# Blessing-Rieman College of Nursing and Health Sciences

# Institutional Review Board (IRB) Application

Blessing-Rieman College of Nursing IRB #1

3609 N. Marx Drive

Quincy, IL 62305

## Instructions

1. The application must be typed. Hand written applications are not accepted.
2. Fill out all items on this form. Incomplete or incorrectly completed applications will be returned to the principal investigator.
3. Submit this application as a **WORD** document; do not convert to a different file format.
4. Submit completed application and all supporting documents to irb@brcn.edu

Type in the gray fields below or next to the item and mark an X in the gray boxes. Remember to click “Save” to save your work. You will lose all information if you do not save before closing this form.

## Section A. General Information

| Research Study/Project |
| --- |
| Title |
|  |
| Anticipated Start Date: |  |
| Anticipated End Date: |  |
| The application is for: |
|  | Use of human participants (including record review). |
|  | Use of animal(s). *The IRB will ask for information about the role, care, and protection of animal participants before approving the research study/project.* |
|  | Other. Specify below: |
|  |  |

| Principal Investigator (PI) |
| --- |
| Name |
|  |
| Address |
|  |
| City, State, Zip Code |
|  |
| Phone Number |
|  |
| Email Address |
|  |
| Completion Date of Human Subjects Training: *(remember to attach to the end of the application)* |
|  |

| Co-principal Investigator |
| --- |
| Is there a co-principal investigator? | No |  | Yes |  |
| If yes, complete the following information about the co-principal investigator: |
| Name |
|  |
| Address |
|  |
| City, State, Zip Code |
|  |
| Phone Number |
|  |
| Email Address |
|  |
| Completion Date of Human Subjects Training: *(remember to attach to the end of the application)* |
|  |

| Research Team |
| --- |
| Do you have additional research personnel/research team? |
| No |  | Yes |  |  |
| If yes, *attach a list of the research personnel/research team to the end of the application*. For each member, provide name, address, phone number, email address, team member role, and completion date of human subjects training. |

| Dissemination of Results |
| --- |
| How are you intending to share results? (check all that apply) |
|  | Journal article. |
|  | Podium presentation. |
|  | Poster presentation. |
|  | Academic white paper. |
|  | Thesis/Dissertation. |
|  | Other: |  |

| Financial Support |
| --- |
| Does/ will this research study/project receive financial support from a grant or other source? |
| No |  | Yes |  |  |
| If yes: check the type of agency and provide name of agency. |
|  |  | Local: |  |
|  |  | Federal: |  |
|  |  | Non-profit: |  |
|  |  | Other: |  |

| Financial Conflict of Interest Disclosure |
| --- |
| Do any investigators, research team members, or their family members have any relationship or financial interest with any institution or sponsors related to this research/project that might present or appear to present a conflict of interest with regard to the outcome of the research study/project. |
| No |  | Yes |  |  |
| If yes, complete the Conflict of Interest Disclosure form for each person who has the conflict of interest and *email the completed form along with this application*. |

| Use of Protected Health Information (PHI) |
| --- |
| Will the research study/project use medical/patient records? |
| No |  | Yes |  |  |
| If yes, complete the Access to Protected Information form and *email the completed form along with this application*. |

## Section B. Signatures

### Directions for Inserting Signature

1. Write your signature on a piece of paper.
2. Scan only the signature and make it a jpeg picture.
3. Insert (paste) the signature as a picture in the space below the following disclosure.

### Disclosure

 I certify that the information provided in this application is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations designated by the IRB. I accept and will conform to all federal, state, and institutional provisions concerning the protection of human participants in research. I will ensure all personnel involved in the research will be appropriately trained for all procedures used in this project. I agree to conduct the research involving human participants as presented in this protocol application as approved by the Blessing-Rieman College of Nursing IRB #1 (IRB), and am qualified to perform the procedures described herein. I will submit any proposed changes/modifications for review and approval before they are implemented. I agree to notify the IRB of any adverse events that may occur during the study. I also assure that I will follow through with the storage and destruction of data as outlined in the protocol.

| Signature of PI |
| --- |
| Date: |  |
| Type Name |
|  |
| Signature of PI |
|  |

## Section C. Review Category and Justification

Read the IRB Handbook to determine the type of review that is appropriate for your research study/project.

| Type of Review Category |
| --- |
| Check the applicable review category for your research study/project. |
|  | Full review. |
|  | Expedited review: (check the category below) |
|  |  | 1. Clinical studies of drugs and medical devices only when the two conditions (a) or (b) as described in the IRB Handbook are met.
 |
|  |  | 1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as described in the IRB Handbook.
 |
|  |  | 1. Prospective collection of biological specimens for research purposes by noninvasive means. See the IRB Handbook for examples.
 |
|  |  | 1. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; and are cleared/approved for marketing.
 |
|  |  | 1. 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).
 |
|  |  | 1. Collection of data from voice, video, digital, or image recordings made for research purposes
 |
|  |  | 1. 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.
 |
|  |  | 1. Continuing review of research previously approved by the IRB.
 |
|  |  | 1. Continuing review of research, not conducted under an investigational new drug application or investigational device.
 |
|  | Exempt review: (check the category below) |
|  |  | 1. Educational research.
 |
|  |  | 1. Surveys, interviews, educational tests, and public observations.
 |
|  |  | 1. Benign behavioral interventions.
 |
|  |  | 1. Secondary research uses of identifiable private information or identifiable biospecimens.
 |
|  |  | 1. Federal research or demonstration projects pre-approved for exemption.
 |
|  |  | 1. Taste and food quality evaluation studies.
 |
| Explain in layman terms why you believe your research study/project meets the review category you selected. |
|  |

