

BLESSING-RIEMAN COLLEGE OF NURSING
Institutional Review Board (IRB)
Policies and Procedures
Approved December 2011

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INTRODUCTION

The policies and procedures in this handbook were designed to protect research participants by safeguarding their treatment during research studies. Research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"(HHS, Code of Federal Regulations, Title 45, Part 46 Section 46.102, 2009). This definition includes data collection that occurs in conjunction with classroom projects unless the work is done as a learning exercise for the student and will never be published or presented.

This handbook was developed and adopted in accordance with federal regulations as mandated by the IRB's Registration with the Office of Human Research Protections (OHRP). In accordance with federal regulations, the policies and procedures described in this handbook apply to **all research involving human participants** conducted at or under the auspices of Blessing-Rieman College of Nursing (the College) whether or not the research is funded. Policies and procedures apply equally to faculty, staff, students, and other individuals seeking approval from the College's IRB.

The role of the College's IRB is to ethically review proposed research. The goals of this review are to a) protect human participants (and animals if applicable) by approving only those studies that meet all the requirements for the protection of human subjects and their rights and b) protect researchers by using an independent process that verifies their studies protect human participants.

Researchers must obtain IRB approval **before they implement their protocols**. Recruitment of participants and data collection begin only after notification of IRB approval.

There are three categories of review for research involving human participants. They are exempt, expedited, and full review. The Chair of the IRB determines which type of review applies to a research study. Who reviews the study and how long it takes for the review vary according to the type of review required. Therefore, the researcher's responsibility is to plan ahead and submit the proposed study in a timely manner that will meet the researcher's timelines.

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PART I: POLICIES

Purpose of the IRB

The IRB's purpose is to review and approve research to ensure the ethical treatment and protection of human research participants and/or their records. This review and approval is needed to secure research grants and to publish the results of research studies. Therefore, the IRB allows faculty, staff, students, and the community to carry out research and disseminate findings.

Mission and Scope of the IRB

The mission of the Blessing-Rieman College of Nursing Institutional Review Board (IRB) is to support research and scholarship that is beneficial to its constituents and the community by approving only those studies that demonstrate ethical treatment and protection of human and animal research participants and/or records.

The scope of the IRB is as follows:

- The IRB reviews research that fits the mission of the College and service to its constituents and the community.
- The priority is to review research within the College and its partner institutions (Culver-Stockton College and Quincy University).
- The second priority is to review research within Blessing Hospital.
- The third priority is to review research within the community.
- The IRB has the option to refuse the review of research that does not fit the expertise of its members or will review such research with consultation from experts in the area of research.
- The IRB does not review clinical trials and FDA-related research.
- The IRB works in collaboration with the Blessing Hospital Research Review Committee so studies involving the hospital fit its mission and resources.

Policy Statement

The IRB is responsible for implementing the policies and procedures outlined in the handbook when approving proposed research studies and when monitoring the conduct of studies. The IRB acknowledges and accepts its responsibilities for assuring that the privacy, safety, health, and welfare of research participants are adequately protected.

The researcher is responsible for following the policies and procedures outlined in the handbook when seeking approval for a proposed study and during the conduct of the study. The expectation is that the researcher assures that the privacy, safety, health, and welfare of the study's participants are adequately protected.

The IRB reports to the President/CEO and Academic Dean of the College. The College of Nursing Board approves the mission and scope of the IRB as well as the membership of the IRB. To meet the needs of

the College and community, the IRB is composed of faculty and staff from varied disciplines as well as community members.

Guiding Principles

The policies and procedures in this handbook are based on the following principles.

Maintaining Participant Autonomy

Participation of human beings in research must be voluntary. Voluntary participation must occur as a result of free choice, without compulsion or obligation, based on disclosure of relevant information in a clear, concise, and understandable way. It is the responsibility of investigators to insure that participants understand the principles described and language used in the explanation of research projects. The investigators must also take care to avoid coercing individuals to participate in the study or to remain in the study.

Adequate standards for informed consent must always be satisfied. The principle of informed consent is derived from the legal and ethical obligations of investigators to insure that prospective participants have sufficient understanding of the benefits and risks of their participation in the study to make an informed decision concerning participation.

Maintaining the Safety of Participants

A paramount responsibility of investigators is to protect participants from physical and emotional discomfort, harm, or danger. The potential for benefit to others does not necessarily justify placing the participants of the study at risk. A research procedure may not be used if it is likely to cause serious and lasting harm to participants (e.g., physical or mental health problems).

During the study, investigators must provide participants with clarification of the nature of the study and remove misconceptions that may arise.

If an investigation uses deception, investigators are required to explain to the participants (i.e., debrief) the reasons for this deception and to restore the quality of the relationship with participants at the earliest possible time in the research procedure.

Where research procedures result in undesirable consequences for participants, the investigators have the responsibility to detect and to remove or correct these consequences, including, where relevant, long-term after-effects.

Where scientific or humane values justify delaying or withholding information, the investigators have a responsibility to insure that there are no damaging consequences to participants.

Promoting Benefits to the Participants and the Larger Community

Wherever possible, research projects must be designed with the intent that the knowledge gained will benefit the participants and/or a larger community.

The benefits of the research must be made available to all participants in the study, regardless of their role in the research projects. For example, positive outcomes found for any treatment group must be made available to all participants at the completion of the study.

Conducting Research in a Fair and Equitable Manner

The research must be designed to treat all individuals fairly. The selection of participants must be based on fair procedures and not overburden, over-utilize, or unfairly favor or discriminate against any participant pool.

Honoring Commitments Made to Participants in a Study

The investigators must honor all commitments made to participants, contributors, or collaborators in a research project. Changes that are made in research design must be clearly presented to all individuals involved in the study. It is the responsibility of the investigators to insure that all parties clearly understand the commitments included in the agreement to participate in or to support the study.

