



New Study Application – Human Subjects Research

IRB Number: [Click or tap here to enter text.](#)

If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.

Section 1: PRINCIPAL INVESTIGATOR (PI)

The Illinois [Campus Administrative Manual](#) allows assistant, associate, and full professors to act as PI. Other individuals may serve as PI after obtaining approval from the necessary party.

Please answer the following questions.

1.1) Personal Information:

Please complete the information below.

Last Name:

First Name:

Degree(s):

Dept. or Unit:

Office Address:

Street Address:

City:

State:

Zip Code:

Phone:

E-mail:



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1.2) Urbana-Champaign Campus Status:

Check the option which applies (please only mark one.)

Note: *Student Investigators and Visitors cannot serve as PI's.*

I am a non-visiting member of:

Faculty

Academic Professional/Staff

1.3) Training:

If you have completed any of the trainings below, please check the boxes that apply. Please also add the completion date(s) in the associated field(s) for any trainings that you have done.

Required CITI Training

Date of CITI Training Completion (valid within the last 3 years):

Additional training

Date of Additional Training Completion:



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Section 2. RESEARCH TEAM

Please check “Yes” or “No” for the question below about your research team.

Important Note: If any other investigators are engaged in research for this project, please submit a [Research Team Form along with this protocol](https://oprs.research.illinois.edu/forms-templates/forms/research-team-form). (The full URL for the Research Team Form is: <https://oprs.research.illinois.edu/forms-templates/forms/research-team-form>)

2.1) Are there other investigators involved in the design, conduct, or reporting of the research?

Note: If other investigators have their own IRB, select “No”. If other investigators need to use UIUC IRB, a Reliance Request Form should be submitted separately to irb-reliance@illinois.edu.

- Yes (requires a Research Team Form)
- No

Section 3. PROTOCOL TITLE

3.1) Protocol Title:

Please enter the protocol title below.



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Section 4. FUNDING SOURCE

4.1. Is the research funded?

Check the box that applies (only one).

- Research is **not funded** and is **not pending** a funding decision (Proceed to Section 5).
- Research is **funded** (funding decision has been made).
- Funding **decision is pending**.

If you checked the “pending” box, what is the funding proposal submission date:

4.2. Indicate the source of the funding.

Check the funding source(s) that apply, and then fill in the specific fund source(s) in the associated field. Also, if you choose commercial sponsorship and industry, please see notes 1 and 2 below.

- University of Illinois Department, College or Campus.

If yes, *please specify*:

- Federal.

If yes, *please specify*:

- Commercial Sponsorship & Industry^{1,2}.

If yes, *please specify*:

- State of Illinois Department or Agency.

If yes, *please specify*:

- Other.

If yes, *please specify*:

¹ Clarify whether or not sponsor requires specific language in the contractual agreement that impacts human subjects research

² Clarify whether or not the sponsor requires the protocol adhere to ICH GCP (E6) standards



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Section 4. FUNDING SOURCE – continued

4.3. Sponsor-assigned grant number, if known:

4.4. A complete copy of the funding proposal or contract is attached.

I am attaching a proposal or contract to this form.

4.5. Funding Agency Official To Be Notified of IRB Approval (if Applicable):

Funding Contact Name:

Funding Contact Agency:

Funding Contact E-mail:

Funding Contact Phone:



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Section 5. CONFLICTS OF INTEREST

Please indicate below whether any investigators or members of their immediate families have any of the following. If the answer to any of the following items is yes, please submit the University of Illinois approved conflict management plan. If you have any questions about conflicts of interest, contact coi@illinois.edu.

5.1. Does any investigator (or any of their immediate family members) have a financial interest or fiduciary relationship with the research sponsor?

(For example, the investigator is a consultant for the research sponsor).

- Yes (if yes, submit the University of Illinois approved conflict management plan)
- No

5.2. Does any investigator (or any of their immediate family members) have a financial interest or fiduciary relationship that is related to the research?

(For example, an investigator owns a startup company, and the intellectual property developed in this protocol may be useful to the company).

- Yes (if yes, submit the University of Illinois approved conflict management plan)
- No

5.3. Are two or more members of the same family are acting as research team members on this protocol?

- Yes (if yes, submit the University of Illinois approved conflict management plan)
- No



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Section 6: STUDY INTRODUCTION

Please answer the following questions. You may attach more pages if needed.

6.1) Study Purposes and Objectives.

The objectives should be stated in such a way that the reader can determine the appropriateness of the study design. If appropriate, state the specific hypotheses being tested and/or study aims. Use lay language.

