Hello

1.0 General Information

You Are Here: _Protocol

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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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**

View 1.4.1 will appear if "Grant with Funding Proposals in AURA Grants" is selected. View 1.4.2 will appear if "Contract or other agreement in ARTEMIS or Oncore Record" is selected.

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

a. * **If study is sponsored by an External Agency, please indicate the sponsor name :**

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

There are no items to display

2. * **Is this a multi-site study?**

● **Yes** ○ **No** Clear

a. **Is UChicago the coordinating center for this study? OR is the UChicago PI responsible for the overall conduct of the study at other sites?**

● **Yes** ○ **No** Clear

1. **If UChicago is the coordinating site, please attach the letter of IRB approval, support or cooperation from each site.**

+ Add

Name

There are no items to display

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

a. **Please specify other research sites in the United States where this research is being conducted and overseen by the UChicago PI:**

+ Add

Name of Site | Street Address | City | State | Type of Site

There are no items to display

b. **Please describe research activities being conducted at all sites. If the activities are the same as those conducted at the UChicago, please simply state that fact. If activities will differ, please specify how they will differ for each site.**

c. **Please attach the letter of IRB approval, support or cooperation from each site.**

+ Add

Name

There are no items to display

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

a. **Please specify the international sites where the research is being conducted and overseen by the UChicago PI:**

+ Add

Name of Site | Street Address | City: | Country | Type of Site | Local Revi | Ethics | FWA | Contact

Name of Site	Street Address	City:	Country	Type of Site	Review	Board Name	#	Info

There are no items to display

b. **Please attach Ethics or IRB Committee Review Document(s) for each site listed or attach memo(s) to explain why this has not been obtained.**

+ Add

Name

There are no items to display

c. **Describe your previous experience in this setting and/or your knowledge of this local research context.**

d. **Who will be conducting study activities at this international site? Please specify if UChicago faculty or staff will be conducting research here and/or will be present while others conduct research.**

5. **Is another site asking the UChicago to be the IRB of record?**

● **Yes** ○ **No** Clear

a. **What site(s) are requesting that UChicago relies upon our IRB?**

Full Name	External Key	Agency Abbreviation	Org Class

There are no items to display

b. **Please describe research activities being conducted at all sites. If the activities are the same as those conducted at the UChicago, please simply state that fact. If activities will differ, please specify how they will differ for each site.**

c. **Please attach request from other site(s) and/or describe existing authorization agreement between UChicago and the other site(s).**