Standards of confidentiality must be respected, particularly in research where this is guaranteed to participants. If there is a possibility that others may obtain access to any information about participants which has been gathered during the investigation, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to participants as part of the procedure for obtaining informed consent.

The principles contained here are generally consistent with the (1) the Nuremberg Code; (2) the Declaration of Helsinki; (3) the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research, "The Belmont Report," U.S. Public Health Service (see Appendix A); and (4) the Code of Federal Regulations (CFR), Title 45 (Public Welfare), Department of Health and Human Services, National Institutes of Health, and Office for Protection from Research Risks, Part 46 (Protection of Human Subjects), effective revision December 13, 2001 (see Appendix B). The CFR, Title 45, Part 46, Subpart A (46.101-46.124) provides federal policy for the protection of human participants in research; Subpart B (46.201-46.207) provides additional protections for pregnant women, human fetuses, and neonates involved in research; Subpart C (46.301-46.306) provides additional protections pertaining to biomedical and behavioral research involving prisoners as research participants; and Subpart D (46.401-46.409) provides protections for children involved as participants in research. These codes and reports are on file and available at Blessing-Rieman College of Nursing.

PART II: PROCEDURES

Code of Federal Regulations

The policies and procedures in this handbook comply with:

TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46
PROTECTION OF HUMAN SUBJECTS
Revised January 15, 2009
Effective July 14, 2009

The above regulations are available online at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Responsibility of the IRB with Reviewing Research Studies

The responsibility of the IRB is to independently review and continuously monitor research involving the use of human participants. Therefore, research conducted under the scope of the College's IRB is submitted to the IRB for review before recruitment of participants and collection of data. When reviewing studies, the IRB has the authority to approve, require modification, or disapprove proposed research activities in accordance with federal and state regulations as well as local institutional policy. IRB approval/disapproval as well as actions requiring modifications is based on determining the study's risks and potential benefits, ascertaining the appropriateness of the methods used to obtain consent, and determining that the rights and welfare of the individuals involved are protected.

Note: Research that has been reviewed and approved by an external IRB may be subject to review and approval or disapproval by officials of the College. However, those officials cannot approve research that was disapproved by the external IRB (Code of Federal Regulations, Title 45, Part 46, 46.112).

Responsibility of the Principal Investigator and Research Team

The principal investigator and the research team (including but not limited to research assistants, faculty advisors, and staff) are responsible for safely conducting the study's research protocol in accordance with the regulations set forth by the IRB. The principal investigator is also responsible for obtaining IRB approval before the study is implemented.

Note: Recruitment and selection of participants and data collection cannot begin until the study is approved by the IRB.

Protection of Human Participants Training

The principal investigator and all members of the research team are required to successfully complete training in the protection of human research participants. Proof of this training is the submission of a certificate indicating completion of training. Certificates are submitted with each and all applications for an IRB review.

The certificate is valid for three years and must be renewed every three years in order to receive approval for any new research or extensions for continuing research. The certificate is submitted to the IRB whether the application is for an exempt, expedited, or full review.

Training is online and a link to this training is available at <http://www.brcn.edu> on the library webpage under Links.

Definitions

Research

The following definitions are used to determine that an activity is research and therefore needs IRB approval before implementation. Although a researcher believes a study is exempt from IRB approval, the IRB, not the researcher, makes this determination based on the following definitions.

Research

Research is a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth objectives and a set of procedures designed to reach those objectives.

Exempt

Activities that are encountered in ordinary daily life may be determined by the IRB Chair to be exempt from further IRB review. However, when ordinary activities impose physical or psychological discomfort, harassment (beyond levels encountered in daily life), invasion of privacy, a threat to the participants' dignity, or other foreseeable risks, these activities will require an expedited or full review.

Classroom Projects Designed for Educational Purposes

All research involving human participants must be submitted to the IRB for review. Class projects for which the data gathered will be used strictly for educational purposes are not considered research and do not require IRB review or approval. However, the data gathered for class projects cannot be used in any research capacity such as fulfilling thesis and dissertation requirements and presenting and/or publishing the data as research findings. If there is any chance that the researchers may wish to use these data for research in the future, obtaining IRB approval is highly recommended.

Responsible Parties

The following definitions identify the parties that are responsible for research involving the College's IRB.

Principal Investigator

The principal investigator (PI) is the person who is primarily responsible for the research study, project, or activities. This responsibility includes obtaining IRB approval of the research.

The PI may be a student depending on the nature of the project. All research in which a student is the PI must be supervised by a faculty advisor.

Research Team

The research team is the group of individuals who have a significant role with recruiting and selecting participants, collecting data, analyzing data, and/or drawing conclusions from findings.

College Administrative Personnel

College administrative personnel are those persons at Blessing-Rieman College of Nursing who oversee the IRB and receive reports of research-related complications. The persons are the Academic Dean and President/CEO of the College.

Risk

The following definitions are used to determine risk and the type of review by the IRB.

Human Participants in Research

Human participants in research are living individuals about whom investigators obtain data through intervention or interaction with these individuals and/or obtain identifiable private information about these individuals.

Identifiable Private Information

Identifiable private information is any information that identifies research participants or allows investigators and/or others handling the information to ascertain the identity of research participants. Whether acquired via self-reporting, behavior, or observation, data are identifiable private information when they can lead to the identifies of research participants.

Risk

Human participants in research are considered to be at risk when exposed to the possibility of physical, psychological, or social harm as a direct consequence of involvement in research and its related activities. The determination of risk is a matter of sound professional judgment and the responsibility of the PI, research team, and IRB members.

Minimal Risk

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.

