Hello

1.0 General Information

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Creating New: Study

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1.0 General Information

This is the first step in your IRB Application. As you complete this application, you will automatically be guided to the appropriate sections needed to complete your submission.

The questions with a red asterisk (*) are required and must be answered – you will not be able to move to the next page in the application form until you answer any questions that are required.

1. * **Full Study Title:**

2. * **Short Study Title: (Limit to 25 characters. This short title will appear with the IRB number for tracking within AURA)**

3. * **Principal Investigator:**

4. **Primary Contact:**

5. **Co-Investigators:**

Last Name	First Name	Division	Department	Affiliate	CNetID / UCHAD	UChicago ID

There are no items to display

6. **Other Study Staff:**

Last Name	First Name	Division	Department	Affiliate	CNetID / UCHAD	UChicago ID

There are no items to display

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- BSD 1.4 Funding Source
- BSD 1.5 Study Locations

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- BSD 2.2 Purpose
- BSD 8.1 Supporting Documents
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1.2 Research Team Details

1. **Is this study supported by a regulatory support group?**

2. **Select the checkbox for all of the people who will be obtaining consent:**

Role	Person	Division	Department	Affiliate	Consent	CITI Human Subjects Training Completed	Non-CITI Human Subjects Training Completed	Submitted Disclosure Date
Principal Investigator	PI First Name PI Last Name	Biological Sciences Division	MED Hematology & Oncology		☐	6/24/2022		9/15/2023
Primary Contact	Name	Biological Sciences Division	BSD Office of Clinical Res		☐	1/20/2015		
Co-Investigator	Name Last Name	Biological Sciences Division	MED Pulm & Critical Care		☐	7/23/2024		7/22/2024
Co-Investigator	Name Last Name	Biological Sciences Division	NEU Neurology		☐		1/31/2023	4/15/2024
Co-Investigator	Name	Biological Sciences Division	PSY Adult Psychiatry		☐	8/28/2023		7/23/2024
Study Coordinator	Name	Biological Sciences Division	BSD Office of Clinical Res		☐	3/11/2019	11/12/2013	

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1.4 Funding Source

1. * **Funding source(s):**
   (Please check all that apply)
   - [ ] **Internally Funded**
   - [x] **Externally Funded/Supported**

   a. * **Check all external funding sources that apply:**
   - [ ] **United States Federal government agency/department**
   - [ ] **State or local government agency/department**
   - [ ] **Private foundation**
   - [ ] **Subcontract/subaward from another institution**
   - [ ] **Pharmaceutical company**
   - [ ] **Other funding source**

   b. * **Primary external funding source**
   - ○ **To Be Determined**
   - ○ **Grant with Funding Proposals in AURA Grants (select on next page)**
   - ○ **Contract or other agreement in ARTEMIS or Oncore Record (select on next page)**

   Clear

2. * **Who is the study sponsor?**
   - ● **UChicago PI**
   - ○ **Other External Agency**

   Clear

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- BSD 3.2 Drugs
- BSD 3.12 Data

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1.4.1 Funding Source (GRANTS)

1. * **Select your AURA Grant / FP**

   Select...

ID	Name	PI Last Name	PI First Name	Sponsor	Prime Grantee	Status	Submission Deadline

   There are no items to display

2. **Is the purpose of this protocol submission only for the approval of an umbrella grant?**
   ○ **Yes** ○ **No** Clear

3. **If this study involves a grant, but the grant will not be uploaded to this submission, please provide the protocol number under which that grant is approved. For example, if the grant funds multiple projects and has its own IRB number, such as the NCI Alliance grant.**

4. **Upload Grant application**

   + Add

Name

   There are no items to display

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1.4.3 Additional Funding Source

1. **Additional funding sources for study related expenses (study interventions, study drug/device provided at no cost, etc.).**

+ Add

ID	Name	PI Last Name	PI First Name	Sponsor	Prime Grantee	Status	Submission Deadline

There are no items to display

2. **Please list any other additional funding sources that are not associated with an FP in AURA Grants.**

