

AURA-IRB Initial Submission

Quick Reference Guide

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Required Views & Branching Views

The Initial Submission SmartForm includes both Required Views (*relevant to all Study submissions*) and Branching views (*appear based on the main purpose of your study*).

Primary branching views in the Initial Submission SmartForm are as follows:

Views 4.0

If the MAIN purpose of your study is to

- Administer drug(s)
- Test device(s)
- and/or compare or conduct a medical intervention

You will be prompted to answer questions in section 4.0 and subsections (such as 4.1 for drugs studies, 4.4 for device studies, etc.)

Views 5.0

If the MAIN purpose of your study is to

- Conduct a survey
- Conduct interviews
- Hold a focus group
- and/or observe

You will be prompted to answer questions in section 5.0 and subsections (such as 5.1 for surveys, 5.2. for interviews or oral histories, etc.)

Views 6.0

If the MAIN purpose of your study is to

- gather or analyze data and/or specimens (such as a chart review or secondary analyses)

You will be prompted to answer questions in section 6.0 and subsections (such as 6.1.1 , 6.2.2, etc.)

***Please note all branching views are not listed/ do not appear in the guide.
Your answers to primary views will determine the various branch views you will receive.***

Initial Submission

- ❑ Select **IRB** on the AURA Homepage (<http://aura.uchicago.edu>)

AURA

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AURA Module Logins

- GRANTS**
AURA Grants allows researchers to create a proposal in response to a funding opportunity announcement (FOA), route it for approvals, and submit it electronically to the sponsor.
- IRB (on campus)**
AURA IRB (Institutional Review Board) allows researchers to create a protocol for the use of human subjects in research and submit it to the IRB for review.
- IRB (off campus)**
Use this link to log in to AURA-IRB if you are not currently connected to the Internet via the University of Chicago network.
- COI-COC**
AURA COI-COC (Conflict of Interest/Conflict of Commitment) allows faculty, as well as other academic staff, to complete their annual disclosure.
- IBC**
AURA IBC (Institutional Biosafety Committee) allows researchers to create a protocol for the use of biological materials in research and submit it for review.

Automating University-wide Research Administration

AURA is an electronic research administrative system which facilitates research administration activities on campus.

AURA streamlines and automates research administration, allowing for process automation, electronic routing and approval, system-to-system submission to Grants.gov, and data warehouse reporting. The system helps reduce administrative burden on faculty and staff as well as the regulatory compliance risk for the University.

Related Offices

- University Research Administration
- Institutional Biosafety Committee
- BSD IRB
- SBS IRB
- SSA/CHC IRB

Select appropriate Login (on or off campus)
Enter Cnet ID or UCHAD Network ID

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Login As
User Name:
Password:
 Remember me
0.1.116 Extranet By ClickCommerce

After signing into this site, you are bound by the terms and conditions set forth when you received your account.

Initial Submission

- ❑ Click **New Study** on your Study workspace

The screenshot shows the AURA IRB Test interface for Abe Lincoln. The header includes the AURA IRB Test logo, The University of Chicago logo, and the user's name 'Abe Lincoln | My Home | Logoff'. The main content area is titled 'Page for Abe Lincoln' and contains a welcome message and a list of links: 'Inbox', 'Protocols', and 'Aura Training Materials and i'. A red box highlights the 'New Study' button in the 'Create Study' section, with a red arrow pointing to it and a callout box containing the text 'Click to draft and complete study'. Below the callout is a navigation bar with tabs for 'PI Inbox', 'Research Team Inbox', 'Sub Templates', 'Profile', 'Protocols', and 'All Projects'. A table of studies is displayed with columns for ID, Name, Date Modified, Type, State, Expiration Date, and Title. The table contains two rows of data. The footer contains copyright information for The University of Chicago and contact information for the University of Chicago IRBs.

AURA IRB Test THE UNIVERSITY OF CHICAGO Abe Lincoln | My Home | Logoff

Grants

Page for Abe Lincoln

My Roles
Principal Investigator
Registered User

Create Study
New Study

Quick Links
BSD
SBS
SSA
(User Workspace)

Page for Abe Lincoln
Welcome to your AURA Personal Workspace.

- **Inbox:** This tab displays all Protocols that are in a state where your action is required, specific to your role.
- **Protocols:** This tab displays all Protocols that are in a state where your action is required, specific to your role.
- **Aura Training Materials and i** <http://aura.uchicago.edu/training/>

Click to draft and complete study

PI Inbox Research Team Inbox Sub Templates Profile Protocols All Projects

Filter by ID [] Go Clear Advanced

ID	Name	Date Modified	Type	State	Expiration Date	Title
Pro00000485	RT Test 2	1/6/2012 10:34 AM	Study	S2 - Pending PI Endorsement		RT Test 2
Pro00000035	saoieufwio	10/11/2011 10:45 AM	Study	S4b - Changes requested by IRB Administrator		saoieufwio

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University Research Administration
6030 South Ellis Ave, Edelstone Building 114
Chicago, Illinois 60637

University of Chicago IRBs
AURA
AURA-Training
AURA-Help: aura-help@uchicago.edu

0.1.23

Initial Submission

1.1 Study Identification

Click to save and navigate to next page

Answer all req. and applicable questions.
Refer to help text (right) for assistance.