Greater than Minimal Risk

The research involves procedures that may induce potentially harmful or altered physical or psychological states or conditions. The most severe examples of placing participants at a greater than minimal risk include the experimental use of surgical and biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of unusual physical exertion; electric shock; intense sensory stimulation (e.g., light, sound); severe acceleration or deceleration; and subjection to deceit, public embarrassment, and/or humiliation. Greater than minimal risk also includes but is not limited to the possibility of embarrassment; loss of confidentiality; physical or psychological harm; physical or psychological discomfort; fatigue; loss of time; monetary costs (e.g., transportation, childcare, time loss from work); exposure to topics of a sensitive nature that cause discomfort or anxiety; harassment; invasion of privacy; and emotional distress resulting from fear of self-disclosure, introspection, fear of the unknown, interacting with strangers, fear of eventual repercussions, and irritation at the type of questions being asked.

Additional Protections against Risk for Vulnerable Populations

The Code of Federal Regulations, Title 45, Part 46, Subparts B, C, and D, delineates additional protections against risk afforded to special populations of research participants. These participants include pregnant women, human fetuses, and neonates (Subpart B); prisoners (Subpart C); and children (Subpart D).

Pregnant women, human fetuses, and neonates: Research is expected to be of direct benefit to participants. When there is no prospect of direct benefit, the risk must be minimal and the purpose of the research is to develop important biomedical knowledge that cannot be obtained by any other means.

Biomedical and behavioral research with prisoners: The selection of research participants must be fair to all prisoners and protect them from arbitrary intervention by prison authorities, parole boards, or other prisoners. The benefits of the research must not be of such a magnitude that they impair the ability of prisoners to weigh the risks of the research in the limited choice environment of the prison.

Children: The research is expected to be of direct benefit to participants. When there is no prospect of direct benefit and the research involves greater than minimal risk, the interventions or procedures must be commensurate with ordinary medical, psychological, social, or educational situations and likely to yield important generalizable knowledge to further the understanding, prevention, or alleviation of a problem affecting the health or welfare of children. Adequate provisions must be made to obtain permission of all children's parents or guardians. For children who are capable of providing assent (a child's affirmative agreement to

participate in research), adequate provisions must be made to obtain that assent. Mere failure to object is not, in the absence of affirmative agreement, to be construed as assent.

Protocol

Protocol is the description of the research to be conducted, providing details about protecting participants, risks inherent to the study, benefits from researching the topic, and methodology. Because this description is submitted to the IRB for review, it must provide sufficient detail to enable the IRB to determine level of risk and ascertain that adequate provisions have been made for the protection of the participants' rights and welfare.

Types of Review

There are three types of review. They are exempt, expedited, and full. The responsibility of the PI is to identify which review is being requested of the IRB. This request is made in a cover letter accompanying the IRB application and checking the appropriate box on the application form. Based on federal guidelines, the IRB Chair makes the final determination as to the type of review.

Exempt Review

An exempt review is requested for studies that:

- Involve no foreseeable risks to participants.
- Do not involve a sensitive subject.
- Do not involve minors unless conducted in educational settings involving normal curriculum/classroom activities.
- Involve normal curriculum/classroom activities conducted in educational settings.
- Use archival data, provided that the information is anonymously collected whereby no names or other identifying information will be collected or recorded.

Below is a description of federally approved exemptions.

- Research conducted in established or commonly accepted educational settings, involving normal educational practices such as research on regular and special education instructional strategies and the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. However, this research is not exempt when (a) information obtained is recorded in such a manner that human participants can be identified directly or through identifiers linked to the participants; (b) any disclosure of the participants' responses could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation; (c) participants are elected or appointed public officials or candidates for public office; or (d) federal statute requires 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 specimens. However, for this research to be exempt, these sources of data

are publicly available and the information is recorded by the investigators in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

- Research and demonstration projects that are conducted by or subject to the approval of a governmental department or agency and are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies. However, for these studies to be exempt, they must involve (a) consuming wholesome foods without additives; or (b) consuming a food that contains a food ingredient, an 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 U.S. Department of Agriculture.

Expedited Review

An expedited review is requested for studies that:

- Involve minimal risks to participants.
- Do not involve sensitive topics.
- Do not use minors except for the exception stated below.

Expedited studies include research using questionnaires, surveys, and interviews that are not anonymous (participants can be identified).

When an Expedited Review Cannot Be Used

An expedited review cannot be used when identification of participants and/or their responses would reasonably:

- Place them at risk of criminal or civil liability.
- Be damaging to their financial standing, employability, insurability, and/or reputation.
- Be stigmatizing.

However, an expedited review can be used when the study's protocol demonstrates that reasonable and appropriate protections will be implemented so the aforementioned risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

An expedited review cannot be used for classified research involving human subjects.

An expedited review does not apply to research activities that involve participants who are under guardianship or are institutionalized. This type of research requires a full review.

Exception for Minors

Federal regulations allow expedited reviews of studies involving minors. However, the policy of the Blessing-Rieman College of Nursing IRB is that only those studies involving minors whereby the loss of confidentiality is the primary risk will qualify for an expedited review.

Categories of Research Appropriate for Expedited Review

Federal guidelines identify the following categories that are appropriate for an expedited review.

- Clinical studies of drugs and medical devices when conditions for an expedited review are met. See federal guidelines for further details.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture when conditions for an expedited review are met. See federal guidelines for further details.
- Collection of biological specimens for research purposes by noninvasive means.
- Collection of data through noninvasive procedures that do not involve general anesthesia or sedation and are routinely employed in clinical practice. Procedures involving x-rays or microwaves are excluded. When medical devices are employed, they must be cleared/approved for marketing.
- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research 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 that includes but is not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
- Research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full Review

A full review is requested for studies that involve:

- More than just minimal risks to participants.
- A sensitive topic.
- Minors unless exempt under federal policies.

Criteria for Review of IRB Applications

The IRB reviews each application to determine that all of the following requirements are met in order to approve a research study. Therefore, it is important to the approval process that PIs submit complete, accurate, and detailed applications for IRB review of their studies.

Criteria for Approving Studies

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. The IRB considers only those risks and benefits that may result directly from participation in the research and not risks or benefits that would likely result although persons did not participate in the research.
- Selection of participants is equitable. When considering the selection of participants, the IRB will be particularly cognizant of the purpose and setting of research involving vulnerable populations.
- Informed consent will be sought from all prospective participants or the participants' legally authorized representatives.
- Informed consent will be appropriately documented as deemed appropriate by the IRB.

- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants as deemed appropriate by the IRB.
- Adequate safeguards are provided to protect the privacy of participants and to maintain the confidentiality of data as deemed appropriate by the IRB.

General Requirements for Obtaining Informed Consent

The IRB reviews each application to determine that all general requirements for obtaining informed consent are met in order to approve a research study. Therefore, it is important to the approval process that PIs submit complete, accurate, and detailed information about obtaining informed consent when submitting applications for IRB review of their studies. The informed consent form must accompany the application for IRB review as a separate document or part of the research proposal that accompanies the IRB review application.

The IRB has the authority to ask PIs to modify the informed consent form and/or the process for obtaining informed consent to assure the protection of the rights and welfare of participants. The IRB also has the authority to have a third party observe the informed consent process, and the research if necessary, in order to assure the protection of the rights and welfare of participants.

Definition of Informed Consent

Informed consent is the process of providing sufficient information to potential research participants about the research activities. The purpose of informed consent is to assure that potential participants freely choose to participate or not participate without undue inducement or any element of fraud, deceit, duress, or coercion. Informed consent includes knowledge, voluntariness, and capacity.

Knowledge

Participants are informed of the tasks, risks, and benefits of participating in the research.

Voluntariness

Participants understand that they have freely chosen without coercion to participate in the study. They also understand that they can voluntarily leave the study at any time without any repercussions.

Capacity

Participants have the legal authority to give permission.

Basic Elements of Informed Consent

The following information must be provided to all participants when seeking informed consent.

- A statement that the study involves research.
- An explanation of the purposes of the research.
- The expected duration of the participation.
- A description of the procedures and identification of any procedures that are experimental.
- A description of all reasonably foreseeable risks or discomforts to participants.
- A description of all reasonably foreseeable benefits to participants or others.

- A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to participants.
- A statement indicating that confidentiality of records identifying participants will be protected to the extent allowed by law.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefit to which participants are otherwise entitled, and participants may discontinue participation at any time without penalty or loss of benefit to which participants are otherwise entitled.
- An explanation of whom to contact for answers to pertinent questions about the research, research participants' rights, and research-related injury.
- For research involving more than minimal risk, an explanation as to whether compensation or medical treatment is available, if physical injury occurs. The BRCN IRB requires the following statements to be included as part of the informed consent process.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, BRCN does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research. You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study, you should ask the researchers; their phone numbers are at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the IRB Chair at Blessing-Rieman College of Nursing at 217-228-5520 or via e-mail at irb@brcn.edu.

Any of the following additional elements of informed consent may be required by the IRB when appropriate.

- A statement that the treatment or procedure to be used may involve risks that are currently unforeseeable.
- Anticipated circumstances under which the participants' involvement in the research may be terminated by investigators without the participants' consent.
- Any additional costs to the participants that may result from their involvement in the research.
- The consequences of the participants' decision to withdraw from the research and procedures for orderly termination of participation.
- A statement that significant new findings developed during the course of the research, which may relate to participants' willingness to continue involvement in the research, will be provided to the participants.
- The approximate number of participants involved in the study.
- Contact information for primary investigator and the IRB chairperson. If the project is a student project, contact information for the faculty of record must be included.

Obtaining Informed Consent

The informed consent of participants must be obtained by methods that are adequate and appropriate. Informed consent, whether written or oral, must not include any exculpatory language through which participants are made to waive or to appear to waive any of their legal rights, including any release of the investigators, the College or its agents, or the sponsors from liability for negligence. The informed

consent information must be provided to participants in language understandable to the participants. Understandable language is clear and unambiguous, including an appropriate reading level for participants and appropriate explanations for all technical terms.

Documentation of Informed Consent

Informed consent must be documented by the use of a written consent form that contains all of the required basic elements of informed consent, has been approved by the IRB, and has been signed by the participants or the participants' legally authorized representatives. A copy of the informed consent form must be provided to all participants. A copy of the informed consent document must be on file with the IRB.

Maintaining Informed Consent Documents

PIs using human participants whereby a signed informed consent is required must keep all consents forms in a secured location. The consents must be kept for five (5) years after completion of the research project

Waiver of Requirement for Informed Consent

The IRB may waive the requirement for investigators to obtain signed, written informed consent from participants. The waiver is based on:

1. The only record linking participants to the research would be the consent document and the primary risk would be potential harm resulting from a breach of confidentiality.
2. The research presents no foreseeable risk of harm to participants and involves no procedures for which written consent is normally required outside of a research context.

Evaluation of Risk

The IRB reviews each application to evaluate risk in order to approve a research study. Therefore, it is important to the approval process that PIs submit complete, accurate, and detailed information about risk and benefits when submitting applications for IRB review of their studies.

Individuals at Risks

Individuals are considered to be at risk if they may be exposed to the possibility of harm be it physical, psychological, or social. Risk includes but is not limited to the possibility of embarrassment, loss of confidentiality, physical or psychological harm, physical or psychological discomfort, fatigue, loss of time, and monetary costs (e.g., transportation, childcare, time lost from work). The most severe examples of placing participants at risk include the experimental use of the following procedures: surgical and biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of unusual physical exertion; electric shock; intense sensory stimulation (e.g., light, sound); severe acceleration or deceleration; subjection to deceit, public embarrassment, and/or humiliation. Also considered as risks are topics of a sensitive nature; discomfort; anxiety; harassment; invasion of privacy; or emotional distress resulting from fear of self-disclosure,

introspection, fear of the unknown, interacting with strangers, fear of eventual repercussions, and irritation at the type of questions being asked.

Minimizing Risk

The IRB must be assured that the following actions will be taken to minimize risk, especially when an activity will expose individuals to risk.