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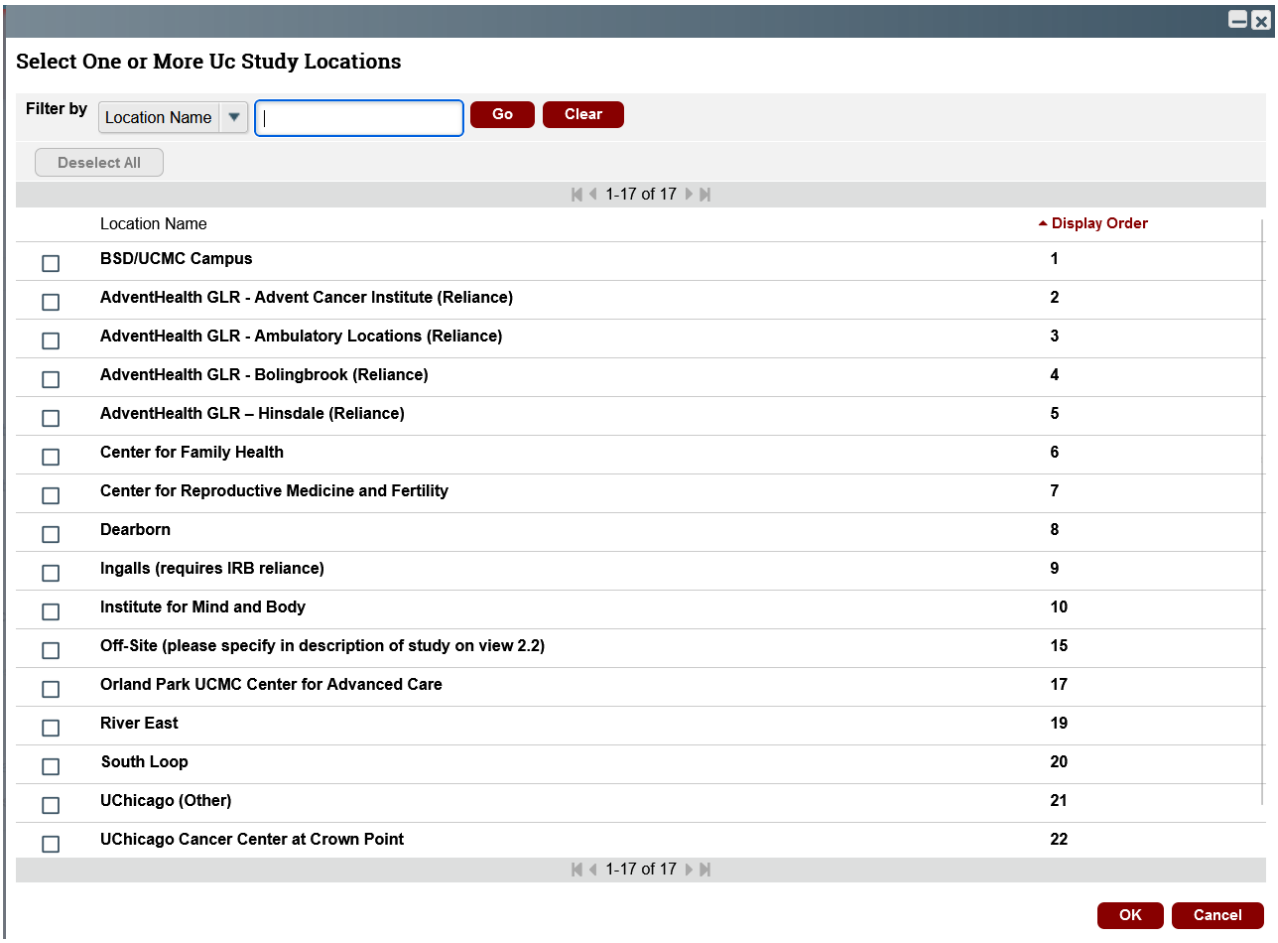
1.5 Study Locations

1. * **Select UChicago locations where this study will be conducted:**

Location Name
BSD/UCMC Campus

2. * **Is this a multi-site study?**
   ○ **Yes** ● **No** Clear
3. * **Are the UChicago researchers conducting this study or any portion of the study at a non-UChicago site (in the United States)?**
   ○ **Yes** ● **No** Clear
4. * **Are the UChicago researchers conducting this study or any portion of the study at an international site (outside the United States)?**
   ○ **Yes** ● **No** Clear
5. **Is another site asking the UChicago to be the IRB of record?**
   ○ **Yes** ● **No** Clear
6. **Are you requesting that an outside IRB (not UChicago) to be the IRB of record for this study?**
   ○ **Yes** ● **No** Clear