New: Study

<< Back

Continue >>

1.1 Study Identification

This is the first step in your IRB Application. As you complete this application, you will automatically be guided to the appropriate forms needed to complete your submission. *Please note that you will see only those sections which apply to your submission based on the information you provide.*

HELP TEXT FIELD

Red asterisk questions are required.

1. * Full Study Title:

Title displayed when users search for studies. Be sure it is distinctive from other study submissions.

2. * Short Study Title: (Limit to 25 characters. This short title will appear v

3. * Principal Investigator:

Abe Lincoln

4. Will the Principal Investigator be obtaining consent?

Yes No

5. * Does the Principal Investigator have a potential conflict of interest associated with this study?

Yes No

Select Uchicago COI Policy link (TBD) to confirm.

Initial Submission

1.2 Study Personnel

Click to save and navigate to next page

Edit: Study - IRB12-0021

Continue >>

HELP TEXT FIELD

Answer all req. and applicable questions.
Refer to help text (right) for assistance.

Sort by name and select contact

AURA IRB Test



THE UNIVERSITY OF CHICAGO

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.2 Study Personnel

1.2 Study Personnel

1. * Primary Contact:

Gale Sayers

2. * Will the Primary Contact be obtaining consent?

Yes No

3. Co-Investigators:

Last Name First Name

There are no items to display

4. Other Study Personnel:

Last Name First Name

Lincoln Abe

5. Do any of the participating study personnel have a potential conflict of interest associated with this study?

Yes No

6. If yes to question 5, please describe below or attach a memo or letter to explain to the IRB Committee how the conflict of interest relates to the specific study being proposed.

Text area for describing conflict of interest.

Name Modified

There are no items to display

7. If yes to question 5, has this conflict of interest been disclosed to University Research Administration (URA)?

Yes No

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.

8. Is this study supported by a regulatory support group?

Dropdown menu for regulatory support group.

Select Person


Filter by First

1-25 of 1

First	Last	Department	Division	Date of Human Subject Training
<input type="radio"/>	Valerie	Abadie	Medicine	20122
<input type="radio"/>	Snezhana I.	Abarzhi	Astronomy & Astrophysics	22251
<input type="radio"/>	Elmer	Abbo	Medicine	20122
<input type="radio"/>	Dorian	Abbot	Geophysical Sciences	22254
<input type="radio"/>	Andrew	Abbott	Sociology	23310
<input type="radio"/>	Robert C.	Abbott	Graham School-Summer Studies	46491
<input type="radio"/>	Steven	Abbott	Click Commerce	
<input type="radio"/>	Mohammad	Abdeljalil S	Political Science	23309
<input type="radio"/>	Amal	Abdelkarim	Pediatrics	20130
<input type="radio"/>	Gillie D.	Abdiraxman-Issa	Student Services	58660
<input type="radio"/>	Zubair	Abdulla	Astronomy & Astrophysics	22251

Initial Submission

1.3 Research Team Summary

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.3 Research Team Summary Continue >>

Review Research Summary to ensure all information is accurate and click Continue to save and move to next page.

1.3 Research Team Summary

1. Principal Investigator:

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Research with Children Training Completed	COI Management Plan on File
Lincoln	Abe	Sociol-Uflp		yes			

2. Primary Contact:

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Research with Children Training Completed	COI Management Plan on File
Sayers	Gale	Institute For Mind And Biology	00000009	yes			

3. Co-Investigators:

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Research with Children Training Completed	COI Management Plan on File
There are no items to display							


4. Other Study Personnel:

Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Training Completed	Research with Children Training Completed	COI Management Plan on File
Lincoln	Abe	Sociol-Uflp		no			

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.3 Research Team Summary Continue >>

Initial Submission

JUMP TO MENU

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.3 Research Team Summary >> **Continue >>**

Note: To Jump to a particular view click the Jump to Menu. A drop down menu will display and you can select the view you want to Jump to!

1. Principal Investigator:						
Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Completed	Training
Lincoln	Abe	Sociol-Uflp		yes		

2. Primary Contact:						
Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Completed	Training
Sayers	Gale	Institute For Mind And Biology	00000009	yes		

3. Co-Investigators:
Last Name First Name Dept Profile Consenting Subjects Human Subjects Training Completed
There are no items to display

4. Other Study Personnel:						
Last Name	First Name	Dept	Profile	Consenting Subjects	Human Subjects Completed	Training
Lincoln	Abe	Sociol-Uflp		no		

Study Personnel and Funding Section

- 1.1 Study Identification
- 1.2 Study Personnel
- **- 1.3 Research Team Summary**
- 1.4 Funding Sources
- 1.5 Study Locations
- 1.5.1 Multi-Site Study
- 1.5.3 International Sites

Research Type & Purpose Section

- 2.1 Research Categories
- 2.2 Purpose
- 2.2.2 Additional Activities (Methods & Procedures II)

Methods & Procedures II Section

Plan on
ent Plan on
Plan on File
Plan on

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.3 Research Team Summary >> **Continue >>**

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Initial Submission

1.4 Funding Resources

When selecting "Internally funded" you must choose an option in Question 2.