+ Add

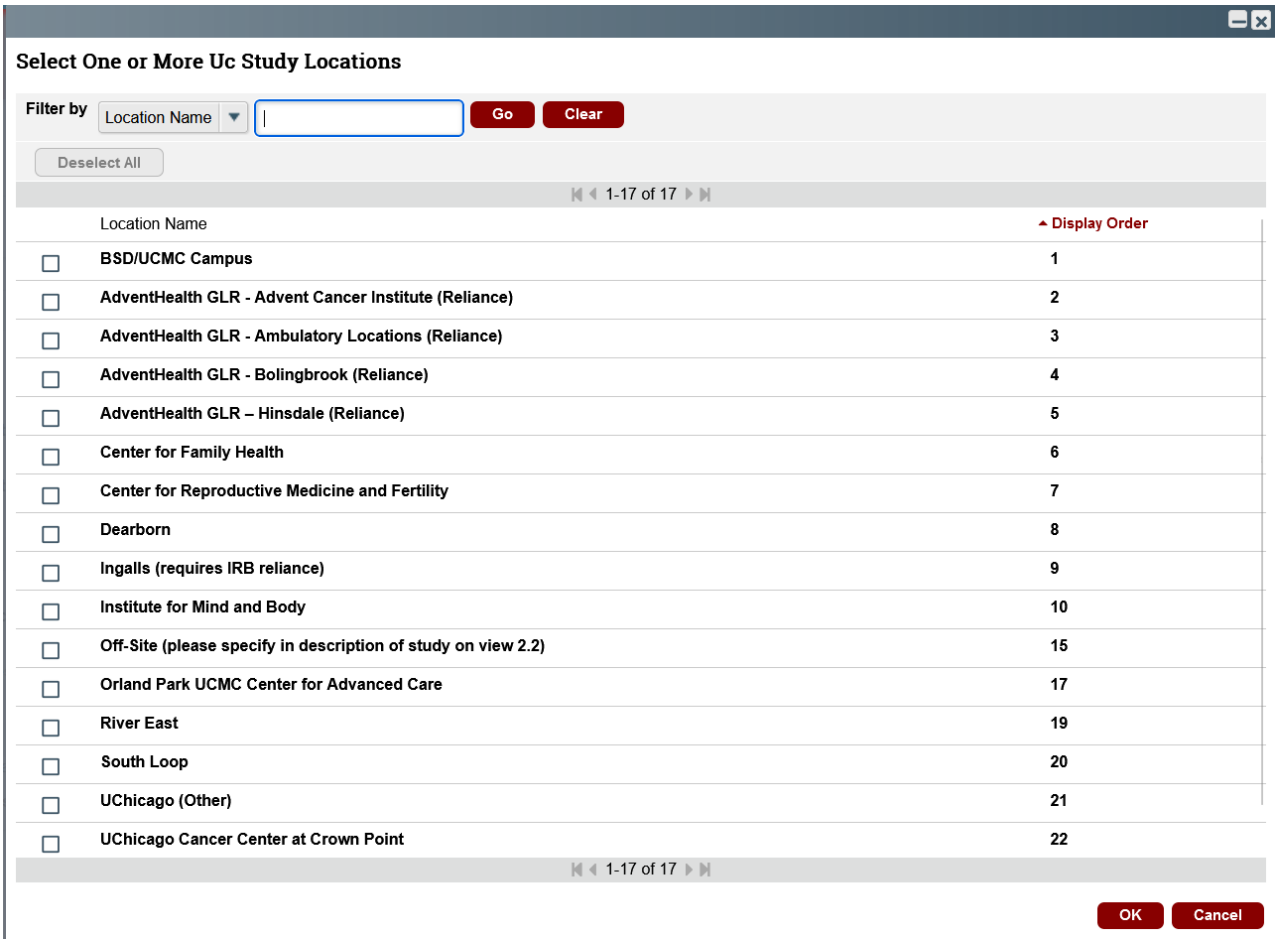
Name

There are no items to display

6. **Are you requesting that an outside IRB (not UChicago) to be the IRB of record for this study?**

● **Yes** ○ **No** Clear

STOP - Please complete the CIRB submission form by exiting this form. 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
1-17 of 17
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**
- [x] **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.**
- [x] **Other**

a. **Please indicate the name(s) of applicable committee(s).**

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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

Exit Save Continue

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  - BSD 5.1 Risks
  - BSD 5.2 Data Confidentiality and Privacy
  - BSD 6.1 Benefits

An additional view will appear for most of the options other than "none" when selected in question 1, e.g. view 3.2 will appear if "Use of Drugs" is selected, view 3.11 will appear if "Specimen Collection or Analysis" is selected, etc.

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2.2 Purpose

1. * **What research procedures does the study involve?**
   Please check all that apply, including the main purpose and any other procedures that may occur on the study.
   - [X] **Use of Drug(s)**
   - [ ] **Use of Medical Device(s)**
   - [ ] **Use of Biologic(s)**
   - [ ] **Use of Vitamin/Herbal Supplement(s)**
   - [ ] **Novel Surgical, Radiological, or Clinical Intervention**
   - [ ] **Stem Cell Research**
   - [ ] **Radiation exposure other than clinically indicated tests and/or therapy**
   - [ ] **Recombinant DNA/ Gene Transfer**
   - [ ] **Surveys/Questionnaires**
   - [ ] **Interviews/Focus Groups**
   - [ ] **Deception**
   - [ ] **Observational Research**
   - [X] **Specimen Collection and/or Analysis**
   - [X] **Data Collection/Chart Review/Secondary Data Analysis**
   - [ ] **None of the above (explain in question 4)**
2. * **Please provide a brief, non-technical (lay) language description of the purpose of the research, including the research question.**
3. * **Please provide an explanation of how this study will contribute to existing knowledge. Please include relevant citations of previous studies that provide a justification for this study. If the relevant citations are in the attached protocol document, please only provide a reference to the applicable section(s) and/or page numbers.**

Exit | Save | Continue

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Views 3.1, 3.13, 5.5, 6.2, and 6.3 will appear if "yes" is chosen in question 5.

4. * **In non-technical language, describe the tasks/tests or procedures subjects will be asked to complete or undergo. Explain step by step what subjects will be asked to do; be sure to distinguish those tasks which are experimental from those which are not being done specifically for research-purposes, as applicable. If subjects are not actively participating in the research (for example, this is a leftover sample collection protocol, chart review, or secondary data analysis), describe what will be done with samples and/or data as well as how they will be obtained.**

5. * **Will the research team have any direct interaction (including on-line interaction) with the research subjects?**
   ● **Yes** ○ **No** Clear

6. * **Is this a resubmission of a previously approved study that has been terminated or has expired?**
   ● **Yes** ○ **No** Clear

   a. * **What is the previous IRB number?**

   b. * **The preliminary results of the project, if any:**

   c. * **Any complaints about the research from subjects:**

Exit Save Continue

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BSD 1.4.2 Funding Source ARTEMIS

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d. * **Any new information regarding the risks to subjects (such as literature search results or new publications) received since the cessation of approval:**

e. * **All unanticipated problems that occurred at the UChicago:**

f. * **Was any research conducted during the lapse in approval:**

g. * **Reason why the study is being resubmitted:**

Exit Save Continue

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Questions a-g appear if "yes" is selected in question 6.

