Blessing-Rieman College of Nursing and Health Sciences
Institutional Review Board (IRB)
Handbook
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Table of Contents

General Information

Purpose of the Handbook

The purpose of the *Handbook* is to communicate the IRB's policies and procedures for approving and monitoring research. These policies and procedures are in accordance with federal regulations governing IRBs registered with the Office of Human Research Protections (OHRP).

The following federal regulations guide the content of the *Handbook*.

TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46
PROTECTION OF HUMAN SUBJECTS
Revised January 15, 2009
Effective July 14, 2009
Revised January 19, 2017
Effective January 23, 2019

Responsibility of the Researcher

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 the researcher assures there is adequate protection of the privacy, safety, health, and welfare of the study's participants.

Purpose of the IRB

The purpose of the IRB is to protect the rights and welfare of human subjects (and animals if applicable) involved in research activities conducted under its authority. The IRB carries out its purpose by approving only those studies that meet all the requirements for the protection of human subjects and their rights and using an independent process that verifies studies protect human participants.

Prior Approval Needed to Implement Research

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

Mission and Scope of the IRB

The mission of the Blessing-Rieman College of Nursing and Health Sciences 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.

The IRB also serves as the Privacy Board for Blessing Corporate Services, reviewing all requests for health-rated patient data from any entity of Blessing Health Systems.

Guiding Principles

The following principles are the foundation for the *Handbook's* policies and procedures. Expectations are researchers incorporate these principles into their protocols, treatment of participants, recruitment of participants, and informed consent. The IRB approves only those research studies and projects that incorporate these principles.

Maintaining Participant Autonomy

Participation in research must be voluntary. Voluntary participation is the result of free choice without compulsion or obligation and based on disclosure of relevant information in a clear, concise, and understandable way. The researcher's responsibility is to ensure individuals understand their role in the study and the benefits and risks of participating in the study before giving consent to participate in the study. Researchers must also take care to avoid coercing individuals to participate in the study or to remain in the study.

Maintaining the Safety of Participants

A paramount responsibility of researchers is to protect participants from physical and emotional discomfort, harm, or danger. The potential for benefit to others does not justify placing participants at risk. Researchers cannot use procedures that are likely to cause serious and lasting harm to participants (e.g., physical or mental health problems).

Researchers must provide participants with clarification of the nature of the study and remove misconceptions that may arise during the study.

When deception is used, researchers are required to explain to participants (i.e., debrief) the reasons for the deception and to restore the quality of the relationship with participants at the earliest possible time in the research procedure.

When research procedures result in undesirable consequences for participants, researchers must correct these consequences, including any long-term after-effects.

When the research methodology justifies delaying or withholding information, researchers are responsible for ensuring there are no damaging consequences to participants.

Promoting Benefits to the Participants and the Larger Community

A study's research design must result in knowledge that benefits participants and/or a larger community. These benefits must be made available to all participants in the study, regardless of their role in the research. 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

A study's research design must fairly treat all individuals. 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

Researchers must honor all commitments made to participants, contributors, or collaborators in a research study. The researcher must ensure all parties clearly understand the commitments included in the agreement to participate in or to support the study. Changes in the research design must be clearly presented to all individuals involved in the study

Standards of confidentiality must be respected. When there is the possibility that others may have access to information gathered about participants during the study, ethical research practice requires that this possibility and the plans to protect confidentiality are explained to participants as part of the procedure for obtaining informed consent.

Definitions and the Responsibilities of the IRB

The following definitions, from Title 45, Part 46, determine the responsibilities of the IRB with approving a research study or project.

Research

Definition: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

IRB Responsibility: Activities that fit this definition are research and the IRB must approve.

Quality improvement (QI)

Definition: A set of activities designed to improve the quality of care provided by a healthcare facility. QI activities involve collecting and analyzing aggregate data and trends to determine changes in outcomes due to specific actions taken by a specific organization.

IRB Responsibility: The IRB does not approve activities that fit this definition. QI becomes research when interventions and/or interactions involve direct contact with individuals in order to systematically test or evaluate the effectiveness of a specific intervention or interaction. The IRB must approve this type of activity.

Human Subject (Participant)

Definition: A living individual about whom an investigator: a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

IRB Responsibility: The IRB must approve research activities when they involve living individuals, their biospecimens, and/or records.

Intervention

Definition: Activities that include physical procedures, manipulations of participants, and/or their environment by which data are gathered for research purposes.

IRB Responsibility: The IRB must approve research studies and projects that involve activities fitting this definition.

Interaction

Definition: Activities that include communication or interpersonal contact between investigator and subject.

IRB Responsibility: The IRB must approve research studies and projects that involve activities fitting this definition.