AURA IRB Test  THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.4 Funding Sources Continue >>

1.4 Funding Sources

1. * Funding Source: (Please check all that apply)

- Internally Funded
- Externally Funded/Supported

Selecting "Externally Funded" will branch to view 1.4.1 to select your primary funding source.

HELP TEXT FIELD

2. If Internally funded, please choose from the following:

Select Funding Source. Information is sourced from AURA Grants and will appear if your grant has been submitted.

<< Back Save | Exit | Hide/Show Errors

1.4.1 External Funding Information

You indicated that this as an externally funded study. Please provide the following information about all external funders of this study. Please note that if your funding source is not listed, please contact the IRB office.

1. * Primary Funding Source:

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

Name	Status	Submission Deadline
There are no items to display		


3. If your protocol is funded by a grant(s), please attach a copy of the entire grant application.

Name	Modified	Version
There are no items to display		

4. Please list any other additional funding sources.

Initial Submission

1.5 Study locations

AURA IRB Test  THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.5 Study Locations Continue >>

1.5 Study Locations

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

← Select and enter all applicable UChicago locations.

Location Name
There are no items to display

2. If "UChicago (Other)" was chosen, please specify the UChicago location.

3. * Is this a multi-site study? (If there are multiple sites conducting this study, please answer "yes" whether or not the UChicago is the lead site)

Yes No ← If Yes, you will branch to view 1.5.1 (Multi-Site Study) and provide info on coordinating center for study.

4. * Are the UChicago researchers conducting this study or any portion of the study at a non-UChicago site?

Yes No ← If Yes, you will branch to view 1.5.2 (Other U.S. Sites) to provide non-UChicago site.


5. * Are the UChicago researchers conducting this study or any portion of the study at an international site (outside the United States)?

Yes No ← If Yes, you will branch to view 1.5.3 (International Sites) for additional information.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 1.5 Study Locations Continue >>

Initial Submission

2.1 Research Categories

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: - 2.1 Research Categories - | Continue >>

2.1 Research Categories

1. *** What type of IRB review are you requesting?**

- Full Board Review (at convened meeting)
- Expedited Review
- Exempt Determination
- Not Human Subjects Research Determination
- Unsure/Do Not Know

Clear

Exempt & Not Human Research Studies will branch to views 2.1.1 and 2.1.2. Upon branch views complete, no additional view req. and PI can submit Study.

2. **Required Additional Reviews**

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
- CTRC – Clinical Trials Review Committee - Involves cancer patients, cancer treatments, or cancer therapies
- PBUC – Pathology Biospecimen Utilization Committee - Use of cancer specimens for research purposes
- GCRC – Conducted within the General Clinical Research Center
- ISAP – Conducted with support of the UChicago BSD CTSA Award
- 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)
- Nursing Research Committee
- 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. <https://hiro.bsd.uchicago.edu/>
- Other

**Note:
Selecting a committee will require Ancillary review during Initial Submission workflow**

3. **If "Other," please indicate the name(s) of applicable committee(s).**

Initial Submission

2.2 Purpose

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back Continue >>

Select the appropriate Primary activity and enter all req. & applicable fields.

2.2 Purpose

1. * **What is the primary activity of the study? (Please check ONE)**

- Administration of survey(s), interviewing, conducting focus groups, observational research, psychological testing, or similar activities
- Administration of drug, use of device, investigation of a medical intervention, or research involving UCMC patients
- Specimen collection and/or analysis
- Collection or study of existing records/data
- Approval of a grant ONLY: Research to be conducted under the grant will be submitted later for separate review and approval

Clear

2. * **Please provide a brief, non-technical (lay) language description of the purpose of the research, including the research question.**

Selection will branch to view 17.1(Supporting Documents) and submit.

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.**

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.

HELP TEXT FIELD

Note:
Each selection will take you to Primary Branching views relevant to the purpose of your study. (see page 13 – 15)

Initial Submission

4.1 – 4.4.2 Drugs and Medical Devices

If the MAIN purpose of your study is to Administer drug(s) , Test device(s) , and/or compare or conduct a medical intervention you will be prompted to answer questions in section 4 and subsections. *Note: All views in section 4 are not shown .*

AURA IRB Test THE UNIVERSITY OF CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 4.1 Drugs -

4.1 Drugs

You have indicated that this research will involve the use of a drug.