- The rights and welfare of the individuals participating in the research are adequately protected.
- Methods used to obtain informed consent are adequate and appropriate.
- Risks to individuals are outweighed by the potential benefits to individuals or society or by the importance of the knowledge to be gained.
- The study's personnel are qualified to conduct the study, including any specialized procedures or testing.

Cases of Great Risk

In cases of great risk, the IRB may call qualified consultants from the faculty or other sources. This consultation is considered particularly appropriate when participants will be recruited from vulnerable populations such as prisoners, children, pregnant women, handicapped, or mentally disabled persons. In such instances, the investigators and the IRB will meet jointly with the consultants for an assessment of the risks and potential benefits of the proposed research. When the IRB believes that a legal opinion is needed, the IRB Chair will contact the College's attorney.

Cases of Deception

PIs are required to fully inform participants about the research and answer all participants' questions. However in some research, it is not possible to fully inform participants of procedures without destroying the validity of the research. In other words, if research participants have knowledge as to the purpose of the study and/or its outcomes, the research will be dramatically altered. Therefore, deception is used whereby participants are not fully informed in advance as to the intent of and/or procedures used in the research. When a study proposes to mislead participants or use deception during data collection, the IRB has the responsibility of assuring that the rights and welfare of participants will not be violated.

Debriefing

A debriefing of participants immediately following the completion of data collection is required when participants are misled or deceived during data collection. Debriefing may be delayed for a reasonable amount of time when debriefing information could adversely affect subsequent data collection in the same study. However, if delaying debriefing could reasonably result in emotional distress to participants, participants must receive a full debriefing immediately following participation and referrals for professional consultation (e.g., psychological, medical) must be provided when appropriate.

Debriefing, whether immediate or delayed, must include detailed descriptions of the deception, the purpose of the deception, and the actual purpose of the research. With research involving minor

children or mentally disabled participants, the explanation or debriefing must be provided to the parents or guardians as well as to the participants.

Research Using Health-related Data

The IRB must be assured that proposed research involving health-related data complies with the privacy standards for protected health information as established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA regulations and guidelines for the transmission and security of health-related information pertain to researchers who solicit access to all forms of health-related data. Therefore, protocols using health-related data must provide written notice of privacy practices as part of the informed consent process, identify who has access to the data for what purposes, explain the storage of data, and describe the destruction processes at end of the study for data that could possibly identify a person.

Civil and criminal penalties for noncompliance include fines ranging from \$25,000 to \$250,000 and imprisonment for a maximum time of ten years. Researchers are expected to know the HIPAA guidelines as they pertain to their research and to fully comply with all required privacy standards.

Forms

IRB forms are online at the College's website on the library web page. The URL for the College is <http://www.brcn.edu>. To access forms, click the Blessing Health Professions Library button on the left navigation panel of the college's home page, click Links on the library page's tab bar, and click the Institutional Review Board (IRB) link.

Procedures for Review of a Proposal

Submission of Application

The application for IRB review of a study is online. See the section on Forms for accessing the application.

The PI submits the completed application to the Chair of the IRB as an attachment to an email addressed to irb@brcn.edu. Accompanying the application are a cover letter, a proposal of the study to be reviewed, and certificates documenting the completion of training in the protection of human research participants

Applications must be signed by their PIs, indicating they read the application and approved its content as well as the proposed research. Applications submitted by a student PI require the signature of the faculty advisor, indicating the advisor also approved the application and the research.

Applications submitted with excessive grammatical errors, unclear writing, or without needed information will be returned without review.

Length of Time for Review

The amount of time that it takes for the IRB to review an application depends on the type of review.

- Exempt: One IRB member (usually the Chair) reviews the application and the PI can expect a response from the IRB within two weeks of submitting an application for IRB review.
- Expedited: Three IRB members review the application and the PI can expect a response from the IRB within three weeks of submitting an application for IRB review.
- Full review: The entire IRB reviews the application at its monthly meeting. See Scheduling of Full Reviews.

Reviews will be completed within the time period specified by a sponsor. For example, reviews of studies involving the National Institutes of Health will be completed within 30 days of the IRB receiving the application for review. In order to meet a sponsor's time frame, the PI must inform the IRB that there is a deadline for submitting an approved proposal.

Scheduling of Full Reviews

Full reviews are done at regularly scheduled IRB meetings at which the majority of members are present and at least one of these members represents a nonscientific discipline. A study is approved when the majority of those present approve the study.

Applications for full review must be received two weeks prior to the scheduled IRB meeting so the study is on the agenda. The PI may be asked to attend the IRB meeting to clarify research procedures or to answer questions regarding the application.

The PI can expect a response from the IRB within two weeks after the meeting in which the application was reviewed.

Notification

The Chair of the IRB notifies the PI of the IRB's decision about the reviewed application. Notification is in writing and will be sent as an email attachment.

Letter of Certification

A letter of certification is the official notification that the IRB has approved the research study, project, or activities. The letter is sent to the principal investigator to notify this person that the research was approved and is sent to any entity requesting proof that the research was approved by the IRB.

Basis of IRB Reviews

The IRB reviews studies to assure that:

- The rights and welfare of the individual participants are adequately protected.
- The methods used to obtain informed consent are adequate and appropriate.
- The risks to individual participants are outweighed by the potential benefits to individuals or society, or by the importance of the knowledge to be gained by the study.

- The study's PI and research team are qualified to conduct the study, including any specialized procedures or testing.

Possible IRB Actions

The IRB may take one of four actions after reviewing a proposed study. The actions are approval, conditional approval, deferred decision, and disapproval.

Approval

The IRB approved the study as proposed, granting permission to proceed with the study. The expectation is that the PI and research team implement the study as described in the application for IRB review.

Conditional Approval

The IRB will approve the study once requested changes are made to its protocols. When changes are requested by the IRB, the PI must submit documentation of making the revisions. The documentation will be reviewed by either the full IRB, an ad hoc committee of the IRB (Chair and two other IRB members), or the Chair as determined by the IRB.

