external monitoring reports; Data Safety, Monitoring Board reports and updates; and FDA annual reviews, if applicable.
6. Research investigators are responsible for reporting to the UIR IRB any non-compliance with regulations or UIR policies and procedures.

Protocol Documentation

1. Research investigators will maintain documentation of their protocols through the use of IRBNet which will contain at a minimum the following documents: approved UIR IRB approved protocol, approved informed consent form, approved recruitment materials; approved study materials (e.g., surveys, questionnaires); UIR IRB approval letters; UIR IRB Action Letters (Conditional Approvals, Deferrals); pertinent correspondence with the UIR IRB (and the sponsor, if applicable), submissions, responses, and pertinent correspondence.
2. Research investigators are responsible for the safe and secure storage of research data (in both paper and electronic formats) and protecting the confidentiality of the data.

Participant/Research Concerns

1. Research investigators are responsible for immediately addressing any concern or question raised by a research subject before, during, or after the conduct of a research study.
2. Research investigators are responsible for addressing any concerns raised by any member of their research team. This responsibility includes the following:
    - Investigators are to meet frequently with their research teams for the purpose of reviewing the progress of the research, and to encourage discussion of any concerns about the research in general, or about a specific research subject.
    - Investigators are to inform each member of the research team, individually, of his or her responsibility to voice any concerns he or she may have, without fear of repercussions.
    - Investigators must take seriously any concern raised. They are to fully investigate each expressed concern, and report back to the individual who raised it. No concern is to be dismissed.
    - Investigators may not punish an individual who brings a concern to their attention.
    - Investigators are responsible for reporting to the UIR IRB any expressed concerns that result in findings regarding subject safety, compliance with the research protocol, informed consent violations, or the integrity of the research data.