- * Please select the types of drugs that will be administered in this study (check all that apply):**
 Experimental/Investigational Drugs
 FDA Approved Drugs (used for approved use or unapproved use)
- Does this study involve a washout period of previous medications?**
 Yes No Clear
- * Does this study involve the use of a placebo or no-treatment arm?**
 Yes No Clear

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 4.1 Drugs -

AURA IRB Test THE UNIVERSITY OF CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 4.1.1 Experimental Drugs -

4.1.1 Experimental Drugs

You have indicated that this research will involve the use of an experimental/investigational drug.

Please note that for any drug requiring an IND, the IND # must be obtained prior to approval of the protocol.

- * Please list all experimental drugs administered in this study:**

Drug Name	Manufacturer	IND Holder	IND #	
<input type="button" value="Update"/> Drug - DP	Merck	Principal Investigator	12345	<input type="button" value="Delete"/>
<input type="button" value="Update"/> Drug 2 - DP	Merck	Other	12346	<input type="button" value="Delete"/>
- Please attach Investigator's Brochure for each experimental/investigational drug:**

Name
<input type="button" value="Upload Revision"/> Brochure
- * Drug Phase (Please choose one)**
 Other
 Phase I
 Phase II

AURA IRB Test THE UNIVERSITY OF CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 4.4.2 Experimental/Investigational Medical Devices -

4.4.2 Experimental/Investigational Devices

You have indicated that this research will involve the use of an experimental/investigational device.

Please note that for any device requiring an IDE, the IDE # must be obtained prior to approval of the protocol.

- * Please list all investigational/experimental devices to be used in this study.**

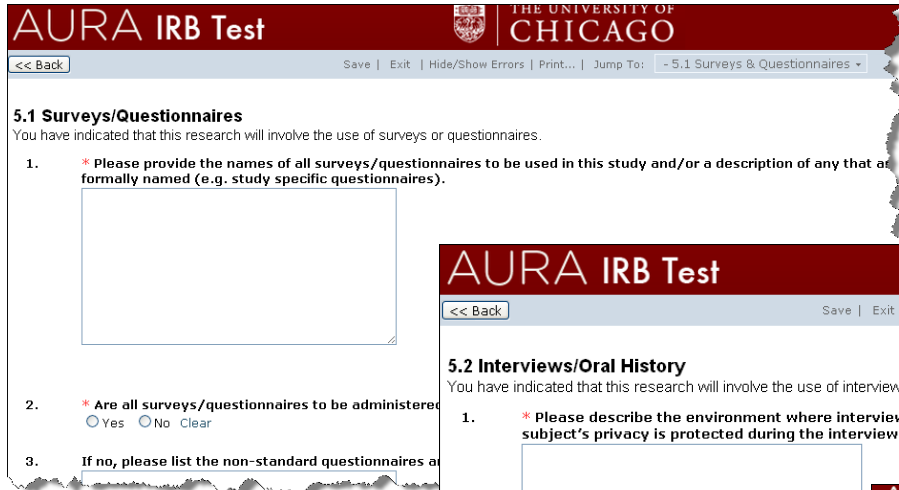
Device Name	Manufacturer	IDE Class	Medicare Category	IDE Holder	IDE Number	
<input type="button" value="Update"/> Device-DP	Manufacturer-DP	Non-Significant Risk	Category A	Other		<input type="button" value="Delete"/>
- * Please attach Instructions for Use and/or Device Brochure for each device listed. Please also attach any FDA correspondence (including IDE or HDE exemption letter).**

Name
<input type="button" value="Upload Revision"/> Instructions
- * Is this device implantable?**
 Yes No Clear
- If Yes - Will subject or their secondary payer be charged for the implant procedure?**
Secondary Payer

Initial Submission

5.1 – 5.7 Surveys, Interviews, Focus groups, Psychological testing

If the MAIN purpose of your study is to Conduct a surveys, interviews, focus groups, psychological testing you will be prompted to answer questions in section 5 and subsections. *Note:* All views in section 5 are not shown.



