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
- BSD Final Page

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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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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

Exit Save Continue

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1.4.2 Funding Source (ARTEMIS or Oncore)

Please select the appropriate Artemis or Oncore Record:

1. **Select the ARTEMIS contract or agreement:**

Select...

ID	Name	PI	Sponsor	Status	Primary Funder	All Funders	Associated Agencies

There are no items to display

2. **Select an Oncore Record:**

ID	Title	PI	Funder	Status

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.**

Exit Save Continue

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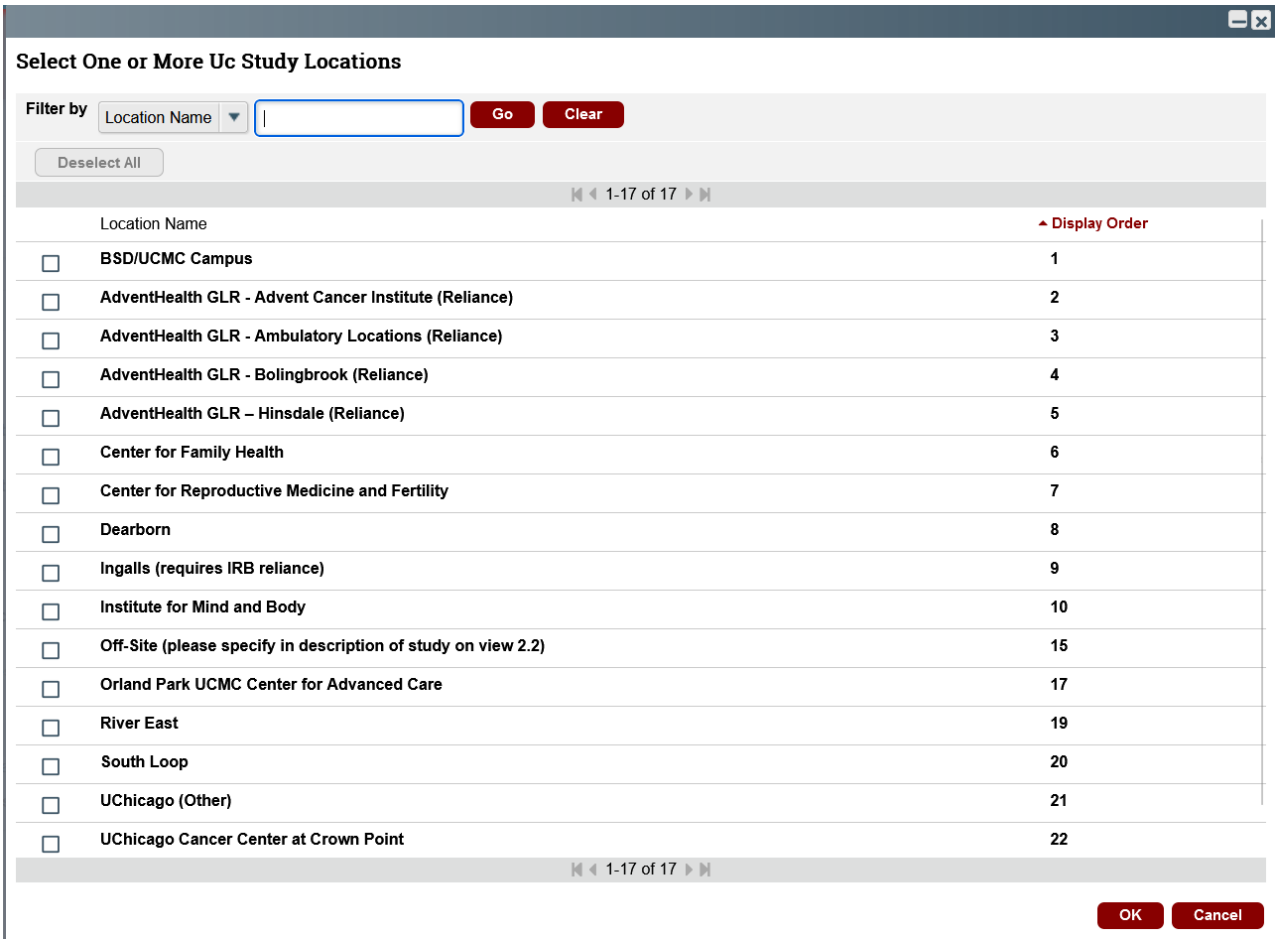
1.5 Study Locations

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**
- [x] **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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BSD 2.1 Determining the Review Requirements

a. * **Is your study a systematic investigation, including research development, testing and evaluation that will develop or contribute to generalizable knowledge?**
● **Yes** ○ **No** Clear

b. * **Will you gather data through either of the following mechanisms:**
a. Physical procedures or manipulations of those individuals or their environment ("intervention").
b. Communication or interpersonal contact with the individuals. ("interaction").
● **Yes** ○ **No** Clear

STOP - This is likely research with human subjects, please revise your response to question 2 'Full review', 'expedited review', 'exempt determination' or 'Unsure/Do Not Know.'

c. * **Will you gather or access data that is either:**
a. About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information").
b. Provided by individuals for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record, insurance information, school information, etc. (i.e. "Private information").
● **Yes** ○ **No** Clear

STOP - This is likely research with human subjects, please revise your response to question 2 'Full review', 'expedited review', 'exempt determination' or 'Unsure/Do Not Know.'

d. * **Can you readily ascertain or associate individuals' identities with the information (i.e., "Identifiable information")?**

By answering "No," you must meet the HIPAA definition of 'de-identified' which cannot include dates or other elements of PHI.
● **Yes** ○ **No** Clear

STOP - This is likely research with human subjects, please revise your response to question 2 'Full review', 'expedited review', 'exempt determination' or 'Unsure/Do Not Know.'

e. **If you will ONLY conduct secondary data analysis, answer the following questions:**
i. Are the data already collected?
ii. When was the data collected?
iii. Who collected the data?
iv. Are the data publicly available? If yes, please provide the website where you will access the data. If the data is not publicly available, please provide an official permission signed by the data owner or data manager and attach as part of question 2-h.

f. **If you will only use de-identified data for analysis, who will de-identify the data for you? Will the person who de-identifies the data for you work as a researcher for your study? Who will maintain the code for the data?**

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See the OHRP guidance document for questions regarding coded, private information. The document can be found on the OHRP website.

g. **Please describe the main purpose of this study. Please also clarify what role researchers at the UChicago will complete as part of this study.**

h. **Please attach any supporting documents for justification of Non-Human Subject research.**

+ Add

Name

There are no items to display

Exit Save Continue

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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**