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3.1 Recruitment and Screening

1. * **How will you identify or screen potential subjects to recruit/include in this study? (Check all that apply)**
   - [x] **Advertisements**
   - [x] **Identifying UCMC patients (including medical record screening)**
   - [x] **Ingalls patients**
   - [ ] **Research Match**
   - [x] **Existing research registry**
   - [x] **Other**

   a. * **Describe details of advertisements where applicable, including names of relevant publications, websites, etc. (For example, please provide the name of the newspaper or location where flyers would be posted.)**

   b. * **Please attach all recruitment documents.**

   + Add

Document	Recruitment Document Type
There are no items to display	

   c. **Please upload the script to be used when potential subjects respond to an ad (e.g. phone script). (If applicable)**

   + Add

Name
There are no items to display

   d. * **What data will be accessed to determine eligibility? (Check all that apply)**
   - [ ] **Name**
   - [ ] **Address**
   - [ ] **Dates**
   - [ ] **Ages over age 89**
   - [ ] **Telephone numbers**
   - [ ] **Fax numbers**
   - [ ] **Email addresses**
   - [ ] **Social security numbers**
   - [ ] **Medical record numbers**
   - [ ] **Health plan beneficiary numbers**
   - [ ] **Account numbers**
   - [ ] **Certificate/license numbers**

Exit | Save | Continue

Questions a-c will appear if "Advertisements" is selected in question 1.

Questions d-h will appear if "Identifying UCMC patients" or "Ingalls patients" is selected in question 1.

Question i will appear if "Existing research registry" is selected in question 1.

Question j will appear if "Other" is selected.

- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [ ] Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification

e. * **Please describe why the identifiers are necessary for screening.**

f. * **Please provide written assurance that you will not reuse the identifiers accessed during screening. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study). For example, please state the following: "I will not re-use identifiers collected or used during the study for other purposes."**

g. * **Please confirm that the use of identifying information during screening is no more than minimal risk to the individuals' privacy.**

- ○ Yes, confirm
- ● No, cannot confirm

Clear

STOP, contact IRB office.

h. * **Did the individual provide permission to allow the use/disclosure of the individual's identifying information for screening?**

- [x] Yes, patient has provided authorization
- [x] No
- [x] Unknown

Question i will appear if "Yes, patient has provided authorization" is selected in question 1.h.
Questions ii-iv will appear if "No" or "Unknown" is selected in 1.h.

i. * **Please provide protocol number under which patient provided authorization for future use of PHI.**

ii. * **Please describe how you will protect the identifiers from improper use or disclosure.**

iii. * **Please describe your plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**

iv. * **Please clarify why the research could not practicably be done without collecting this PHI prior to subject enrollment.**

i. * **Please provide protocol number associated to the existing research registry.**

j. * **If "Other" was selected in question 1, please describe the recruitment method and specify who would make initial contact with the potential subject.**

2. * **Please specify who will make initial contact both over the phone (if applicable) and in person with the potential subject, including if the treating physician will be involved.**

Question a will appear if "Experimental" is selected in question 1. Question b will appear if "FDA approved drugs" is selected in question 1.

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3.2 Drugs

1. * **Please select the types of drugs that will be administered in this study (check all that apply):**
   - [x] **Experimental/Investigational Drugs**
   - [x] **FDA approved drugs (used for approved use or unapproved use)**

   a. * **Please list all experimental drugs to be administered in this study:**

   + Add

Drug Name	Manufacturer	IND Holder	IND #
There are no items to display			

   b. **Please list all approved drug(s) to be administered in this study:**

   + Add

Drug Name	Generic Name	Manufacturer	Off-Label Use	IND#	IND Exempt	IND Holder
There are no items to display						

Off-Label, IND exempt, and IND questions will appear in a popup

2. * **Please attach investigator brochure or package insert for each of the drugs listed above.**

   + Add

Name
There are no items to display

3. **Drug Phase:**
   - ( ) **Other**
   - ( ) **Pilot**
   - ( ) **Phase I**
   - ( ) **Phase I/II**
   - ( ) **Phase II**
   - ( ) **Phase II/III**
   - ( ) **Phase III**
   - ( ) **Phase III/IV**
   - ( ) **Phase IV/Post-Approval**

   Clear

   a. **Please explain the drug phase "Other":**

4. * **Does this study involve a washout period of previous medications or drugs after subject have consented?**
   ● **Yes** ○ **No** Clear

   a. **Please describe the washout period (e.g. length of time, requirements for subject, etc.).**

   b. **Please describe the risks associated with the washout.**

   c. **Please describe the plan for minimizing the washout risks outlined above.**

5. * **Does this study involve the use of a placebo or no-treatment arm?**
   ● **Yes** ○ **No** Clear

   a. **Please describe any risks to participants in the placebo or no-treatment arm of the study. Please include information as to whether those on the placebo arm may also receive standard of care drugs either on or off study.**

   b. **Please provide a scientific or ethical justification for using a placebo or no-treatment arm. (If the justification is in the separate protocol document, please reference the specific pages.)**

6. * **Will arrangements be made for the Pharmacy Department to receive or dispense the drugs involved in this study?**
   ○ **Yes** ● **No** Clear

   a. **Where and how will the drug be stored and other than the PI, who is responsible for drug storage?**

   b. **Who is the contact person for drug management?**
   PLEASE NOTE: This individual should be listed on the AURA submission as a co-investigator or other research personnel.