AURA IRB Test THE UNIVERSITY OF CHICAGO

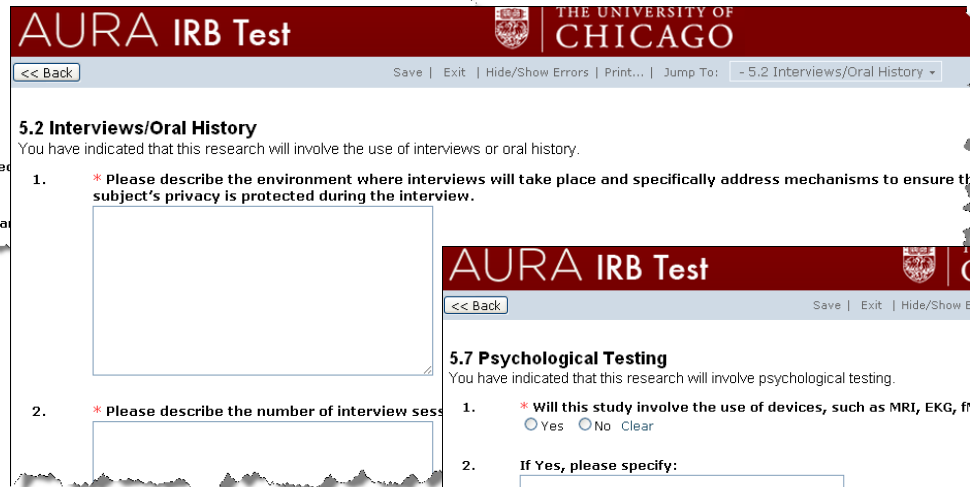
<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 5.1 Surveys & Questionnaires -

5.1 Surveys/Questionnaires

You have indicated that this research will involve the use of surveys or questionnaires.

- * Please provide the names of all surveys/questionnaires to be used in this study and/or a description of any that are formally named (e.g. study specific questionnaires).
- * Are all surveys/questionnaires to be administered?

Yes No Clear
- If no, please list the non-standard questionnaires and their use.



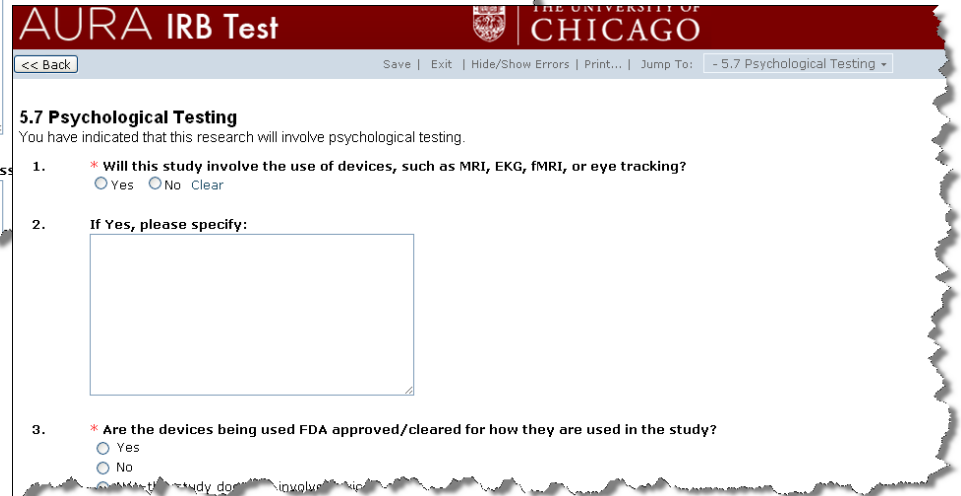
AURA IRB Test THE UNIVERSITY OF CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 5.2 Interviews/Oral History -

5.2 Interviews/Oral History

You have indicated that this research will involve the use of interviews or oral history.

- * Please describe the environment where interviews will take place and specifically address mechanisms to ensure that subject's privacy is protected during the interview.
- * Please describe the number of interview sessions.



AURA IRB Test THE UNIVERSITY OF CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 5.7 Psychological Testing -

5.7 Psychological Testing

You have indicated that this research will involve psychological testing.

- * Will this study involve the use of devices, such as MRI, EKG, fMRI, or eye tracking?

Yes No Clear
- If Yes, please specify:
- * Are the devices being used FDA approved/cleared for how they are used in the study?

Yes No

Initial Submission

6.1 – 6.2 Analyze data and/or specimens

If the MAIN purpose of your study is to gather or analyze data and/or specimens (such as a chart review or secondary analyses you will be prompted to answer questions in section 6 and subsections. *Note:* All views in section 6 are not shown.

AURA IRB Test CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 6.1 Specimen Collection and/or Analysis -

6.1 Specimen Collection and/or Analysis

You have indicated that this research will involve specimen collection and/or analysis.

- * What type of specimens will be involved in this study? (Check all that apply)**
 - Existing (already sitting on the shelf at the time of initial IRB submission)
 - Prospective (will be collected)
- * Will HIV testing be done on the specimens?**
 - Yes No Clear
- * Will genetic analysis/testing be done on any of the specimens?**
 - Yes No Clear
- * Will this study involve banking of specimens (storing for future research use)?**
 - Yes No Clear
- * Will specimens be shared with other UChicago investigators (not listed as part of the research) outside of UChicago?**
 - Other UChicago Investigators

AURA IRB Test THE UNIVERSITY OF CHICAGO

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 6.2 Data Collection/Record Review -


6.2 Data Collection/Record Review

You indicated that this study involves data collection and/or analysis. Please provide the following information about the data collected/used in the study.

