AURA-IRB Initial Submission
Quick Reference Guide

Table of Contents

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

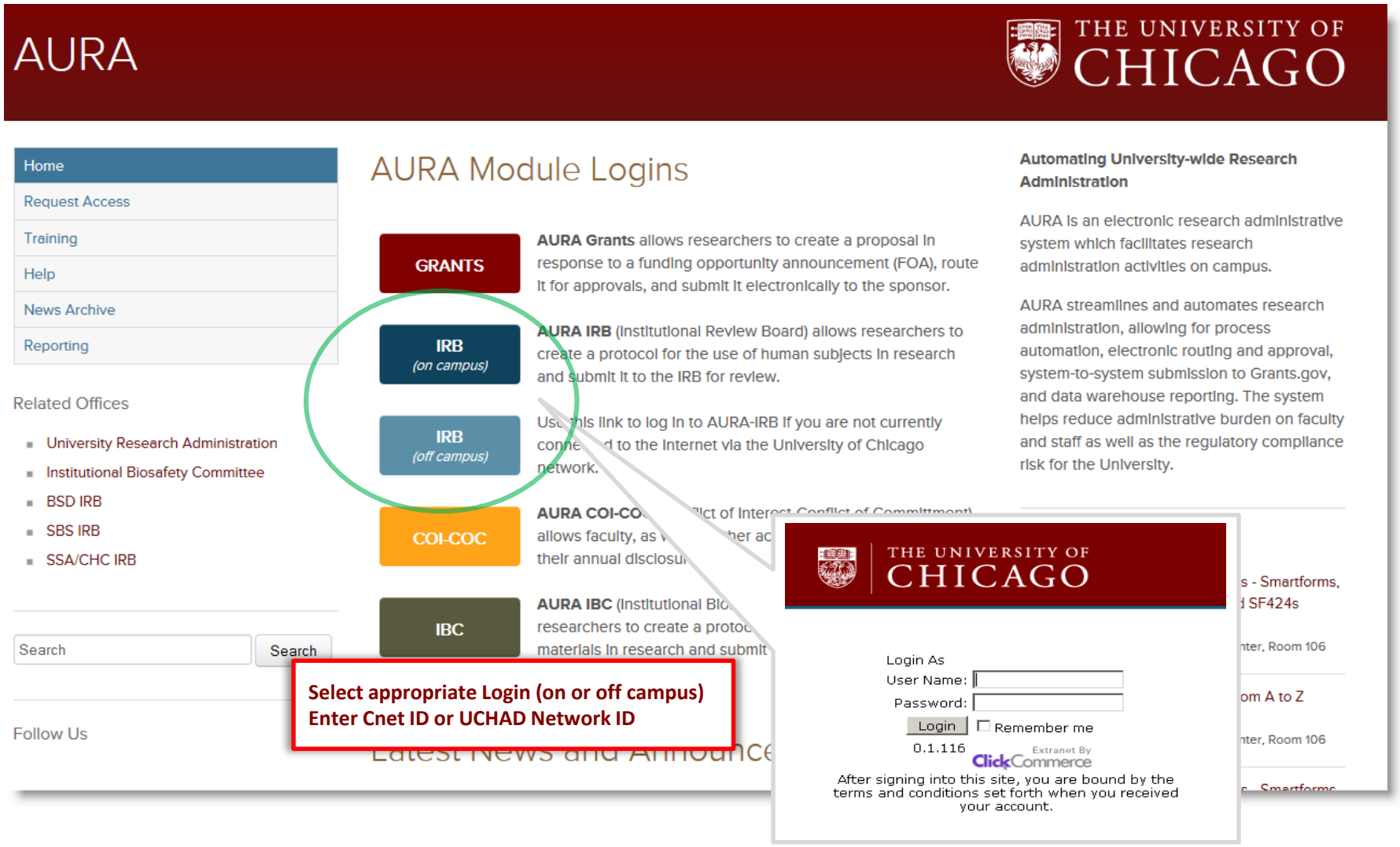
If the MAIN purpose of your study is to
- gather or analyze data and/or specimens (such as a chart review or secondary analyses)

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.