## Section D. Research Study/Project Protocol

| Purpose |
| --- |
| What is the research question or project problem statement? State any hypotheses. |
|  |
| Provide a summary of the purpose of your research study/project. Include information about the background and rationale for the study/project and goal(s) of the proposed study/project. Use language understood by a person outside the discipline. Specific jargon should be avoided or explicitly explained. |
|  |

| Methodology |
| --- |
| The research design is: |
|  | Experimental. |  | Quasi-experimental. |
|  | Non-experimental (e.g. descriptive) |  | Qualitative |
|  | Secondary data/collection/analysis |  | Program evaluation or QI |
| Instruments include: *(attach all instruments to the end of the application)* |
|  | Standardized tests/tools. |  | Reviewing records. |
|  | Questionnaire/survey. |  | Videotaping. |
|  | Interviews. |  | Photographing. |
|  | Observations. |  | Audiotaping. |
|  | Focus groups. |  |  |
|  | Other. Specify |  |  |
|  |  |
| Does the research study/project involve biomedical procedures? |
| No |  | Yes |  |  |
| If yes, list all biomedical procedures that apply to your research/project: |
|  |
| What are you going to ask participants to do? Provide a step-by-step description. A numbered orbulleted list of steps is helpful.  |
|  |
| Does the research study/project involve the storage or maintenance of identifiable bio-specimens? |
| No |  | Yes |  |  |
| Does the research study/project involve the storage or maintenance of identifiable private information? |
| No |  | Yes |  |  |
| Will you be keeping the identifiable private information or bio-specimens for future use in research? |
| No |  | Yes |  |  |
| If yes, provide information on how long the data or specimens will be stored, what kind of future research will occur, and if the data and/or specimens will be used to create a repository: |
|  |
| Describe where data collection and data analysis procedures will take place: |
|  |

| Sites |
| --- |
| List all the locations where research/project activities will take place: |
|  |
| Will multiple institutions participate in the study? |
| No |  | Yes |  |  |
| If yes, list all the participating institutions: |
|  |
| Has the IRB at the institutions(s) listed above approved the study/project? |
| No |  | Yes |  | *(submit copy of approval letter)* |
| If no, explain: |
|  |
| Will the Blessing-Rieman College of Nursing IRB #1 be the primary IRB for this research study/project? |
| No |  | Yes |  |  |
| If yes, describe the PI’s plans to oversee or coordinate the research/project at the other sites, including how the PI will ensure adherence to the study protocol, obtain informed consent, secure and maintain IRB approval at the other sites, monitor adverse events or other unanticipated problems, and ensure general coordination of study conduct: |
|  |

| Participants |
| --- |
| Number of participants or records: |  |
| Age range of subjects: |  |
| Identify the vulnerable populations to be recruited: |
|  | N/A |  | Cognitively impaired persons. |
|  | Children. |  | Prisoners. |
|  | Minorities. |  | Not fluent in English. |
|  | Educationally disadvantaged |  | Economically disadvantaged |
|  | Other. Describe: |  |  |
| If vulnerable populations are targeted for the study/project, describe the special protections being implemented to minimize risk of coercion or undue influence: |
|  |
| Describe the inclusion criteria: |
|  |
| Describe the exclusion criteria: |
|  |
| Is compensation being offered:  | No |  | Yes |  |  |
| If yes, describe the amount, type (e.g. gift card) and when: |
|  |

| Recruitment |
| --- |
| The following recruitment materials will be used: *(attach all items to the end of the application)* |
|  | Recruitment scripts. |  | Recruitment emails. |
|  | Cover letters |  | Flyers |
|  | Advertisements |  | Posters |
|  | Other. Specify: |  |  |
|  |  |
| Identify who will recruit potential participants: |
|   |
| Describe how, when, and where individuals will be first contacted about participating in the study/project: |
|  |
| Are you directly emailing or mailing participants? |
| No |  | Yes |  |  |
| If yes, describe how you are obtaining emails and/or mailing addresses: |
|  |
| Describe how you will protect email and/or mailing addresses: |
|  |
| Will Blessing-Rieman students be recruited and participate in the research study/project? |
| No |  | Yes |  |  |
| If yes, describe the special protections being implemented to minimize risk of coercion or undue influence from faculty and staff: |
|  |