- * What type of data will be collected/analyzed in this study? (Check all that apply)**
 - Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
 - Prospective (data is not yet in existence and/or collected)
- * Will this study involve adding data to a registry or database?**
 - Yes No Clear
- * Will data be shared with other UChicago investigators or with investigators outside of UChicago? (Check all that apply)**
 - UChicago Investigators
 - Investigators outside of UChicago
 - Both
 - N/A-data won't be shared
 - Clear
- If data will be shared, describe how the data will be shared and specify with whom it will be shared.**
 -

Initial Submission

7.1 Study Population

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back Save | E tion >> Continue >>

7.1 Study Population

Answer all req. and applicable questions. Refer to help text (right) for assistance.

HELP TEXT FIELD

Selections will branch to additional views for more information on populations. Check ALL that apply to study.

1. *** Select the population(s) that will be enrolled 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, Fetus
- Placenta, Dead Fetus, or Fetal Material
- Nonviable Neonates
- None of these vulnerable populations will be enrolled in the study


2. *** Please select any additional populations that will be enrolled in this study. (Please check all that apply)**

- Healthy Adult Volunteers
- Decisionally Impaired Individuals
- Individuals with Mental Retardation
- Non-English Speakers
- Subordinates of the Research Team or Employees of the UChicago or the UChicago Hospitals
- Undergraduate Students of the UChicago
- Illiterate Subjects
- Chicago Public School (CPS) students
- Clients
- Agency Administrators/Staff
- International Subjects
- Medical Students/Fellows/Staff
- None of the above populations will be enrolled in the study

3. *** 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.**

Initial Submission

8.1 Recruiting and Screening

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 8.1 Recruitment and Screening ▾ Continue >>

8.1 Recruitment & Screening

1. * Will any member of the UChicago research team be approaching potential participants for involvement in this study and/or will the UChicago researchers be recruiting with advertisements?
 Yes No Clear

2. If no, briefly explain why not.

8.1.1 Recruitment
You indicated that this study will be recruiting subjects for this study. Provide the following information about how you will identify or screen potential subjects to recruit/include in this study. (Check all that apply.)

1. * How will you identify or screen potential subjects to recruit/include in this study? (Check all that apply.)

- Directly Approaching Subjects
- Newspaper/Magazine Advertisements
- Radio/Television Announcements
- Email
- Flyers
- Letter from Investigator
- Letter from Personal Physician
- Informational Recruitment Letter
- Other
- Brochure

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 8.1 Recruitment and Screening ▾ Continue >>

If Yes, will branch to view 8.1.1 (see below).

Selections (Medical records review or Request waiver for authorization in 8.1.1 will branch to view 8.1.2 & 8.1.3

Initial Submission

9.1 Compensation


The screenshot displays the AURA IRB Test interface for The University of Chicago. The header includes the text "AURA IRB Test" and "THE UNIVERSITY OF CHICAGO" with its logo. The study ID "Edit: Study - IRB12-0021" is shown in the top right. The main navigation bar contains buttons for "<< Back", "Save | Exit | Hide/Show Errors | Print...", "Jump To: - 9.1 Compensation", and "Continue >>".

The "9.1 Compensation" section contains a question: "1. * Will subjects be paid or otherwise compensated for participation in the study?" with radio buttons for "Yes" and "No", and a "Clear" button. A red box highlights the text "If Yes, will branch to view 9.1.1 (see below).", with a red arrow pointing to the "Yes" radio button. A green line connects the "Yes" radio button to the "9.1.1 Compensation Details" callout box.

The "9.1.1 Compensation Details" callout box, which has a torn-edge effect, contains the following text: "9.1.1 Compensation Details. You indicated that this study involves compensation. Provide the following information about the compensation used in this study." It lists two questions: "1. * How much will subjects be compensated (total and prorated amounts)?" with a large text input field, and "2. * What type of compensation will subjects receive (e.g. monetary, course credit, gifts, gift card)?" with a smaller text input field. The callout box also includes a "Continue >>" button.

Initial Submission

10.1 Risk Assessment

AURA IRB Test  THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

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10.1 Risk Assessment

Risks can include deception, punishment, use of drugs, covert and/or participant observation, induction of mental and/or physical stress, procedures which could physically harm the subject, materials and behaviors commonly regarded as socially unacceptable within the setting of research, procedures that might be regarded as an invasion of privacy, possible/probable disclosure of information that could be harmful to the subject (e.g. child abuse, criminal behavior, political repression, immigration status, HIV status, employment status, sexual orientation, etc.)