Principal Investigator (PI)

Definition: The person responsible for the research study, project, or activities. This responsibility includes obtaining IRB approval of the research.

IRB Responsibility: The IRB communicates with the PI when reviewing and approving research.

Research Team

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

IRB Responsibility: The PI identifies these Individuals as the research team on the IRB Application and the IRB reviews the roles of these individuals as part of the review and approval process.

Identifiable Private Information

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

IRB Responsibility: Collecting this type of information determines whether the IRB review is a full or expedited review. When this information is protected health information (PHI), the PI completes the Access to Protected Information form and submits it along with the IRB Application. The IRB approves the use of PHI based on the use and protection of these data.

Risk

Definition: The possibility of exposure to physical, psychological, or social harm as a direct consequence of participation in a research study 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.

IRB Responsibility: The degree of risk determines the type of IRB review. Reviews are either full, expedited, or exempt.

Minimal Risk

Definition: The probability and/or 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.

IRB Responsibility: Proposed research that has minimal risk are either an exempt or an expedited review.

Greater than Minimal Risk

Definition: 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.

IRB Responsibility: Proposed research that has greater than minimal risk are a full review.

Protocol

Definition: The description of the research, providing details about protecting participants, risks inherent to the study, benefits from researching the topic, and methodology.

IRB Responsibility: The IRB reviews the protocol to determine level of risk and ascertain that adequate provisions to protect participants' rights and welfare from these risks are in place.

Informed Consent

The process of providing sufficient information to potential research participants about the research study's 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 forms are part of the IRB Application and must provide sufficient detail to enable the IRB to determine that consent to participate is informed and voluntary.

IRB Approval

Definition: The IRB determined the research met all the requirements for the protection of human subjects and their rights and based on this determination approved the research.

Vulnerable Population

Definition: A group of individuals who are at a disadvantage, cannot protect oneself, and/or have decreased freewill or inability to make informed consent due to their age, characteristics, or circumstances. Vulnerable populations include but not limited to children, minors, pregnant women, fetuses, human in vitro fertilization, prisoners, employees, military persons and students in hierarchical organizations, terminally ill, comatose, physically and intellectually challenged individuals, institutionalized, elderly individuals, visual or hearing impaired, ethnic minorities, refugees, and economically and educationally disabled individuals.

IRB Responsibility: Because of this vulnerability, the IRB must determine that extra protections against risk for these individuals are in place in order to approve the research study or project.

Categories of Potential Risks to Participants

Potential risks fall within the following five categories. Because the IRB must weigh these risks against potential benefits as part of the review process, the PI must check the risk categories on the IRB application and provide a detailed description of the nature and degree of these risk(s).

Physical Risk

This category of risks includes physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. Engaging participants in social situations that could involve violence may also create a physical risk

Psychological Risk

This category of risks includes anxiety, depression, guilt, shock and loss of self-esteem or body image, and altered behavior brought about by the methods and procedures of the research. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are also examples of psychological risks.

Social Risk

This category of risks includes changes in relationships with others due to embarrassment, loss of respect, negative labeling, loss of personal dignity, bullying, and isolation brought about by the methods and procedures of the research.

Economic Risks

This category of risks includes payment by participants for procedures not otherwise required, loss of wages or other income, and any other financial costs such as damage to a participant's employability brought about by the methods and procedures of the research.

Loss of Confidentiality

This category of risks includes injury or illegal invasion of privacy as well as identify theft. This type of risk is always possible when personal identifiable information is collected.

Legal Risks

This category of risks involves activities that could lead to participants being criminally or civilly liable.

Protection of Human Participants Training

The PI and all members of the research team must successfully complete training in the protection of human research participants. Proof of this training is the submission of a certificate indicating completion of training. The PI must submit certificates with each and all proposals for an IRB review because the IRB does not file and track certificates for individual researchers.

Training is online and a link to this training is available on the College's library website under Online Research. Click the Institutional Review Board link to access the IRB's webpage and click the Protecting Human Research Participants link. The link goes to the Protecting Human Research Participants (PHRP) Online Training site. Remember to print or download the certificate as proof of completing the course. Although the course is a federal resource, it is no longer free. Researchers must pay a fee to access the course.

Submitting a Study for IRB Review

Submitting a study for review is electronic and the application is on the College library's website under Online Research. Click the Institutional Review Board Link to access the IRB's webpage. Click the Forms link and then download the IRB Application. The PI is responsible for completing the application, attaching the necessary documents, and submitting it as an email attachment to the IRB at irb@brcn.edu.

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

Types of Review

There are three types of review. They are exempt, expedited, and full. PIs request the type of review as part of the IRB application and the IRB Chair validates the request is appropriate given the nature of the research study or project. The following criteria determine the type of review.