Detail the study purposes and objectives below and attach additional pages if needed:

6.2) Background and Introduction:

Identify the research area being studied and provide a review of the literature that provides the basis for understanding the objectives of the study. This review should be written such that scientists outside the investigator's area of expertise can understand the issues involved. Any information about previous research related to this study involving animals and/or humans should be summarized. Include studies on pregnant animals if the research is conducted on pregnant women, fetuses, or neonates.



Enter the background and Introduction below and attach additional pages if needed.

6.3) Studies Being Done in Conjunction with Carle Foundation Hospital

Is this study being conducted in conjunction with Carle Foundation Hospital (with Carle employees or any Carle facilities?) Check below if yes.

Yes, this is a study being done in conjunction with Carle

If “Yes” (i.e if this is a Carle-related study), has an application been submitted to Carle IRB or another Carle department?

Yes (Carle Application Submitted)

No (Carle Application Not Submitted)

Carle ID number, if available:



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Section 7: SUBJECTS

7.1) Ages of Subjects

Please select the age range(s) for this study (check all ranges that apply):


- Less than 7 (Parental Permission Needed)
- 7-17 (Parental Permission and Assent Needed)
- 18 and older (Consent form needed)

What are the specific age range(s) of subjects to be used for this study (e.g. 7-12 years old, 60+, etc.):



7.2) Are you working with Vulnerable Populations?

(Check yes or no)

- Yes, this study includes vulnerable populations 
- No, this study does not include vulnerable populations

Please also answer question 7.3 below, even if you select “no”.

Additional guidance on specific vulnerable populations:

- Pregnant women and fetuses: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-research-involving-pregnant-women-fetuses>
- Prisoners: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-research-involving-prisoners>
- Neonates: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-research-involving-neonates>
- Economically or Educationally disadvantaged: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-research-involving-economically-or-educationally-disadvantaged>
- Students, staff, and faculty of the research institution: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-recruitment-enrollment-employees-research>





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Section 7 Subjects - continued

7.3) Indicate any vulnerable population groups (other than children) that will be included:


Select only those groups which you are specifically studying, or those which have a high likelihood of being included in the project. See section 7.2 above for more guidance on these groups.

If children or any vulnerable populations are being included in the study, please also complete and include the additional **Vulnerable Populations form** (<https://oprs.research.illinois.edu/forms-templates/forms/vulnerable-populations-form>) with this application.

- Pregnant women and fetuses (CFR Part 46, Subpart B)
- Neonates (45 CFR Part 46, Subpart B) 
- Prisoners (45 CFR Part 46, Subpart C)
- Individuals with Cognitive or Decisional Impairment
- Students, staff, and faculty of the research institution
- Mentally Disabled
- Economically or Educationally disadvantaged persons
- Other 
If "Other", please specify:
- None (if no vulnerable groups are included, please see question 7.4 below)

If you answered "No" or "None" to the Vulnerable Populations questions above, and no children are involved in the study, please answer the following question (7.4):

7.4) Has the participant selection process overprotected potential subjects who are considered vulnerable, so that they are denied opportunities to participate in research?


- Yes
- No 
- Not Applicable



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7.5) Number of subjects to be enrolled in this entire study:

(Use of records and databases containing human information should also be considered in counting the number of participants.)

Number of UIUC subjects - total: 

Number of UIUC male subjects:

Number of UIUC female subjects:

Number of subjects from all sites participating in study:

7.6) Participant Inclusion Criteria:

Participant-entry criteria should be as detailed as needed to define the participant population under study and, for clinical studies, to reduce confounding treatments or diseases. Precise criteria for age, gender, or another other factors (e.g. diagnoses, extremes in signs or symptoms, etc.) should be included.

Please detail this study's criteria for participant inclusion:

7.7) Participant Exclusion Criteria:

Specific exclusion criteria should be listed which could interfere with the study design or place a participant at risk during the study.

Please detail this study's criteria for participant exclusion. If no exclusion criteria, please state "None."

7.8) Will data be collected from participants or received from participants or other researchers who are outside the U.S.?

Yes, data will be collected or received from participants or researchers outside the U.S.

No, not applicable.



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If you checked “Yes”, please also include the **International Research Form** with the application.
(<https://oprs.research.illinois.edu/forms-templates/forms/international-research-form>)



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Section 8: STUDY INFORMATION

8.1) Design of Study

8.1.a) Non-Experimental and/or Descriptive Research Design

Applies to the collection and assessment of the participant's data and information without prospective manipulation of the participant's body, environment, or treatment.

Please check all that apply below.