- * Will the research include any of the following items? (Check all that apply)**

 - Induction of mental and/or physical stress
 - Procedures that might be regarded as an invasion of privacy
 - Possible disclosure of information that could be harmful to the subject
 - No. The research will not include any of these items.
- * 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 is available, estimate expected frequency, degree of severity, and potential reversibility, including any potential late effects.**
- * Please describe the precautions that will be taken to minimize risks/harms, including rescue provisions, if applicable. Where appropriate, discuss provisions for ensuring necessary professional intervention in the event of a distressed subject.**

**Answer all req. and applicable questions.
Refer to help text (right) for assistance.**

Initial Submission

10.2 Data Confidentiality

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: - 10.2 Data Confidentiality - | Continue >>

10.2 Data Confidentiality

1. *** How will data be recorded? (Check all that apply)**

- Identified (Data will be linked directly to individuals)
- Coded (Data will be linked to subjects via encrypted codes)
- Anonymous (No identifying information, including NO unique codes)

2. *** Where will the research data be stored? Please specify the physical location and how it will be secured to protect confidentiality. (E.g. password-protected computer, locked office, locked files, etc.). In addition, please specify the individual responsible for ensuring data confidentiality (please include name and contact information).**

3. *** Please indicate how long the data will be kept.**

4. *** Who, other than the specified study team, will have access to the study records or data? Specify their name, role, and affiliation.**

Identified or Coded will branch to 10.2.1.

10.2.1 Data Confidentiality


You indicated that this study involves use of coded or identifiable data. Provide the following information about the identifiable or coded data used in this study.

1. *** If coded or identified data will be released to individuals outside of the study team, please indicate the provisions that will be taken to ensure that the transmission of the data will maintain confidentiality. Please also indicate how subjects will be informed that data may be shared. If coded or identified data will not be released to individuals outside of the study team, please state that below.**

2. *** Describe what will happen to the data or data set when the study is completed. Please indicate your plans for the destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.**

Initial Submission

11.1 Data Safety & Monitoring Plan

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

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11.1 Data Safety & Monitoring Plan

Answer all req. and applicable questions.


- * Choose the ONE choice below that most accurately reflects the plan 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 formally constituted Data and Safety Monitoring Board (DSMB) will monitor the study.
 - A Monitoring Committee (not a formally constituted DSMB) will monitor the study.

[Clear](#)
- * How often will adverse events and safety information be analyzed?**
- * Please provide a description of the reporting mechanism for reporting unanticipated problems and periodic safety information to the IRB, and, if applicable, to the study sponsor and/or the FDA.**

Initial Submission

13.1 Benefits

AURA IRB Test  THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

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13.1 Benefits

Answer both required questions.

1. *** Please describe any potential for direct benefits to participants in this study. If none, state that here and in the consent form.**


Compensation should not be described as a benefit.

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

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 13.1 Benefits >> Continue >>

New Study Pre-Submission

13.2 Alternative/ Options

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 13.2 Alternatives / Options Continue >>

13.2 Alternatives/Options

Answer all req. and applicable questions.

- * 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.**
- If this is a clinical trial, please explain the standard of care for subjects 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?**

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 13.2 Alternatives / Options Continue >>

Initial Submission

14.1 HIPAA

The screenshot displays the AURA IRB Test interface. At the top, the header includes the AURA IRB Test logo, The University of Chicago logo, and the text 'Edit: Study - IRB12-0021'. Below the header is a navigation bar with buttons for '<< Back', 'Save | Exit | Hide/Show Errors | Print... | Jump To: - 14.1 HIPAA', and 'Continue >>'. The main content area is titled '14.1 HIPAA' and contains a question: '1. * Will the study view, access, share, collect, use, or analyze health information that is individually identifiable?' with radio buttons for 'Yes', 'No', and a 'Clear' link. A red box with the text 'If Yes, will branch to view 14.1.1 (see below).' has a red arrow pointing to the 'Yes' radio button. To the right, a red box with the text 'HELP TEXT FIELD' has a red arrow pointing to a greyed-out area. Below the main question, a callout window titled '14.1.1 Protected Health Information' is shown, containing the text 'You indicated that this study will use or disclose PHI. Provide the following information about the PHI used/disclosed in this study.' and a list of checkboxes: '1. * Which PHI elements will be used or disclosed in this study? (Check all that apply)' followed by 'Name', 'Address (if more specific than Zip Code)', 'Dates', 'Ages over age 89', 'Telephone numbers', 'Fax numbers', 'Email addresses', 'Social security numbers', 'Medical record numbers', and 'Health plan beneficiary numbers'. A green line connects the 'Yes' radio button to the callout window. A red box at the bottom right contains the text 'Selection (Requesting waiver for authorization....will branch to view 14.1.2)' with a red arrow pointing to the callout window.

AURA IRB Test THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 14.1 HIPAA Continue >>

14.1 HIPAA

1. * Will the study view, access, share, collect, use, or analyze health information that is individually identifiable?
 Yes No Clear

If Yes, will branch to view 14.1.1 (see below).

HELP TEXT FIELD

14.1.1 Protected Health Information
You indicated that this study will use or disclose PHI. Provide the following information about the PHI used/disclosed in this study.


1. * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- Name
- Address (if more specific than Zip Code)
- Dates
- Ages over age 89
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers

Selection (Requesting waiver for authorization....will branch to view 14.1.2)

Initial Submission

15.1 Costs

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - IRB12-0021

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: - 15.1 Costs | Continue >>

15.1 Costs

1. *** Are there any costs associated with the study (that the subject will be responsible for or will be billed to someone else)? This includes costs to subjects, costs to subject's insurance, or costs to the research account.**
 Yes No Clear

If Yes, will branch to view 15.1.1 (see below).

<< Back | Save | **15.1.1 Cost Details** | Continue >>

You indicated that costs are associated with this study. Provide the following information about who will be responsible for these study related costs.

1. *** 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

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

Initial Submission

16.1 Informed Consent Determination

AURA IRB Test THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 16.1 Informed Consent Determination Continue >>

16.1 Informed Consent Determination

1. * Please indicate the type(s) of consent that will be involved in this study (Check all that apply).

- Written Consent Form
- Request to Waive Signed Consent - Verbal/Oral Consent
- Request to Waive Consent/Parental Permission - Consent is not being obtained
- Request to Alter Consent (Some Elements Waived)

<< Back Save | Exit | Hide/Show Errors | Print... Continue >>

Selection will branch to view 16.2 & 16.3

Selection will branch to view 16.4

Selection will branch to view 16.2 & 16.5

Initial Submission

16.8 Consent/ Assent Documents

The screenshot shows the AURA IRB Test interface. At the top, there is a dark red header with the text 'AURA IRB Test' on the left, 'THE UNIVERSITY OF CHICAGO' in the center, and 'Edit: Study - IRB12-0021' on the right. Below the header is a navigation bar with buttons for '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: - 16.8 Consent/Assent Documents', and 'Continue >>'. The main content area is titled '16.8 Consent/Assent Documents' and contains the following text: 'The IRB has prepared several different types of consent form templates with some of the information you have already provided. Please follow the instructions below to complete the process. Instructions: 1. Download the applicable consent form template to your machine and modify this where applicable. • BSD Consent webpage • SSA/Chapin Hall Consent webpage • SBS Consent webpage What are the targets of these links supposed to be? 2. Attach consent forms, assent forms, short forms/summary documents, oral consent scripts, translated consent forms or information sheets.' Below the instructions, there is an 'Add' button and a table with columns 'Name', 'Modified', and 'Version'. The table is currently empty, with the text 'There are no items to display' below it. Two red annotations are present: a box with the text 'Download the consent form and modify it accordingly.' pointing to the list of links, and another box with the text 'Click to upload all forms, modified documents, etc.' pointing to the 'Add' button. The bottom navigation bar is identical to the top one.

AURA IRB Test THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 16.8 Consent/Assent Documents Continue >>

16.8 Consent/Assent Documents

The IRB has prepared several different types of consent form templates with some of the information you have already provided. Please follow the instructions below to complete the process.

Instructions:

- Download the applicable consent form template to your machine and modify this where applicable.
 - BSD Consent webpage
 - SSA/Chapin Hall Consent webpage
 - SBS Consent webpage

What are the targets of these links supposed to be?
- Attach consent forms, assent forms, short forms/summary documents, oral consent scripts, translated consent forms or information sheets.

There are no items to display


<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 16.8 Consent/Assent Documents Continue >>

Download the consent form and modify it accordingly.

Click to upload all forms, modified documents, etc.

Initial Submission

17.1 Additional Supporting documents

AURA IRB Test  THE UNIVERSITY OF CHICAGO Edit: Study - IRB12-0021

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 17.1 Additional Supporting Documents Continue >>

17.1 Additional Supporting Documents

- Use this space to 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 Informed 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.

Name	Modified	Type of Document
There are no items to display		

HELP TEXT FIELD

Click to upload all documents. Please title documents appropriately, include version date in title. Title inserted will appear on IRB letters and other correspondence.

<< Back documents Continue >>

Initial Submission

19.1 Final Page

AURA IRB Test  **THE UNIVERSITY OF CHICAGO** Edit: Study - Pro00000205

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 19.1 Final Page ▾ Finish

19.1 Final Page

You have completed your IRB submission form. However, the study **has not yet been submitted to the IRB for review.**

Next Steps:

In order to complete your submission:

1. Click the "Hide/Show Errors" button in the header above to show any questions that need to be answered before submitting to the IRB. Ensure that all required questions have been answered.

Click to make sure all questions are complete and there are no errors.

Submit to the IRB:

2. Exit the Form (click Finish below) to navigate to the Study Workspace
3. Only the study PI can submit to the IRB. If you are the PI, Click the "Submit to IRB" Activity in the study workspace. If you are NOT the PI, then select "Submit to PI for Endorsement" to notify the PI that the study is ready to submit.

The study State (in the upper left corner of the submission workspace) will show "IRB Assignment" when the study is successfully submitted to the IRB.

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 19.1 Final Page ▾ **Finish**

Click Continue and SmartForm is Complete!
(You can make edits to Smartform at any time during Pre-Submission)