Exit Save Continue


Select One or More Uc Study Locations
Filter by
Location Name
Go
Clear
Deselect All
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Location Name
Display Order
BSD/UCMC Campus 1
AdventHealth GLR - Advent Cancer Institute (Reliance) 2
AdventHealth GLR - Ambulatory Locations (Reliance) 3
AdventHealth GLR - Bolingbrook (Reliance) 4
AdventHealth GLR – Hinsdale (Reliance) 5
Center for Family Health 6
Center for Reproductive Medicine and Fertility 7
Dearborn 8
Ingalls (requires IRB reliance) 9
Institute for Mind and Body 10
Off-Site (please specify in description of study on view 2.2) 15
Orland Park UCMC Center for Advanced Care 17
River East 19
South Loop 20
UChicago (Other) 21
UChicago Cancer Center at Crown Point 22
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OK
Cancel

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2.1 Determining the Review Requirements

1. * **Dependent upon your research activities, consideration of this research may be required by other UChicago Committees. Please consider the research categories below and seek approval from the designated Committee if needed.**
Please select any applicable committees below. (Check all that apply)

- ☐ **None of these committees are required to the review this study**
- ☐ **PRMC – Protocol Review and Monitoring Committee - Includes patients with a cancer diagnosis, patients being screened for cancer, cancer treatments or cancer therapies**
- ☐ **PBUC – Pathology Biospecimen Utilization Committee - Use of diagnostic material for research purposes**
- ☑ **CRC – Conducted within the Clinical Resource Center**
- ☐ **ISAP – Conducted with support of the UChicago Institute for Translational Medicine/CTSA**
- ☐ **RADRAC – Radioactive Drug Research Advisory Committee – Reviews the use of radioactive drugs as well as the purchase and use of radioisotopes in humans (including research and routine)**
- ☐ **IBC – Institutional Biosafety Committee - Reviews the research use of biohazardous materials (examples include recombinant DNA, agents infectious to humans, animals or plants and other genetically altered organisms and agents)**
- ☐ **NRC - Nursing Research Committee - responsible for the review of research proposals that are 1) Developed by nurses, 2) Involve UCM nursing employees as research participants, or 3) Involve additional resources to be provided by UCM nursing**
- ☐ **HIRO – Human Imaging Research Office - By checking this box the HIRO office will be informed that you are conducting a human research study involving imaging.**
- ☐ **Other**

2. * **What type of IRB review are you requesting?**
- ○ **Full Board Review (at convened meeting)**
- ○ **Expedited Review**
- ● **Exempt Determination**
- ○ **Not Human Subjects Research Determination**
- ○ **Determination That Project is Not Research (including QI)**
- ○ **Unsure/Do Not Know**

Clear

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a. * **If you believe that your protocol qualifies for exemption, select the category for which you believe it qualifies. The IRB must make the final determination regarding eligibility for exemption.**

Note: To qualify for an exemption, the research must involve no more than minimal risk to subjects and must fall under at least one of the categories below. § 46.102(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The BSD IRB has not recognized exempt categories 7 or 8.

(Choose ALL that apply)

☐	**Exempt Category 1**	**Research, conducted in established or commonly accepted educational settings, which specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.** **Note: Access to student school records for research purposes without a FERPA exception, such as §99.31(a)(6), is not permitted unless the researchers have received prior permission from the student or student's legal guardian** **Research studies do not qualify for this exemption category if the study is likely to adversely affect assessments of teachers or required learning materials for students is not equally provided in a classroom or students are not given materials they ought to have in order to succeed)**
☐	**Exempt Category 2**	**Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met. Please check each applicable box:** **Note: Exemption category #2 is only applicable for children/minors under either c only if their in**

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		educational tests or observation of public behavior when the researcher does not participate in the activities observed - check the box to see criteria details)
☐	***Exempt Sub-Category 2.i***	***The information obtained is recorded by the research team in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.***
☐	***Exempt Sub-Category 2.ii***	***Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation. Disclosure of data will not be harmful to subjects or population groups.***
☐	***Exempt Sub-Category 2.iii***	***The information obtained is recorded by the research team in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by the Common Rule at §46.111(a)(7). Please note that in order for the IRB to conduct a limited review additional information is required. Please select "Expedited Review" rather than "Exempt Determination" in View 2.1 of the AURA submission form and resubmit after answering all additional questions.***
☐	**Exempt Category 3**	**Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.** **For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to alloca of received ca**