| Informed Consent |
| --- |
| Check the type of waiver you are requesting. |
|  | N/A. Participants’ informed consent will be obtained. |
|  | Requesting to waive the required documentation of informed consent (i.e. waive obtaining the signature for anonymous internet-based survey, telephone survey, mailed survey, etc.).  |
|  | * Check the box next to the condition that best fits your research study and justify how your research study meets that condition. If waiving the signature, you must still submit a verbal script or cover letter for participants that addresses the eight required elements of consent as stated in 45 CFR 46.116 (a)(1-8).
 |
|  |  | Condition 1:  |
|  |  | The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern.If you checked Condition 1, explain how your study/project meets this condition: |
|  |  |  |
|  |  | Condition 2: |
|  |  | The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside the research context (i.e. no questions are being asked that could result in potential embarrassment, personally or professionally.)If you checked Condition 2, explain how your study/project meets this condition: |
|  |  |  |
|  | Requesting to alter the informed consent process. |
|  | Describe which elements of consent will be altered or omitted: |
|  |  |
|  | Requesting to waive the informed consent process. |
| You must justify your request to waive or alter the informed consent process in accordance with each of the following four criteria established under 45 CFR 46.116 (d) (1-4). Provide supporting information for ALL FOUR criterion: |
|  | 1. The research involves no more than minimal risk to the participants. Explain how your study/project meets this criterion: |
|  |  |
|  | 2. The waiver or alteration will not adversely affect the rights and welfare of the participants. Explain how your study/project meets this criterion: |
|  |  |
|  | 3. The research could not practicably be carried out without the waiver or alteration. Explain how your study/project meets this criterion: |
|  |  |
|  | 4. Whenever appropriate, the participants will be provided with additional pertinent information after participation. Explain how this will be done: |
|  |  |
| Describe how, when and where the informed consent process will take place and who will obtain informed consent: |
|  |
| If the participants are not able to give legal consent (e.g., minors), explain how assent will be secured. |
|  |
| Into what languages will the consent be translated? |
|  |
|  |
| *Remember to attach informed consent to the end of the application.* |

| Participant Privacy and Confidentiality of Data |
| --- |
| Describe the provisions to protect the privacy of participants during data collection procedures: |
|  |
| Provide details as to how you will protect data while on site and during travel. Address the storage and security of electronic data as well as any physical data, such as paper consent forms or surveys, during travel: |
|  |
| Describe how you will maintain confidentiality of data after they have been collected, including measures to protect the identity of participants and their responses (coding procedures, encryption, etc.): |
|  |
| Describe where will you store data, both electronic and hard copy data: |
|  |
| Describe the people who will have access to the data: |
|  |
| Identify in what format will data will be stored (e.g. paper or electronic copy): |
|  |
| Describe how long you plan to retain data and describe how you will dispose of the data: |
|  |

Read the IRB Handbook to determine the type of risk that is possible with your research study/project.

| Risk and Benefits |
| --- |
| Check the potential risk exposure to participants: |
|  | Physical (cognitive or motor). |
|  | Psychological/emotional stress or discomfort.  |
|  | Social/economic. |
|  | Loss of confidentiality. |
|  | Legal risks. |
| Describe the nature and degree of the risk(s). Do not type N/A. You cannot assume there are no risks. Be sure all risks are described in the informed consent document. |
|  |
| Describe how risks and discomforts will be minimized: |
|  |
| Describe how results will benefit the greater good: |
|  |
| Will participants receive any direct benefit from participating in the study/project?  |
| No |  | Yes |  |  |
|  | If yes, describe the benefits for participants: |
|  |  |
| Does the study/project involve deception |
| No |  | Yes |  |  |
|  | If yes, explain why deception is necessary and how participants will be debriefed about the deception after the completion of their participation: |
|  |  |

## Section E. Attachments

Check the items that are attached at the end of this application.

| Attachments |
| --- |
| 1. Certificate of Training
 |
| a. Principal investigator: |
| Yes |  |  |
| b. Co-principal investigator: |
| Yes |  | N/A. No co-principal investigator  |  |  |
| c. Each member of the research team: |
| Yes |  | N/A. No research personal/team |  |  |
| 1. List of research personnel/research team.
 |
| Yes |  | N/A. No research personal/team |  |  |
| 1. All data collection instruments. (e.g. standardized tests/tools, questionnaire/surveys, interview questions, focus group questions, observation items)
 |
| Yes |  |  |
| 1. All recruitment materials. (e.g. recruitment scripts, cover letters, recruitment emails, flyers, content of advertisement and posters, and any other materials to recruit participants)
 |
| Yes |  |  |
| 1. Consent (e.g. informed consent form, cover letter, web-based cover letter, assent form, parent/guardian informed consent form, verbal consent script)
 |
| Yes |  |  |
| 1. Deception debriefing script
 |
| Yes |  | N/A. Not using deception. |  |  |
| 1. Authorization form to access PHI and other data from medical/patient records.
 |
| Yes |  | N/A. Not using medical/patient data. |  |  |

September 2019