Exempt Review

The exempt review is for studies that present no more than minimal risk to participants and fit one of the following six categories.

Category 1. Educational Research

Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' opportunity to learn or assessment of educators

Category 2. Surveys, Interview, Educational Tests, and Public Observations

Research that involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior; and

- Recorded information cannot readily identify participants (directly or indirectly/linked), OR
- Any disclosure of responses outside of the research would NOT reasonably place participants at risk (criminal, civil liability, financial, employability, educational advancement, reputation).

Category 3. Benign Behavioral Interventions

Research involving benign interventions using verbal or written responses, (including data entry or audiovisual recording) from adult participants who prospectively agree; and ONE of following conditions is met:

- Recorded information cannot readily identify the subject (directly or indirectly/linked), OR
- Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation).

Benign interventions are activities "deemed harmless."

Category 4. Secondary Research Uses of Identifiable Private Information or Identifiable Biospecimens

Secondary research with identifiable Information/specimens collected for some other initial activity, if ONE of following:

- Biospecimens or information is publically available.
- Information recorded so subjects cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify subjects.
- Collection and analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes."
- Research information collected by or on behalf of the federal government using government generated or collected information obtained for non-research activities.

Category 5. Federal Research or Demonstration Projects

Research and demonstration projects supported by a Federal Agency/Department and designed to study public benefit or service programs. The project must be on the federal agency's list of projects covered by this exemption.

Category 6. Taste and Food Quality Evaluation Studies

Studies that are taste and food quality evaluation and consumer acceptance studies,

- If wholesome foods without additives are consumed, OR
- 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 U.S. Department of Agriculture

Expedited Review

The expedited review is for studies that present no more than minimal risk to participants and fit one of the following eight categories.

Category 1.

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. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.).
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.

Category 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3

Prospective collection of biological specimens for research purposes by noninvasive means.

Category 4

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.)

Category 5

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). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category 6

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

Category 7

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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Category 8

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.

Category 9

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.

Full Review

A full review is required for research that is not eligible for an exempt or an expedited review. The research poses greater than minimal risk, or involves minors or vulnerable populations.

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 the proposal.
- Expedited: Three IRB members review the application and the PI can expect a response from the IRB within four weeks of submitting the proposal.
- Full review: The entire IRB reviews the application at its monthly meeting. Depending on the time between submitting the proposal and the IRB meeting, the length of time for a response may by 30 days or more.

The expected time for a response is not absolute because factors such as time and work constraints of IRB members, holidays, and College breaks influence turn-around time for a review.

Possible IRB Decisions

The IRB will make one of four decisions after reviewing a proposed study. The decisions are approval, conditional approval, deferred decision, and disapproval.

Approval

The IRB approves 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 submits a revised proposal or 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 does not approve the study because the IRB determined that its protocol did not adequately protect the research participants' rights and welfare.

The IRB's written notification of the disapproval includes the reasons for the decision and gives the PI/research team an opportunity to revise and resubmit an IRB application that incorporates all the changes required for approval by the IRB.

Notification of IRB Decisions

The Chair of the IRB notifies the PI of the IRB's decision in regards to approving the research. Notification is a letter sent as an email attachment.

Approval letters service as the IRB's *letter of certification* that are sent to any entity requesting proof the research was approved by the IRB.

Notification at End of Study/Extension of Timeline

The Chair of the IRB notifies the PI when the timeline for collecting data is over and therefore the study is done from the IRB's point of view. The PI/research team can no longer collect data unless more time is requested of the IRB. A request is made by completing a Timeline Extension form. The form is on the College library's website under Online Research. Click the Institutional Review Board Link to access the IRB's webpage. Click the Forms link and then download the Timeline Extension form. Follow the directions and submit it as an email attachment to irb@brcn.edu.

PI Reporting to the IRB

The PI is responsible for completing the following reports during the study.

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.

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 for Change in Protocol form is on the IRB's webpage.

Reporting Adverse Effects

PIs are required to inform the IRB of adverse events within 24 hours after the event occurred or is discovered. Notification is done by submitting the Adverse Event form that is on the IRB's webpage.

The Chair of the IRB reports all adverse effects to the IRB membership as well as the College's President/CEO and any other entities needing to know that the event occurred. Action taken 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 be done by anyone who is aware of the deviation. Reporting is by emailing the IRB Chair at irb@brcn.edu with a full description of what occurred. When the deviation in protocol results in an adverse event, the Adverse Event form must be completed.

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.

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.