Secondary/Archival Data Analysis or Retrospective Chart Review

Survey/Questionnaire Research

(Attach any non-validated surveys or questionnaires that will be studied as part of the project.)

Interviews and Focus Groups

(Attach interview or focus group scripts, or outline for guided discussion, a draft may be submitted at this time, but the final version must be approved before used.)

Oral History

Observational Research (e.g. ethnographic field work)

If you checked "Survey/Questionnaire Research" in the options above, please list the names of any validated surveys that will be used in the project:

If edits are being made to validated surveys, attach the survey.



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Design of Study - continued

8.1.b) Experimental and/or Interventional Research Design


Applies to prospectively manipulating the participant's body, environment, treatment, or strategies for receiving information in order to observe a resulting effect or outcome.

Check all that apply below.

- Prospective Social/Behavioral Intervention or Experiment
- Prospective Biomedical Intervention or Experiment
- Randomized Design
- Placebo or Sham Controlled Design
- Phase I Clinical Trial
- Phase II Clinical Trial
- Phase III Clinical Trial
- Phase IV Clinical Trial or Post-Approval Monitoring
- Open Label Trial

8.1.c) Development of a Research Resource (repositories, databases, etc.) for Research Design

Check if applicable.

- Study will develop research resources such as repositories, databases, etc. 

8.1.d) Other Type of Research Design

Check if applicable.

- Study will include a research design that is not listed in the previous sections.

Please describe the other type of research design:



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Design of Study - continued

8.2) Does your study involve the use of any placebo or sham procedure?

Check if applicable.

Yes

No

8.3) Length of entire study from initiation to closeout (including data analysis):

Enter the length of the study below.

8.6 Length of individual subject's participation

Enter the length of the subject's participation below (e.g. one-time visit for 2 hours, 4 weeks, 15 minutes, etc.)



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8.7 How will subjects be recruited or identified for inclusion in the study?

See more guidance on all types of advertising at: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-advertisements>

Select all methods that will be used:

In-person contact (e.g. students in class, patients in clinic, etc)

Referrals from other individuals


Written or electronic record review

Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

Note: Attach any recruitment materials to be used, final versions must be approved before use.

Audio/Video advertising (radio and television advertisements, etc.)

Note: Attach script and video if applicable, final version must be approved before use

From a database or participant pool, for which participants have given prior permission to be contacted for future research studies* 

Specific online population such as MTurk, Qualtrics Panel or similar*

Other**

*If you checked either “from a database or participant pool” or “specific online population”, please list the name(s) of the database(s) or participant pool(s):

**If you checked “Other”, please detail:

8.8) Describe the recruitment/participant identification process in detail.

Please detail the recruitment and participant identification process below.

For example: who will review records, who can refer subjects to the study , where will flyers be posted, how often recruitment letters will be sent, when will follow-up phone calls be made, etc. Attach additional pages if needed.



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Design of Study - continued

8.9) How will consent be obtained?

Review the information and questions below.

8.9.1) Informed Consent

Select this option if participants will have a choice to participate.

This study will use an Informed Consent Process (with or without a document). (Select if participants will have a choice to participate.) 

**If you select “Informed Consent”, please include the Informed Consent Process form (<https://oprs.research.illinois.edu/forms-templates/forms/informed-consent-process-form>)

Note: The informed consent process may or may not include a consent document. Also, check if requesting that documentation of informed consent be waived (e.g. consent process without signature, questionnaire cover letter, web-based consent, etc.)

8.9.2) Waiver of Informed Consent Process

Select this option if participants will not have a choice to participate. Learn more at:

<https://oprs.research.illinois.edu/forms-templates/guidance/guidance-waiver-or-alteration-consent>

This study will use a Waiver of Informed Consent Process. (Select if participants will not have a choice to participate.) 

**If you select “Waiver of Informed Consent”, please include the Request for Waiver of Consent form (<https://oprs.research.illinois.edu/forms-templates/forms/waiver-informed-consent-form>.)

Note: A Waiver of Informed Consent should be used if requesting an Alteration of Informed Consent to remove or alter a required element of consent (e.g. deception in consent, incomplete disclosure of information).

8.10) Describe all procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

Detail all procedures below, and attach more pages if needed.

Click or tap here to enter text.



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Design of Study - continued

8.11) Are all procedures for research purposes only (non-standard or non-standard of care procedures, or occurring only related to participation in the research)?

Check yes or no below.

- Yes, all procedures are for research purposes only
- No, not all of the procedures are for research purposes only

If “no”, please list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures or only occurring as part of the research):

Note: “Non-standard” refers to procedures that are only occurring because the participant agrees to participate in the research.