Add UcDrugDetails

Experimental Drugs

1. * **Name of Drug:**

2. * **Manufacturer:**

3. **IND Holder:**

5. **IND #:**

Options in question 3 dropdown:
- PI
- Co-investigator
- Sponsor
- Funder
- Drug Manufacturer
- Non-U of C Investigator

* Required

OK | OK and Add Another | Cancel

Add UcDrugDetails

FDA Approved Drugs

1. **Drug Name:**

2. **Generic Name:**

3. **Manufacturer:**

4. **Is this drug being used Off-Label?**
   ● **Yes** ○ **No** Clear

   a. **Is the drug being used in this study IND Exempt?**
   ○ **Yes** ● **No** Clear

   i. **IND Number:**

   ii. **IND Holder:**

Options in dropdown in 4.a.ii:
- PI
- Co-investigator
- Sponsor
- Funder
- Drug Manufacturer
- Non-U of C Investigator

* Required

OK | OK and Add Another | Cancel

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3.11 Specimen Collection and/or Analysis

1. * **What type of specimens will be involved in this study? (Check all that apply)**
   - [x] **Existing (already sitting on the shelf at the time of initial IRB submission)**
   - [x] **Prospective (will be collected)**

Questions a-c will appear if "Existing" is selected in question 1. Question d will appear if "Prospective" is selected.

a. **What is the date range when these existing specimens were originally collected?**

Beginning Date:

End Date:

b. **Why were these existing specimens originally collected? (check all that apply)**
- [ ] **Clinical purposes**
- [x] **Research purposes under a different study**
- [ ] **Commercial (for profit) purpose**
- [ ] **Unknown**

i. **If "Research purposes under a different study," provide name of study, where study was conducted, and UChicago IRB number (if applicable).**

c. **Did the subjects agree to allow their samples to be used for future research purposes?**
- (●) **Yes** ( ) **No** Clear

i. **How was this agreement documented? If subjects consented under a research protocol, please provide the IRB number.**

d. **What type of specimens will be prospectively collected? (check all that apply)**
- [ ] **Leftover specimens that were obtained for clinical purposes (no additional research procedures required)**
- [ ] **Specimens obtained specifically for research purposes-additional taken during a clinical procedure**
- [ ] **Specimens obtained specifically for research purposes-obtained via a separate collection procedure done solely for the purposes of the study**
- [ ] **Commercial (for profit) specimens**

2. * **What type of specimens will be analyzed? (Check all that apply)**
   - [ ] **Blood**
   - [ ] **Tissue**
   - [ ] **Bone Marrow**
   - [ ] **Cells from Swabs**
   - [ ] **Urine**
   - [x] **Other**

a. **If "Other," indicate type of specimen(s).**

3. * **How are the specimens labeled? For example, do they contain name, initials, date of birth, Social Security number, medical record number, or any other unique code?**

4. * **Will HIV or Hepatitis testing be done on the specimens?**
If yes, please include mandatory reporting to the State of Illinois language in the consent form.
○ Yes ○ No Clear

5. * **Will genetic analysis/testing be done on any of the specimens?**
● Yes ○ No Clear

View 3.11.1 will appear if "yes" is selected in question 5.

6. * **Are there plans for, or could the research involve, whole genome sequencing (i.e., sequencing of a human germline or somatic specimens with the intent to generate the genome or exome sequence of that specimen)?**
● Yes ○ No Clear

Please include this disclosure in the consent form.

View 3.11.2 will appear if "yes" is selected in question 7.

7. * **Will this study involve banking of specimens (storing for future research use)?**
● Yes ○ No Clear

8. * **With whom will you share specimens? (Check all that apply) Note, if specimens will be shared outside UChicago, a contract, grant, or material transfer agreement (MTA) should be place outlining sharing of specimens.**
- ☑ Other UChicago Investigators
- ☑ Investigators outside of UChicago
- ☑ Sponsor
- ☑ NIH
- ☐ N/A - no specimens will ever be shared

Questions a-b will appear if any option other than "N/A" is selected in question 8.

a. **Describe how the specimens will be shared, what information will be shared with the specimens, including how specimens are labeled, and specify with whom the specimens will be shared.**

b. **Will the UChicago principal investigator determine with what other investigators the specimens may be shared?**
○ Yes ○ No Clear

9. **Will samples from the UChicago Medical Center Pathology Department be used?**
○ Yes ○ No Clear

10. **What will happen to specimens at the end of the study? If specimens will not be destroyed, where and how will they be stored? What will happen to identifiers associated with those specimens (i.e. will samples be de-identified and links to identifiers removed)?**

11. **Are there specific plans to develop cell lines from the specimens?**

Yes No Clear

12. **Are there plans for commercial products to be developed from the specimens? Does the contract or protocol include plans for development of commercial products?**

Yes No Clear

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3.11.1 Genetic Analysis

1. * **Are there plans for subjects to receive any information resulting from the genetic analysis?**
   ● **Yes** ○ **No** Clear

   a. **If "Yes," describe the information that subjects will receive.**
   Please note: genetic analysis results should only be shared if the testing will be performed in a CLIA certified lab.