The IRB notifies PIs in writing of the suspension or termination of their research. The IRB also notifies the College's President/CEO as well as other parties that need to be aware of the study's suspension or termination. The Secretary of the Department of Health and Human Services is notified in the case of a federal grant or grant application. Notification includes 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 be used in any research capacity.

Criteria Used to Approve Studies

The IRB reviews each application to determine that all of the following requirements are met in order to approve a research study or project

- Risks to participants are identified and actions to minimize these risks are appropriate.
- 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.

Informed Consent

Criteria Used to Approve a Study's Informed Consent

The IRB reviews each proposal to determine all general requirements for obtaining informed consent are met in order to approve the research study. Therefore, it is important to the approval process that PIs submit complete, accurate, and detailed information about obtaining informed consent when submitting a proposal for IRB review. The informed consent form must be included in the proposal for IRB review.

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 or obtain the informed consent.

Informed consent is approved when the following criteria are met:

- Participants are informed of the tasks, risks, and benefits of participating in the research.
- 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.
- Participants have the legal authority to give permission.
- Any exculpatory language through which participants are made to waive or 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.
- Language is understandable to participants. Understandable language is clear and unambiguous, including an appropriate reading level for participants and appropriate explanations for all technical terms.

The IRB also checks to make sure the following basic information is 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 the PI and the IRB chairperson. If the project is a student project, contact information for the faculty of record must be included.

Assent of Minors

Participants who are minors (under the age of 18 and not legally emancipated) cannot give their *informed consent* to participate in a study. Therefore, they must give *assent* to participate in research. Assent is defined as “a child’s affirmative agreement to participate in research.” Assent from a minor must be obtained in a language that is understandable to him/her and requires using an age appropriate assent form.

Children 8 Years of Age and Younger

The parental consent form for this age group includes a statement about obtaining assent and should also include the following statement in the "Risks" section: "If your child indicates through his/her behavior, or any other means, that they do not want to participate in one or any of the research activities, their participation will be stopped immediately." Before obtaining assent with this age group, a simple verbal explanation about the study's research activities is given, using simple and age-appropriate language. Children who say "yes" become participates unless their parents did not give consent. Children who say "no" are not participants although their parents might have given consent.

Children 9 to 13 Years of Age

The parental consent form for this age group includes a statement about obtaining assent and that their child will no longer be a participant when he/she states not wanting to participate in one or any of the research activities. Before obtaining assent with this age group, a verbal explanation about the study's research activities is given, using age-appropriate language. Assent is obtained by signing a form that is simple and states what will happen, using non-technical, jargon-free language and appropriate to participants' reading/comprehension level.

Children 14 to 17 Years of Age

The parental consent form for this age group includes a statement about obtaining assent and that their child will no longer be a participant when he/she states not wanting to participate in one or any of the research activities. Before obtaining assent with this age group, a verbal explanation about the study's research activities is given, using age-appropriate language. Assent is obtained by signing a form that is a simplified version of their parents' informed consent. The form's language is non-technical, jargon-free language, and is written at the eight-grade reading/comprehension level.

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 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.

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 PIs to obtain signed, written informed consent from participants. The waiver is based on:

- 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.
- 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.

Studies Involving Deception

PIs are required to fully inform participants about the research and answer all their 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, when 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. To provide information that will assist the IRB with approving studies involving health-related data, the PI must file a Access to Protected Information form along with the IRB Application. The form is on the College library's website under Online Research. Click the Institutional Review Board Link to access the IRB's webpage. Click the Forms link and then download the Access to Protected Information form. Submit the form along with the IRB Application as an email attachment to irb@brcn.edu.

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 College's IRB will accept this institution's IRB approval. Because the PI/research team is affiliated with the College, the letter of certificate must be submitted to the College's IRB for record keep and will be classified as exempt in light of the other institution's IRB approval.

Non-college Affiliated Researchers

Researchers not affiliated with the College 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

Organization of the IRB

The IRB reports to the President/CEO of the College and the College 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.

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 and Health Sciences 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 IRB.

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.

The College of Nursing Board approves new members based on recommendations from the IRB. The Chair of the IRB with consultation of IRB members and the College's President/CEO solicit 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 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.

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.

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 Office for Human Research Protections (OHRP) at National Institutes of Health - Department of Health and Human Services when registering the IRB with OHRP. Changes in IRB membership are forward to the College Board for approval and updated at the OHRP website.

Conflict of Interest

The IRB will not permit a member to participate in the initial or continuing review of any research 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.

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 President/CEO and College Board about IRB activities.

The IRB chair is someone knowledgeable in both research and regulations relevant to the protection of human participants in research and has served at least 24 months as a member of the IRB.

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.

A quorum whereby a majority of the members are present is needed for a full review of proposed studies or to take action with adverse effects. 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 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.