8.12) Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study.

Please enter your summary below. Factors for determining the proposed sample size (e.g. power) should be stated.



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Section 9: DATA MONITORING

The purpose of data monitoring is to ensure the integrity of the research data, adherence to the approved research plan, and that privacy and confidentiality risks are minimized. The complexity of a data monitoring plan depends on the complexity and risk of the study. You should design a monitoring plan that is suitable and realistic for your project.

Learn more at: <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-elements-data-monitoring-plan>

9.1) Privacy Protections:

Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

9.1.1) What precautions will be used to ensure subject privacy is protected?

Select all that apply:

- The research intervention/interaction is conducted in a private place.
- Discussing the study with participants individually instead of in front of a group.
- The collection of information about participants is limited to the amount necessary to achieve the goals of the research, so that no unnecessary information is being collected (can be used for research with no participant contact, e.g. secondary data analysis or chart reviews)
- De-identification of photos, audio tapes, or video tapes of the participant that will be made during the study
- Allowing for anonymous submission of surveys and questionnaires

9.1.2) Other or additional subject privacy-related details (specify):

Please describe any other subject privacy details besides the ones listed above.



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9.2) Confidentiality Precautions:

Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information, or visual information such as photographs.

9.2.1) What precautions will be used to maintain the confidentiality of identifiable information?

Select all that apply:

- Storing research data on password protected computers or in locked cabinets or offices
- Participant identifiers will be stored separately from the coded, participant data
- Complete de-identification of study data
- All data that will be transferred or transported outside of the institution will be encrypted
- Destroying photos, audio recordings, or video recordings at the end of the study
- A Certificate of Confidentiality (from the NIH) will be used

9.2.2) Other or additional confidentiality details (specify):

Please add any confidentiality details not included above.

9.2.3) Where will electronic and/or hard copy research data be stored?

Please detail here.

9.3) Will photos, audio recording, video recordings, or medical images of subjects be made during the study?

Select Yes or No below.

- Yes, photos, audio recording, video recordings, or medical images of subjects will be made during the study
- No, not applicable

If you answered yes, describe the recording/images and what will become of them after creation (e.g., show at scientific meetings, stored in the research/medical record, transcribed, erased, etc.):



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9.4) How will study data and documentation be monitored throughout the study?

Check all those that apply.

- Periodic review and confirmation of participant eligibility
- Periodic review of informed consent documentation (See additional notes below)
- Periodic review of the transfer/transcription of data from the original source to the research record (See additional notes below)
- Confirmation that all appropriate information has been report to the sponsor, oversight agencies such as the FDA), and/or IRB
- Other or additional details about monitoring

If you selected “Other” for monitoring options, please specify:

Notes on periodic review of informed consent documentation - this option may include:

- a) verifying there is an original signed and dated consent document for every participant;
- b) verifying participants signed a non-expired consent document;
- c) verifying parental permission or consent from a legally authorized representative was obtained correctly;
- d) verifying the consent process was conducted and documented appropriately for non-English speakers.

Notes on periodic review of the transfer/transcription of data - this option may include:

- a) verifying data was entered correctly into the research database;
- b) verifying case report forms (CRFs) are completed correctly;
- c) verifying transcripts were properly recorded



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9.5) Who will be the primary monitor(s) of the study data and documentation?


Select all that apply:

- Principal Investigator (PI)
- Research Assistant
- Study Coordinator or Research Nurse
- Study Monitor or Contract Research Organization (CRO)
- Independent Faculty or Staff member, Physician
- Data Monitoring Board or Committee
- Other or additional details about primary monitor

If you selected “Other” for monitoring options, please specify:

9.6) How often is study data and documentation monitoring planned?

(For example - monthly, twice a year, annually, after N subjects are enrolled, etc.)

Enter details: 

9.7) Is there a SAFETY monitoring plan for this study?

(Note: A safety monitoring plan is required for all studies with greater than minimal risk research. Learn more at: <https://opr.research.illinois.edu/forms-templates/guidance/guidance-elements-safety-monitoring-plan>). Check yes or no below.

- Yes, there is a safety monitoring plan
- No, there is not a safety monitoring plan

If you answered “yes” above, please include the Safety Monitoring Plan form (<https://opr.research.illinois.edu/forms-templates/forms/safety-monitoring-plan>).



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Section 10: RISKS AND BENEFITS

10.1) Describe the reasonable foreseeable risks or discomforts to the subjects.

Only include the risks of research-related procedures. If study involves genetic research, include risk to participants related to returning results.