2. * **Will the genetic analysis possibly result in any genetic information related to the subject's (or his/her relatives') health or susceptibility to a disease or condition currently or in the future?**
   ● **Yes** ○ **No** Clear

   a. **Please explain what information will be made available. In addition, please state whether the results will be shared with the subject's relatives.**

3. **If samples are existing samples, did subjects originally consent to genetic analysis on their samples?**
   ○ **Yes** ● **No** Clear

   a. **Please explain whether subjects consented to use of samples for any purpose and why they did not consent to genetic analysis.**

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3.11.2 Specimen Banking

1. * **Where will the specimens be banked (stored)?**

2. * **Who will have oversight over the stored specimens and/or data?**

3. * **Who will have access to the banked specimens? (check all that apply)**
   - ☐ **UChicago Investigators (this study team)**
   - ☐ **UChicago Investigators (not part of this study team)**
   - ☐ **Investigators outside of UChicago**
   - ☐ **Sponsor**
   - ☐ **Funder**

4. **How long will the specimens be stored?**

5. **How will stored specimens be labeled? Please specify if specimens will be labeled with any identifiers.**

6. **Are participants in the study allowed to request their specimens be destroyed?**
   ○ **Yes** ● **No** Clear

   a. **If the samples are not de-identified, please explain why subjects will not be able to withdraw specimens or ask that they be destroyed.**

7. **Will these specimens be banked under a separate repository protocol?**
   ● **Yes** ○ **No** Clear

   a. **Please provide the UChicago IRB number or attach a copy of the IRB approval for the repository, if it is housed at a different institution.**

+ Add

Name

There are no items to display

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3.12 Data Collection

1. * **What type of data will be collected/analyzed in this study? (Check all that apply)**
   - [x] **Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)**
   - [x] **Prospective (data is not yet in existence and/or collected)**

Questions a-b will appear if "Retrospective /Secondary Analysis" is selected in question 1. Help text in italics ("Informed consent from the research subject ...") will appear if "Prospective" is selected in question 1.

a. **What is the date range when the existing data were originally collected?**

Data collected outside of this date range may not be utilized for research purposes after IRB approval without additional approval from the IRB.

Beginning Date:

End Date:

b. **What outcomes data will be collected? If applicable, please confirm that any outcomes data to be used in the research were also collected during the above specified time period.**

Informed consent from the research subject is typically required for prospective data collection. You may be asked more questions about obtaining consent/assent in section 7.

2. * **What is the source(s) of the data that will be collected and/or used during the study (as opposed to during screening or for feasibility)?**
   - [ ] **UCM Medical records (Manual viewing/abstraction)**
   - [ ] **Ingalls Medical records (manual viewing/abstraction)**
   - [ ] **EPIC Downloads (i.e. Slicer Dicer, Reporting Workbench, etc.)**
   - [ ] **Medical images**
   - [ ] **CRI (Clinical Research Data Warehouse)**
   - [ ] **Commercial (for profit) entity**
   - [x] **Data collected under a different research study**
   - [ ] **Publically available records**
   - [ ] **From subject self-report**
   - [ ] **Federal dataset, e.g. dbGap, Framingham dataset, etc.**
   - [x] **Other**

Question a will appear if "Other" is selected in question 2. Question b will appear if "Data collected under a different research study" is selected.

a. **If "Other," please indicate the source of the data.**

b. **If data was collected under a different research study, please provide the name of study, where the study was conducted, and the UChicago IRB number (if conducted here).**

3. **Were data collected using a limited data set (LDS) - (PHI in data is limited to dates and/or zip codes)?**
   ● **Yes** ○ **No** Clear

   a. **If you will be using a limited data set (LDS), please attach the Data Use Agreement (DUA).**
   + Add

   Name

   There are no items to display

4. * **Will this study involve adding data to a registry or database?**
   ● **Yes** ○ **No** Clear

   a. **What is the name and purpose of the registry that the data will be added to?**

   b. **Who has oversight over the registry?**

   c. * **Who will have access to the registry? (check all that apply)**
   - ☐ **UChicago Investigators**
   - ☐ **Investigators outside of the UChicago**
   - ☐ **Sponsor**
   - ☐ **Funder**
   - ☐ **Public**

   d. **How long will the data be stored in the registry?**

   e. **Are participants in the study allowed to request that their data be removed?**
   ○ **Yes** ● **No** Clear

   i. **Please explain why subjects will not be able to request that their data be removed.**

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3.13 Costs and Compensation

1. * **Does this study involve clinical care expenses that are either billed to the patient, their insurance, or to research?**
   ○ **Yes** ○ **No** Clear

2. * **Will the subjects be charged for any research-related procedures?**
   (For example, will subjects be charged for extra tests related to the research? Note that in general, subjects should NOT be charged for procedures that are specific to the research and are not part of their standard of care.)
   ● **Yes** ○ **No** Clear

   a. **If "Yes," explain the charges below.**

3. * **Will subjects be paid or otherwise compensated for participation in the study?**
   ● **Yes** ○ **No** Clear

   a. **How much will subjects be compensated (total and prorated amounts) and how (gift card, cash, check, etc.)?**

   b. **When will subjects receive the compensation (e.g. after each study visit, at the end of the study, etc.)?**

   c. **If payment will not be prorated, provide a justification as to why not.**

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4.1 Study Population

1. * **Select the population(s) that will be studied from the list of vulnerable populations below. (Please check all that apply)**