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		themselves and someone else. **If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.** **The protocol study must meet at least one of the following criteria:**
☐	***Exempt Sub-Category 3.i***	***The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;***
☐	***Exempt Sub-Category 3.ii***	***Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or***
☐	***Exempt Sub-Category 3.iii***	***The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by§46.111(a)(7). Please note that in order for the IRB to conduct a limited review additional information is required. Please select "Expedited Review" rather than "Exempt Determination" in View 2.1 of the AURA submission form and resubmit after answering all additional questions.***
☐	**Exempt Category 4**	**Secondary research use of identifiable private information and identifiable bio specimens for which consent is not required, and if at least one of the following criteria is met:**
☐	***Exempt Sub-Category 4.i***	***The identifiable private information or identifiable bio specimens are publicly available;***
☐	***Exempt Sub-Category 4.ii***	***Information, which may include information about bio specimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, th contact the subj***

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		will not re-identify subjects;
☐	***Exempt Sub-Category 4.iv***	***The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44U.S.C. 3501 et seq.***
☐	**Exempt Category 5**	**Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.** **Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a l and demonsti**

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		the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
☐	**Exempt Category 6**	**Taste and food quality evaluation and consumer acceptance studies:**
☐	***Exempt Sub-Category 6.i***	***If wholesome foods without additives are consumed, or***
☐	***Exempt Sub-Category 6.ii***	***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.***

NOTE: Exempt category 4.iii is not permissible at this site.

b. * **Please provide the purpose and a brief description of the study. Please also clarify what role researchers at the UChicago will complete as part of this study and provide a rationale for the exempt category claimed for this research.**

The justification must include how this study is minimal risk and a specific description of the procedure(s) involving the human subjects in sufficient detail to demonstrate that the research protocol meets the requirements for each category of exemption claimed for this protocol.

c. **Please attach any documents that provide justification or support of the exempt category or categories listed above (e.g. protocol, data permissions, etc.). If you selected Exempt category 2 or 3, please ensure that all surveys and/or interviews scripts are uploaded, as well as any consent script(s) or form(s).**

+ Add

Name

There are no items to display

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Final Page

Please take this opportunity to review the information you have provided. It is very important that the responses in this protocol be thorough and specific. Failure to respond to all requested items, to submit required documents, or complete all personnel training will result in a delay in the review of this protocol and may result in the protocol being returned to the study team for correction or completion. Thank you for completing the information required to submit this IRB Study.

THIS APPLICATION IS NOT YET SUBMITTED.

ONLY THE PRINCIPAL INVESTIGATOR (PI) of the protocol may submit the application for review. If you are the PI, you must click the SUBMIT activity on the study workspace to initiate the review of the submission.

Submit to IRB

1.0 ☐ * I certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only with the approved principal investigator and, if any, co-investigator(s). All records of this research will be maintained as required by the University of Chicago's policies and procedures.

In addition, I agree to the responsibilities of a PI, per University guidelines, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting Unanticipated Problems to the IRB per the IRB Unanticipated Problem reporting policy.
- Obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Performing all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- No changes will be made in the protocol or consent form until approved by the IRB.

2.0 **Enter comments below, if applicable:**

3.0 * **Does the work proposed involve any data, materials, drugs or devices from a company in which you have a financial interest or in the case of a corporate sponsor have you received any payments, stock or equity from this sponsor in the past 2 years?**

Link to policy: UChicago COI Policy

◯ **Yes** ◯ **No** Clear

4.0 **To the best of your knowledge, is the work described in this proposal related to an outside financial interest of any Co-Investigators or Other Research Personnel?**

◯ **Yes** ◯ **No** Clear

5.0 **If yes to question 3 or 4, please describe below or attach a memo or letter to explain to the IRB Committee the conflict as it relates to the specific study being proposed.**

Note that this memo will be accessible to all members of the research team. If you do not wish all members of the research team to have access to this memo, please send it to the IRB administrator assigned to this submission (after this study has been submitted) as an email.

+ Add

Name

There are no items to display

6.0 **If yes to question 3 or 4, has this conflict of interest been disclosed to University Research Administration (URA)?**

◯ **Yes** ◯ **No** Clear

If yes, note IRB has access to the final management plan and will consult this plan when reviewing this study.

If no, contact URA to disclose this conflict.

Click OK to submit to the IRB for review. Click Cancel to return.

OK **Cancel**