Detail any foreseeable risks below:

10.2) Describe the potential benefits to society AND to participants (do not include compensation).

Statements such as 'None' or 'N/A' are not acceptable. The IRB will not approve research without some benefit to either the participant or society. Benefits to society, field of study, or direct benefits to participants should be included. There may be no direct benefit to participants (this is common) and that should also be stated.

Detail potential benefits below:

10.3) Using lay language, please describe the significance of this research and what you hope to show with the results of the project.

Detail significance below:



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10.4) Are there any costs to the subjects from participation in research?

Check yes or no.

Yes (there are costs to subjects from participation)

No, not applicable.

If you answered “Yes” and there are costs to subjects, please specify what those are:

10.5) Is there any compensation to subjects (including monetary or class credit)?

Select yes or no.

Yes, compensation will be given to subjects

No, not applicable.

If you answered “yes”, please answer question 10.6 below.

10.6) If there is compensation being given to subjects, please answer the following:

A) Specify overall amount:

B) Specify when participants will be paid (e.g. at each visit, at end of study, etc):

C) If applicable, please specify payment by visit or other time interval (e.g. \$10 per visit, etc.):

D) If applicable, explain the plan for prorating payments if subject does not complete the study:




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Section 11: RESOURCES AND RESPONSIBILITIES



11.1) State and justify the qualifications of the study staff: 

Detail below:

11.2) Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions.

Detail below: 

11.3) Describe the facilities and list any campus locations where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissues banks, etc.)

Detail below:  

11.4) Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.

Detail below:





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Section 12: Additional Information

12.1) Does this study involve any of the following special considerations?

Please check yes or no to each item below. There are 11 questions in this section.

12.1.1) Sharing data with researchers outside of UIUC?

Yes No  

12.1.2) Sharing data with researchers from UIUC?

Yes No 

12.1.3) Are you planning, or is it possible, some research procedures or participants will be outside of the U.S.?

Yes No

(If you checked yes, please include the **International Research form**:
<https://oprs.research.illinois.edu/forms-templates/forms/international-research-form>)

12.1.4) Creating or sending data and/or samples to a repository or database to be saved for future research uses?

Yes No 

(If yes, please the include the **Databases and Repositories form**:
<https://oprs.research.illinois.edu/forms-templates/forms/databases-repositories-form>)



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12.1.5) Are you collecting samples of blood or tissues from subjects for research purposes?

Yes No

(If yes, please include the **Biological Materials form**: <https://oprs.research.illinois.edu/forms-templates/forms/biological-materials-form>)

12.1.6) Exposure to radioisotopes or ionizing radiation?

Yes No

12.1.7) Genetic testing and/or analysis of genetic data?

Yes No

(If checked, please include the **Genetic Research form**: <https://oprs.research.illinois.edu/forms-templates/forms/genetic-research-form>)

12.1.8) Studying the safety, effectiveness, or outcomes of a drug, dietary supplement, biologic product, or cosmetic?

Yes No

(If yes, please include the **Drugs and Supplements form**: <https://oprs.research.illinois.edu/forms-templates/forms/drug-supplements-form>)



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12.1.9) Studying the safety, effectiveness, or outcomes of any type of device, algorithm, or mobile application (medical or non-medical)?

Yes No

(If yes, please include the **Devices form**: <https://oprs.research.illinois.edu/forms-templates/forms/device-form>)

12.1.10) Obtaining data/information from a medical record or entering data/information into a medical record?

Yes No

12.1.11) Using the MRI at Beckman Institute Biomedical Imaging Center (BIC)?

Yes No

If yes, you must obtain approval from the BIC (217-244-0446, bic@beckman.illinois.edu and attach the BIC approval, BIC screening form, and BIC consent form to this application.



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Section 13. INVESTIGATOR & DEPARTMENTAL ASSURANCES

- I certify that the information provided in this application is complete and correct.
- I certify that I will follow my IRB Approved Protocol.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all applicable federal, state and local laws regarding the protection of human subjects in research.
- I will ensure that the personnel performing this study are qualified and adhere to the provisions of this IRB-certified protocol.

The original signature of the PI is required before this application may be processed (electronic signatures are acceptable).

The original signature of the PI is required before this application may be processed (electronic signatures are acceptable).

Principal Investigator

Date

If the PI is not eligible to serve as PI under the [Campus Administrative Manual](#), the applicable academic dean, institute director, or campus administrative officer indicates their approval of the researcher to act as Principal Investigator. Please note that departmental assurance only needs to be provided in the initial application.

Name of Authorizing Individual

Signature of Authorizing Individual

Date