- [ ] Healthy Children (under the age of 18)
- [ ] Children with a Disease, Disorder, or Condition (under the age of 18)
- [ ] Wards of the State
- [ ] Prisoners
- [ ] Pregnant Women, Fetuses
- [ ] Placenta, Dead Fetus, or Fetal Material
- [ ] Nonviable Neonates
- [ ] Neonates
- [ ] None of these vulnerable populations will be enrolled in the study

An additional view will appear if any option other than "None" is selected in question 1, e.g. view 4.1.1 will appear if "Healthy Children" is selected.

2. **Please select any additional populations that will be studied. (Please check all that apply)**

- [ ] Healthy Adult Volunteers
- [ ] Decisionally Impaired Individuals
- [ ] Individuals with Intellectual Disability
- [ ] Non-English Speakers
- [ ] Subordinates of the Research Team or Employees of the UChicago or the UCMC, including medical students, residents, fellows, and staff
- [ ] Undergraduate Students of the UChicago
- [ ] Illiterate Subjects
- [ ] Chicago Public School (CPS) students
- [ ] None of the above populations will be enrolled in the study

An additional view will appear for selections of Decisionally Impaired (view 4.2), Non-English Speakers (view 4.9), Subordinates (view 4.3), and Undergraduate Students (view 4.4).

3. **What are the inclusion criteria?**

4. * **Describe any populations to be excluded from the research.**
Research should involve equitable selection of subjects; researchers should not select subjects on the basis of discriminatory criteria. Selection criteria that excludes individuals based on age, gender, language or racial or ethnic group requires a clear, scientific rationale for the exclusion.

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Directions will appear to describe the consent process for Individuals with Intellectual Disability or Illiterate Subjects in section 7.1 if these populations are selected. Note, if there are multiple study populations, describe procedures that differ from the consent process for other populations. If CPS students will be studied, upload IRB approval documentation from CPS in 8.1.

5. * **Please provide the number of subjects to be enrolled (this is the expected number of subjects needed to complete all study procedures).**

6. * **In order to enroll this number of subjects, will you be screening 50 or more patient records?**
○ Yes ○ No Clear

7. **Please specify the exact age range to be enrolled.**
For example, 0-6 months, 18 and up, 18-24 yrs, etc.

8. **If applicable, please provide more information regarding multiple study groups and the total number of subjects needed for each group. (e.g. 100 healthy children and 100 children with autism or chart review of 100 subjects and prospective enrollment of 100 subjects)**

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5.1 Risks

1. * **Please describe the risks associated with the study. Include consideration of physical, psychological, financial, social, legal and other factors. Please include any non-physical risks (risks to employment, loss of confidentiality, etc.). For studies that involve a drug or device, if data are available, estimate expected frequency, degree of severity, and potential reversibility, including any potential late effects.**

2. * **Please describe the precautions that will be taken to minimize risks/harms, including rescue provisions, if applicable.**

3. * **Please provide a specific explanation as to why the identified risks are reasonable. Risks may be justified in relation to the anticipated benefit to subjects and/or in relation to the importance of that knowledge that may reasonably be expected to result from the research.**

4. **Is there a possibility for incidental findings as a result of this research? If so, please describe and explain how findings would be communicated to the subject, as applicable.**

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5. **If applicable, please describe the process that will be followed if subjects disclose or it has been found that there is intent to harm themselves or others.**

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In question 1:
- question b will appear by selecting "Electronic"
- View 5.3 will appear by selecting "Audio/Video"
- question a will appear by selecting "Other"

5.2 Data Confidentiality and Privacy

1. * **How will research data be collected and stored?**
   - [ ] **Paper**
   - [x] **Electronic (see BSD Information Security Policy)**
   - [x] **Audio/Video recording**
   - [x] **Other**

   a. **If "Other", please specify:**

   b. **Please specify the electronic means by which you will collect and store your data:**

☐	**RedCap (BSD Center for Research Informatics (CRI))**
☐	**Center for Research Informatics (CRI)**
☐	**University of Chicago Box**
☐	**Datamart**
☐	**Research Computing Center (RCC) Secure Data Enclave (SDE)**
☐	**Research Computing Center (RCC) other infrastructure**
☐	**Self-managed laptop(s)/desktop(s)**
☐	**Unit-managed laptop(s)/desktop(s)**
☐	**Sponsor or 3rd party Database**
☐	**Database or similar on an approved encrypted storage device**
☐	**Cloud account (e.g. AWS, Google Cloud, MS Azure, MS O365 One drive) managed by the University.**
☑	**Other**

Exit Save Continue

i. **You've selected other electronic data source - please specify:**

2. * **Explain what security measures will be in place for non-electronic research data (e.g. locked office, locked files, etc.) and who will have access to these data.**

