**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.

About the Facilitated Review Form

This form must be submitted for every project that uses an external IRB. This form is used for the UIUC HRPP to review study information that UIUC is required to review and approve. This application is not reviewed by the IRB, although OPRS staff members conduct the HRPP review on behalf of the institution.

Learn more about Facilitated Reviews at: <https://oprs.research.illinois.edu/glossary/facilitated-review>

How to Use This Form

Instructions

Complete the form.

Include a draft version of the full protocol and consent documents. Although these do not need to be the final IRB-approved versions of the protocol and consent document, they should be finalized draft versions.

Once the UIUC PI has completed the Facilitated Review application, email the completed form to the IRB at: irb@illinois.edu

Section 1: PRINCIPAL INVESTIGATOR (PI)

The Illinois [Campus Administrative Manual](http://cam.illinois.edu/policies/eligibility-to-serve-as-principal-investigator/) 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:

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:

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](https://oprs.research.illinois.edu/forms-templates/forms/research-team-form) along with this protocol. (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](https://oprs.research.illinois.edu/forms-templates/forms/research-team-form))

[ ]  No

Section 3. PROTOCOL TITLE

3.1) Protocol Title:

 Please enter the protocol title below.

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]](#footnote-1)**,**[[2]](#footnote-2)**.
If yes, *please specify*:

[ ]  State of Illinois Department or Agency.

If yes, *please specify*:

[ ]  Other.
If yes, *please specify*:

*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:*

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

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:

6.4) Who will be the IRB of Record for this Study?

Detail below:

Click or tap here to enter text.

Section 7: SUBJECTS

7.1) 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:

Section 8 and Section 9: Draft Protocol and Consent Documents

Include a draft version of the full protocol and consent documents and attach them to this form. Although these do not need to be the final IRB-approved versions of the protocol and consent document, they should be finalized draft versions.

Section 10: RISKS AND BENEFITS

10.1) 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 10.2 below.

10.2) 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:

Section 11: RESOURCES AND RESPONSIBILITIES

11.1) 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:

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)](https://oprs.research.illinois.edu/forms-templates/forms/databases-repositories-form%29)

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> )

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.

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).

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**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**](http://cam.illinois.edu/policies/eligibility-to-serve-as-principal-investigator/)**, 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

1. Clarify whether or not sponsor requires specific language in the contractual agreement that impacts human subjects research [↑](#footnote-ref-1)
2. Clarify whether or not the sponsor requires the protocol adhere to ICH GCP (E6) standards [↑](#footnote-ref-2)