Deferred Decision

Additional information is needed before the IRB can make a decision about approving the study. Decisions to defer approval occur when the IRB has concerns about how the study is or is not protecting the rights and welfare of its research participants. To help the IRB make a decision, the PI is asked to attend an IRB meeting in order to provide IRB members with the necessary information to make a fully informed decision about approving the study's protocols.

Disapproval

The IRB did not approve the study because the IRB determined that its protocols did not adequately protect the research participants' rights and welfare.

Full Review Disapproval

A study under full review is not approved when the majority of those present disapprove the study.

Expedited Review Disapproval

When one of the three IRB members participating in an expedited review disapproves of the study, the study is forward to the full IRB for consideration. The study may be approved or disapproved by the full IRB. The study is disapproved when the majority of those present at the IRB meeting did not approve the study.

The IRB's written notification of the disapproval will include the reasons for the decision and give the PI/research team an opportunity to respond to the decision.

The PI may appeal the IRB's decision to disapprove a study. In order to appeal, the PI must submit a brief summary outlining the reasons for the appeal and attend the IRB meeting at which the full membership will review the appeal.

The IRB will make every effort to resolve their concerns with the PI when a study is disapproved. After resolving the issues, the PI must re-submit a proposal that incorporates all the changes required for approval by the IRB.

Handing of Submitted Materials

IRB Responsibilities

All materials submitted to the IRB are retained at Blessing-Rieman College of Nursing for a period of at least five (5) years after the most recent approval or disapproval date. Documentation may be retained longer than five years when required by terms and conditions of grants or contracts.

The IRB Chair is responsible for communicating with PIs, distributing materials to IRB members for review, and overseeing the storage of submitted materials and correspondences with PIs.

PI Responsibilities

Researchers using human participants in studies that require signed informed consent must keep all consent forms in a secured location. The consents must be kept for five (5) years after completion of the study. Researchers are also responsible for safeguarding data and participants' personal identifiable information.

When a proposal is submitted for external or internal funding, the PI is responsible for furnishing evidence to the sponsor that the project was approved by the IRB.

Suspension or Termination of Approval

The IRB has the authority to suspend or terminate its approval of research that is:

- Not conducted in accordance with the IRB's requirements.
- Associated with unexpected serious harm to participants.
- Delinquent in the submission of materials required by the IRB for purposes of granting extensions.

PIs will be notified in writing of the suspension or termination. The College's administrative personnel will also be notified and the Secretary of the Department of Health and Human Services will be notified in the case of a federal grant or grant application. Notification will include the reasons for the suspension or termination.

PIs/research teams cannot collect data, in any form, when their studies have been suspended or terminated. Any data collected during the suspension or after termination must be discarded and not used in any research capacity.

Procedures for Interim Reports, Extension of Timeline, Change in Protocol, Completion of a Study, Reporting Adverse Effects, Reporting Deviations from Protocol

Exempt Studies

Studies that were approved by an exempt review by definition are exempt from further IRB review and oversight. However, changes in protocol must be approved by the IRB before they are implemented and adverse effects as well as deviations from protocol are to be reported. PIs are expected to inform the IRB when their studies are done.

Interim Reports

The IRB may ask the PI to submit a progress report when the study poses more than minimal risk and/or is longitudinal in nature. The purpose of this report is to assure that the rights and welfare of the study's participants continue to be protected. The PI is expected to submit reports according to the timetable established by the IRB.

Extension of Timeline

The IRB approves a study for a period of 12 months unless the study is longitudinal in nature. Therefore, recruitment and selection of the sample, activities asked of participants, and data collection and initial analysis must be completed within the 12 months. When the study is longitudinal in nature, the protocol must be completed within the time frame specified by the study.

PIs are responsible for monitoring the timelines for their studies. When a study is anticipated to go beyond the IRB approval period, a request for an extension must be submitted to the IRB one month before the expiration date. The request form is online. (See the section on Forms for accessing the form.) The completed form is emailed to the Chair of the IRB at irb@brcn.edu.

The Chair of the IRB will send reminders to PIs about the expiration date of their studies. PIs are expected to respond, indicating whether or not they will need an extension for their studies.

Extensions for studies approved by an expedited review can be granted by the Chair of the IRB. Extensions for studies approved by a full review must be granted by the IRB at a regularly scheduled meeting.

Change in Protocol

PIs must obtain IRB approval for any proposed changes to approved protocols. This approval must be done before any changes are implemented. However, changes that are necessary to eliminate immediate hazards can be implemented without prior IRB approval. The request form for this approval is online. (See the section on Forms for accessing the form.) The completed form is emailed to the Chair of the IRB at irb@brcn.edu.

The Chair of the IRB determines the type of review for the proposed changes to protocols. Changes can be approved by the IRB Chair when changes are considered minor. Changes are considered minor when they do not increase the risks to participants. Any change to a study that increases the risks to participants must be approved as a full review. As with any full review of a study, changes in protocol needing a full review are done during a regularly scheduled meeting of the IRB.

The IRB must also be informed of changes with principle investigators and/or the research team.

Completion of a Study

PIs are required to inform the IRB that their research projects have been completed. A study is done when there is no further contact or interaction with participants. Quantitative studies are usually done when the last data are collected. Qualitative studies are done after initial analysis and member checking of findings by participants.

The completion form is online. (See the section on Forms for accessing the form.) The completed form is emailed to the Chair of the IRB at irb@brcn.edu.

Reporting Adverse Effects

PIs are required to inform the IRB of adverse events by telephone within 24 hours after the event occurred or is discovered. The telephone number is 217-228-5520, extension 6968. In addition, the PI must file a report within 72 hours. The report form is online. (See the section on Forms for accessing the form.) The completed form is emailed to the Chair of the IRB at irb@brcn.edu.

The Chair of the IRB reports all adverse effects to the IRB membership as well as the College's administrative personnel. Action taken by the IRB and/or the College's administrative personnel depends on the circumstances of the adverse effect.