3. * **Will data be shared with other UChicago investigators or with investigators outside of UChicago?**

- [x] **UChicago Investigators**
- [ ] **Investigators outside of UChicago**
- [ ] **Funder**
- [x] **Sponsor**
- [ ] **N/A-data won't be shared**

Any selection other than "N/A" will cause questions a-c to appear.

a. **Describe how the data will be shared and specify with whom it will be shared.**

b. **Will the UChicago principal investigator determine with what other investigators the data may be shared?**

○ **Yes** ● **No** Clear

i. **If "No," who will have control of the data and decide with whom it is shared?**

c. **What data will be shared? Please explain whether identifiable data will be shared, whether all identifiers will be removed before sharing (including dates and zip codes) or whether the only ide those in a limited data set (dates and/or zip c**

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BSD 2.1 Determining the Review Requirements

4. * **If you are aware of a data incident , what is your process for reporting the event to the IRB? What is the process for reporting to others, as applicable?**

5. * **Explain what will happen to data at the end of the study (at time of study termination).**

6. * **Which HIPAA identifiers will be used or disclosed in the study?**

- [ ] **Name**
- [ ] **Address**
- [ ] **Dates**
- [ ] **Ages over age 89**
- [ ] **Telephone numbers**
- [ ] **Fax numbers**
- [ ] **Email addresses**
- [ ] **Social security numbers**
- [ ] **Medical record numbers**
- [ ] **Health plan beneficiary numbers**
- [x] **Account numbers**
- [ ] **Certificate/license numbers**
- [ ] **Vehicle identifiers and serial numbers, including license plate numbers**
- [ ] **Device identifiers and serial numbers**
- [ ] **Web universal resource locators (URLs)**
- [ ] **Internet protocol (IP) address numbers**
- [ ] **Biometric identifiers, including fingerprints and voiceprints**
- [ ] **Full-face photographic images and any comparable images**
- [ ] **Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification**
- [ ] **None**

Any selection other than "None" will cause questions a-b to appear.

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a. * **Please describe why the identifiers are**

b. * **Provide written assurance that you will not re-use the identifiers accessed on study. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of data during the current study). For example, please state the following: "I will not re-use identifiers collected or used during the study for other purposes".**

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5.5 Data Safety and Monitoring

1. **Is there a formally constituted Data and Safety Monitoring Board (DSMB) or Data Safety Monitoring Committee (DSMC) to monitor the study?**
   ● **Yes** ○ **No** Clear

   a. **Describe how frequently the DSMB will meet and/or review study data.**

2. **Please select any other plans for data and safety monitoring for this study.**
   - ☐ **The study will be monitored by the study investigator(s).**
   - ☐ **The study will be monitored by the study sponsor.**
   - ☐ **The study will be monitored by at least one individual who is not associated with the study, but not by a formally constituted Data and Safety Monitoring Board (DSMB).**
   - ☐ **A Monitoring Committee (not a formally constituted DSMB) will monitor the study.**
   - ☐ **Cancer Center Monitoring**

3. **How often will adverse events and safety information be analyzed?**

Selecting "yes" in question 4 will prompt a question to describe the planned analysis. Selecting "no" prompts the question shown here.

4. **Are there any plans to perform an interim efficacy analysis?**
   ○ **Yes** ● **No** Clear

   a. **If no, please detail why not.**

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6.1 Benefits

1. * **Please describe any potential for direct benefits to participants as a result of this study. If none, state that here and in the consent form.** ***This description should not include benefits of procedures/interventions, etc. the subjects would receive regardless of their participation in this study.***

   Compensation should not be described as a benefit.

2. **Please describe any potential benefits to society.**

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6.2 Alternatives

1. * **Please describe the alternatives to participation in this study. If there are no alternatives, please state that participation is voluntary and the alternative is not to participate.**

   For intervention studies, please describe appropriate alternative clinical procedures or courses of treatment available to subjects.

2. **If this is a clinical trial, please explain the standard of care for subjects at UChicago if they do not participate in the study. If the trial were not in existence, what course of action would the PI recommend for patients who will be approached for study participation?**

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6.3 Results

1. **Will clinically relevant research results, including individual research results, be disclosed to subjects?**
   (●) **Yes** ( ) **No** Clear

   a. **Please specify what information would be disclosed and under what conditions.**

   Please ensure to describe this disclosure in the consent.

2. **If the study is NIH funded, please clarify which groups, including dbGap, would have access to the data resulting from this study. Please specify the conditions in which this data will be shared.**

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BSD 2.1 Determining the Review Requirements

Views 7.2 and 7.4 will appear if either "Informed Consent" or "Waiver of Consent Process with Consent Documentation Obtained or Altered" is selected in question 1.

View 7.2.1 will appear if the second option is selected.

Questions a-b appear if "Informed Consent" is selected in question 1. Questions c-g appear if another selection is chosen in question 1.