Deviations from Protocol

PIs are required to report any deviations from the approved protocol. This reporting may also be done by anyone who is aware of the deviation. The report form is online. (See the section on Forms for accessing the form.) The completed form is emailed to the Chair of the IRB at irb@brcn.edu.

The Chair of the IRB reports all deviations from protocol to the IRB membership. Action taken by the IRB depends on the circumstances of the deviation from the approved protocol.

Research Involving Other IRBs

Researchers Affiliated with the College

Individuals affiliated with the College may conduct research at another institution. Before conducting this research, they need to determine whether or not approval from this institution's IRB is needed. In the event approval is obtained from this institution's IRB and all participants in the study are located at

this institution, the Blessing-Rieman College of Nursing IRB will accept this institution's IRB approval. Because the PI/research team is affiliated with the College, an application for IRB approval must be submitted to the Blessing-Rieman College of Nursing IRB. The study will be classified as exempt in light of the other institution's IRB approval.

The application process for this exempt review involves submitting:

- A memo requesting that the Blessing-Rieman College of Nursing IRB accepts the IRB approval from the other institution.
- Verification that all participants will be located at the site where the original IRB approval was obtained.
- A copy of the approval letter from the other institution's IRB.
- A copy of all materials that were submitted to and approved by the other institution's IRB. Please note that the Blessing-Rieman College of Nursing IRB may require more information than that required by the other institution's IRB.

Non-college Affiliated Researchers

Researchers not affiliated with Blessing-Rieman College of Nursing may conduct research at the College provided their studies are approved by another institution's IRB. However, recruitment of BRCN faculty, staff, and/or students may require permission from the President/CEO, Deans and/or class instructors. Individuals granting permission should ask for validation that the research was approved by an institution's IRB.

Operations of the IRB

Policy Development

The development and implementation of policies and procedures related to research that falls within the scope of the IRB is the responsibility of the Blessing-Rieman College of Nursing Institutional Review Board.

Membership

Membership consists of a minimum of five (5) members who have the experience, expertise, and diversity to promote complete and adequate reviews of research activities commonly conducted by researchers who fall under the scope of the Blessing-Rieman College of Nursing IRB.

Membership Composition

The composition of the membership is to include:

- Male and female members.
- Members representing more than one profession.
- At least one member who is not affiliated with the College and who is not part of the immediate family of a person who is affiliated with the College.
- At least one member whose primary concerns are in scientific areas.
- At least one member whose primary concerns are in nonscientific areas.

Conflict of Interest

The IRB will not permit a member to participate in the initial or continuing review of any project in which that member has a conflicting interest, except to provide information as requested by the IRB.

Use of Consultant Reviewers

The IRB has the discretion to invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals do not have voting privileges.

New Members

The College of Nursing Board approves new members based on recommendations from the IRB.

The Chair of the IRB with consultation of IRB members, the Academic Dean, and President/CEO of the College solicits new members to fill vacant positions on the IRB. Consideration is given to individuals whose qualifications are needed to fill any gaps in expertise among the membership and/or maintain the federally mandated composition of the membership.

Diversity of Membership

Diversity will be considered when soliciting a new member. Diversity includes experience, expertise, race, gender, cultural background, and sensitivity to community attitudes.

The purpose of maintaining a diverse membership is to promote respect for the recommendations of fellow members when safeguarding the rights and welfare of human participants.

Membership Qualifications

The following qualifications will be considered when soliciting a new member:

- Professional competence necessary to review specific research activities.
- Ability to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice.
- Knowledge in working with vulnerable populations such as children, prisoners, pregnant women, handicapped, or mentally disabled persons.

Membership Terms

New members serve for a three-year term. After serving three years, a member's term is annually re-approved by the College of Nursing Board. A member can serve without limits as long as the member continues to possess the qualifications necessary to review studies and fulfills the responsibilities of membership.

IRB members will be notified of their College of Nursing Board approval or re-approval to serve.

Membership Duties

Membership duties include but are not limited to regular attendance at convened meetings of the IRB, timely review of assigned IRB applications, and maintaining updated vitae/resumes and training certificates.

Members may be removed for lack of participation in IRB activities, unwillingness to review studies, or due to incapacity to adequately serve on the IRB. Removal of members is approved by the College of Nursing Board with recommendations from the IRB membership.

Maintaining List of Members

The Chair of the IRB is responsible for maintaining a list of IRB members. The list is to include the following information about each member: name, earned degree, representative capacity, indications of experience such as board certifications and licenses, employment, and relationship with the College.

The list is submitted to the College of Nursing Board in June and the Board uses the list to approve the membership of the IRB.

The list is also submitted to the Office for Protection from Research Risks (National Institutes of Health - Department of Health and Human Services).

Changes in IRB membership are forward to the College of Nursing Board for approval and updated at the above agency.

Leadership

The duties of the IRB chair are to preside over meetings of the IRB, review exempt studies, coordinate expedited and full reviews, correspond with PIs on behalf of the IRB, oversee storage of IRB materials, maintain the list of members, and report to the College's administrative personnel about IRB activities.

Qualifications

The IRB chair:

- Is someone knowledgeable in both research and regulations relevant to the protection of human participants in research.
- Has served at least 24 months as a member of the IRB.

Term of Office

The President/CEO with input from the IRB membership appoints a member to be Chair. The appointment is approved by the College of Nursing Board.

The Chair is appointed for an initial three-year term with the option for reappointment for a second two-year term.

A term begins with the start of the fall semester of an academic year.

Guidelines

IRB members are expected to follow the policies and procedures in this handbook as well as the requirements for the Protection of Human Participants in Research as specified in the Code of Federal Regulations, Title 45 (Public Welfare), Part 46 (Protection of Human Subjects).

Meetings

The IRB meets monthly as necessary to provide initial and continuing reviews of research and to take action when adverse events or a deviation from protocol are reported. At meetings or by email when a meeting is not held, the IRB Chair will provide a monthly activity report on the status of ongoing research and the approval of exempt and expedited studies.

Quorum

A quorum whereby a majority of the members are present is needed for a full review of proposed studies, to take action with adverse effects/deviations from protocol, and approve business items needing action. A quorum is 2/3 of the membership. When conducting a full review, at least one of the members must represent a nonscientific discipline.

Conference Call

Conference calling may be used to conduct a monthly meeting or allow a member to participate in a monthly meeting.

IRB Records

The IRB is responsible for maintaining documentation of its activities that includes:

- Copies of all research proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved informed consent documents; progress reports submitted by investigators; and reports of adverse events experienced by participants.
- Minutes of all IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; votes on these actions, including the number of members voting for, against, and abstaining; the basis for changes in or disapproval of research; and a written summary of the discussion of controversial issues and resolutions.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and PIs.
- List of IRB members and copies of their vitas.
- Written procedures for the IRB.
- Statements of significant new findings provided to participants.

IRB records are retained for at least five (5) years after the most recent approval of protocols and these records are accessible for inspection and copying by authorized representatives of the Department of Health and Human Services.

Special Considerations for Research Involving Vulnerable and other Populations

Children (Minors under the age of 18)

The Code of Federal Regulations provides that educational and social research with children as participants may be considered Exempt and not require signed informed consent (see Section C.3.a of this document). Expedited and Full Review research studies involving children will require signed informed consent from parents or legal guardians (see Sections C.5.a, b, and c of this document).

The IRB must make adequate provisions for soliciting the **assent** of children, when in the best judgment of the IRB the children are capable of providing assent. Assent refers to an affirmative agreement by children (who cannot give legal consent) to participate in research. A mere failure to object, absent affirmative agreement, must not be construed as assent. In determining whether children are capable of assenting, the IRB will take into account the ages, levels of maturity, and psychological states of the children involved. The IRB may require assent of some or all of the children participating in research projects. If the IRB determines that some or all of the children in research studies cannot reasonably be expected to have the capacity to assent or the interventions or procedures involved in the research hold out the prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, then the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may ordinarily be waived (see Section C.5 in this document).

Prisoners

As prisoners may be under constraints due to their incarceration, which could impact their ability to make truly voluntary and uncoerced decisions whether or not to participate as participants in research, the IRB is obligated to provide additional safeguards for the protection of prisoners involved in research activities.

The Code of Federal Regulations mandates that the majority of IRB members have no association with the prisons involved in research (apart from IRB membership) and that at least one member of the IRB must be a prisoner or have the appropriate background to serve as a prisoner representative.

The selection of research participants must be fair to all prisoners and immune from arbitrary intervention by prison authorities, parole boards, or other prisoners. The risks involved in this research must be commensurate with risks that would be accepted by nonprisoner volunteers. The benefits of the research must not be of such a magnitude that they impair the ability of prisoners to weigh the risks of the research given the limited choice environment of the prison. Adequate assurance must be provided to the IRB that parole boards will not consider prisoners' decisions about participation in research in making decisions regarding parole. All prisoners must be clearly informed, in advance, that participation in the research will have no effect on their parole. Where the IRB finds a need for any sort of follow-up procedures following participation, adequate provisions for prisoners must be made, taking into account varying lengths of prisoners' sentences, in order to inform prisoner participants of the follow-up.

Biomedical and behavioral research involving prisoners as research participants may be conducted only if (a) the above requirements have been met; and (b) the proposed research involves solely the following purposes:

- 1) Possible causes, effects, and processes of criminal behavior or incarceration, with no more than minimal risk and inconvenience to participants;
- 2) Prisons, as institutional structures, or prisoners, as incarcerated persons, with no more than minimal risk and inconvenience to participants;

- 3) Conditions particularly impacting prisoners as a group, in that certain conditions are more prevalent in prisons than elsewhere (e.g., hepatitis, alcohol/drug addiction, sexual assaults), following consultation with appropriate experts and published notice in the Federal Register;
- 4) Practices with the intent and reasonable probability of improving the health or wellbeing of participants. Where prisoners are to be assigned to control groups in which they may not benefit from the research, consultation with appropriate experts and published notice in the Federal Register are required.

Except as provided above, biomedical or behavioral research will not involve prisoners as research participants.

Pregnant Women, Fetuses, and Neonates

Research involving pregnant women, human fetuses, and neonates (i.e., newborns) is expected to present a reasonable opportunity to further the understanding, prevention, or alleviation of serious problems impacting the health or welfare of these populations. Research involving pregnant women, fetuses, and neonates is generally expected to hold out the prospect of direct benefit. If no such prospect of direct benefit is available, then the risk must be minimal and the purpose of the research must be the development of important biomedical and behavioral knowledge, which cannot be obtained by any other means. For pregnant women and fetuses, any risks associated with the research will be the least possible for achieving the objectives of the research. For neonates, no risks may be added as a result of the research. Researchers will not: (1) offer any form of inducement to terminate a pregnancy; (2) determine the timing, method, or procedure used to terminate a pregnancy; or (3) determine the viability of a neonate. Researchers conducting studies with these populations must follow sound ethical principles and follow all appropriate provisions regarding informed consent.

Non-English Speaking

Department of Health and Human Services regulations for the protection of human participants require that informed consent information be presented "in language understandable to the subject". Thus participants who do not speak English should be presented with consent documents and other research related documents (such as questionnaires or cover letters) written in a language understandable to them. In addition any verbal explanation of the consent or research procedures should be presented in a language understandable to the participant. The IRB must receive all foreign language versions of the written documents as a condition of approval.

The IRB must also be fully informed as to the ability of the person performing the translations. By signing and submitting the IRB application the PI assures the IRB that any translated documents are accurate representations of the corresponding English documents. The IRB, at their discretion, may request additional information regarding translated documents. Translators involved only in translation of written documents are not required to fulfill the training requirement.