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7.1 Informed Consent Process

1. * **Will there be any type of consent process for this study (in person, online, or over the phone)? Please indicate the type(s) of consent process that will be involved (check all that apply).**
   - [x] **Informed Consent**
   - [x] **Waiver of Consent Process with Consent Documentation Obtained or Altered**
   - [x] **Waiver of Consent Process and Waiver of Consent Documentation**

   a. * **Since you will have an informed consent process:**

   Please describe procedures to obtain consent, including how, when and where consent will be discussed and documentation obtained. Be specific regarding when consent will be obtained (e.g. "immediately before beginning screening" or "two days before surgery, during pre-op visit").

   b. * **How will you determine whether the subject understands the study? Throughout the course of the study, how will you continue to ensure the subject understands the study?**

   c. * **Since you will have a Waiver of Consent Process and Waiver of Consent Documentation:**

   Please describe why the research involves no more than minimal risk to subjects.
   If the research involves multiple conse

research is minimal risk specifically for the subjects for whom the waiver is requested, as the risk level may differ for other subjects.

d. * **Why is it impracticable to carry out the research without a waiver of informed consent? (Why is it impossible to conduct the research if consent is required?)**

e. * **If the research involves using identifiable private information or identifiable biospecimens, why could the research not practicably be carried out without using such information or biospecimens in an identifiable format?**

f. * **Why would a waiver not adversely affect the rights and welfare of the subjects?**

g. * **If applicable, explain how subjects will be provided with additional pertinent information after participation. (e.g. an information sheet) If not applicable, please explain why sub any additional information.**

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7.2 Consent Documentation

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View 7.2.1 will appear if "Request to Alter Documentation of Consent" is selected.

1. * **Please indicate the type(s) of consent documentation that will be involved in this study (Check all that apply).**
   - ☐ **Written Consent Form: Signed consent will be sought from the subject or the subject's legally authorized representative**
   - ☑ **Verbal/Oral Consent (Request to Waive Signed Consent)**
   - ☐ **Request to Alter Documentation of Consent (Some Elements Waived)**

Questions a-b only appear if "Verbal/Oral Consent" is selected in question 1.

a. **Please indicate why oral consent is being requested for your study.**
   - ○ **The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.**
   - ○ **The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.**

   Clear

b. **Please provide a justification/explanation for your choice above.**

Exit Save Continue

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7.3 HIPAA Authorization

1. * **Please indicate how authorization for use/disclosure of PHI will be documented (check all that apply). Authorization forms and/or consent/ authorization forms should be uploaded in the following section.**
   - [ ] **Signed HIPAA authorization (combined with consent form)**
   - [x] **Signed HIPAA authorization (separate from consent form)**
   - [x] **Request for waiver of HIPAA authorization**
   - [ ] **Request for a Limited Data Set (Only dates and/or zip codes will be utilized)**
   - [ ] **HIPAA does not apply - no PHI will be used or disclosed**
   - [ ] **Does not apply - data will be sourced from an existing IRB approved research registry/database**
   - [ ] **Does not apply - all data will be sourced from CRDW**

Question a will appear if "Signed HIPAA authorization (separate from consent form)" is selected in question 1.

a. **Since a signed HIPAA authorization will be used:**

Please explain why the consent and authorization documentation are not being combined.

Questions b-g will appear if "Request for waiver of HIPAA authorization" is selected.

b. * **Since you are requesting a waiver of HIPAA authorization:**

Please describe your plan to ensure the protection of identifiers collected during this study from improper use and disclosure.

c. * **Please describe your plan to destroy the identifiers collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain identifiers, provide a justification.**

d. * **Please explain why the research could not practicably be conducted without the waiver of authorization.**

e. * **Please clarify why the research could not practicably be done without collecting the identifiers.**

f. * **Please provide written assurance that you will not re-use Protected Health Information. For example, please state the following: "I will not re-use PHI collected or used during the study for other purposes."**

g. * **Please confirm that the use of identifying information is no more than minimal risk to the individuals' privacy.**

- ○ **Yes, confirm**
- ● **No, cannot confirm**

Clear

STOP - Please contact IRB office.

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7.4 Consent/Assent/Authorization Documents

Consent form templates can be found on the IRB webpage: http://bsdirb.bsd.uchicago.edu.

1. * **Attach consent forms, assent forms, short forms/summary documents, oral consent scripts, translated consent forms or information sheets.**

   + Add

   Name

   There are no items to display

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8.1 Supporting Documents

A protocol document is required for non-exempt submissions. Templates are available if needed from the IRB website: https://biologicalsciences.uchicago.edu/irb/irb-forms-and-templates

1. **Please upload the study protocol document here:**

   + Add

Name
There are no items to display

2. **Please attach any additional supporting documents. Please be clear and concise in the "Title" field when attaching a document, so the IRB can readily identify documents.**

   PLEASE NOTE: Do NOT attach documents here that are requested throughout the SmartForm, including Consent Forms, Advertisements, Questionnaires, Surveys, etc. Use the "Jump To" menu above to navigate to the appropriate section to ensure that all documents are attached in the proper sections.

   When uploading documents, please title the document appropriately and include a version date in the title. The title that is inserted is the identifier that is printed on IRB letters and all other correspondence.

   + Add

Name	Type of Document
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**