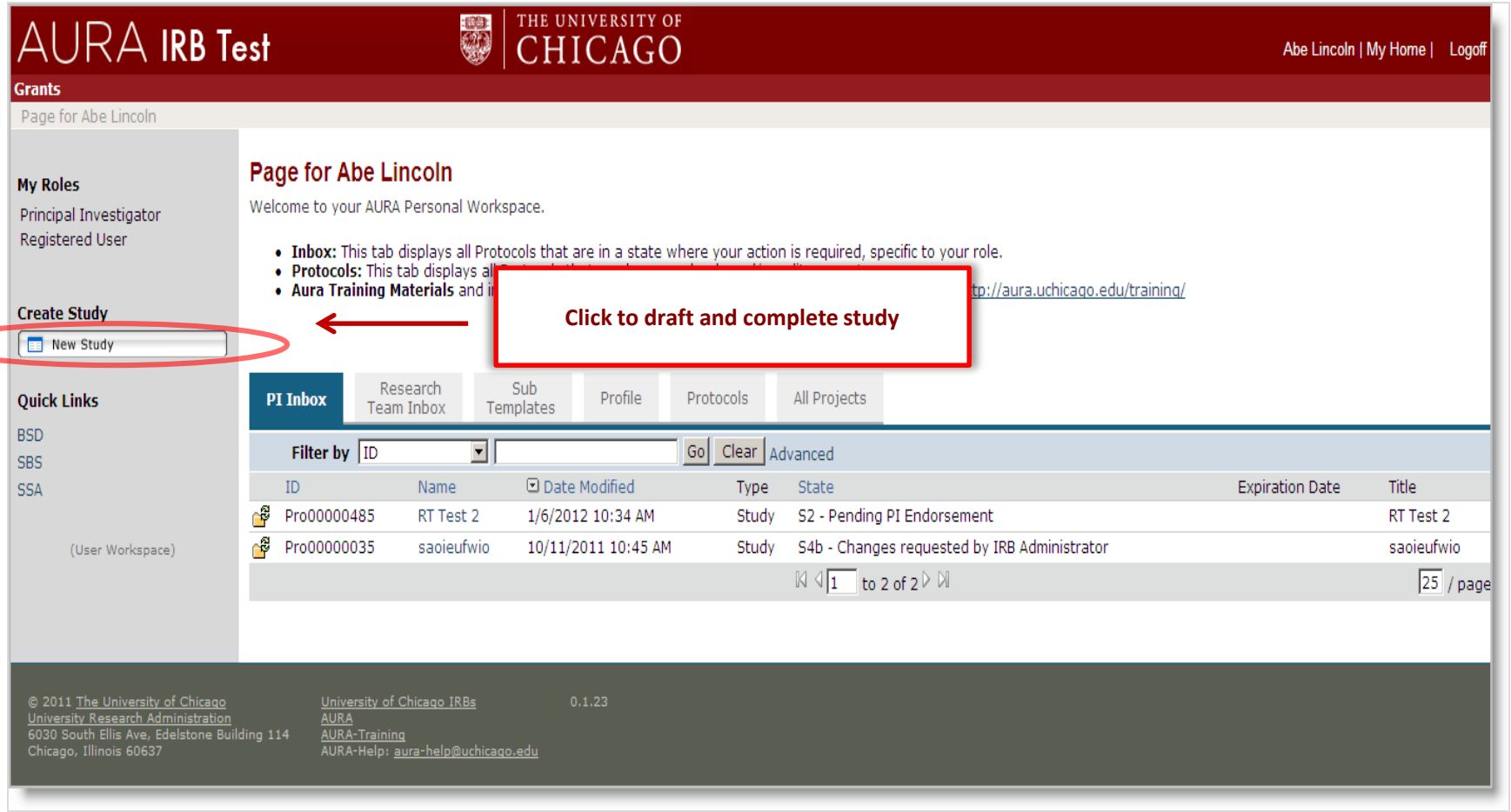
Initial Submission

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



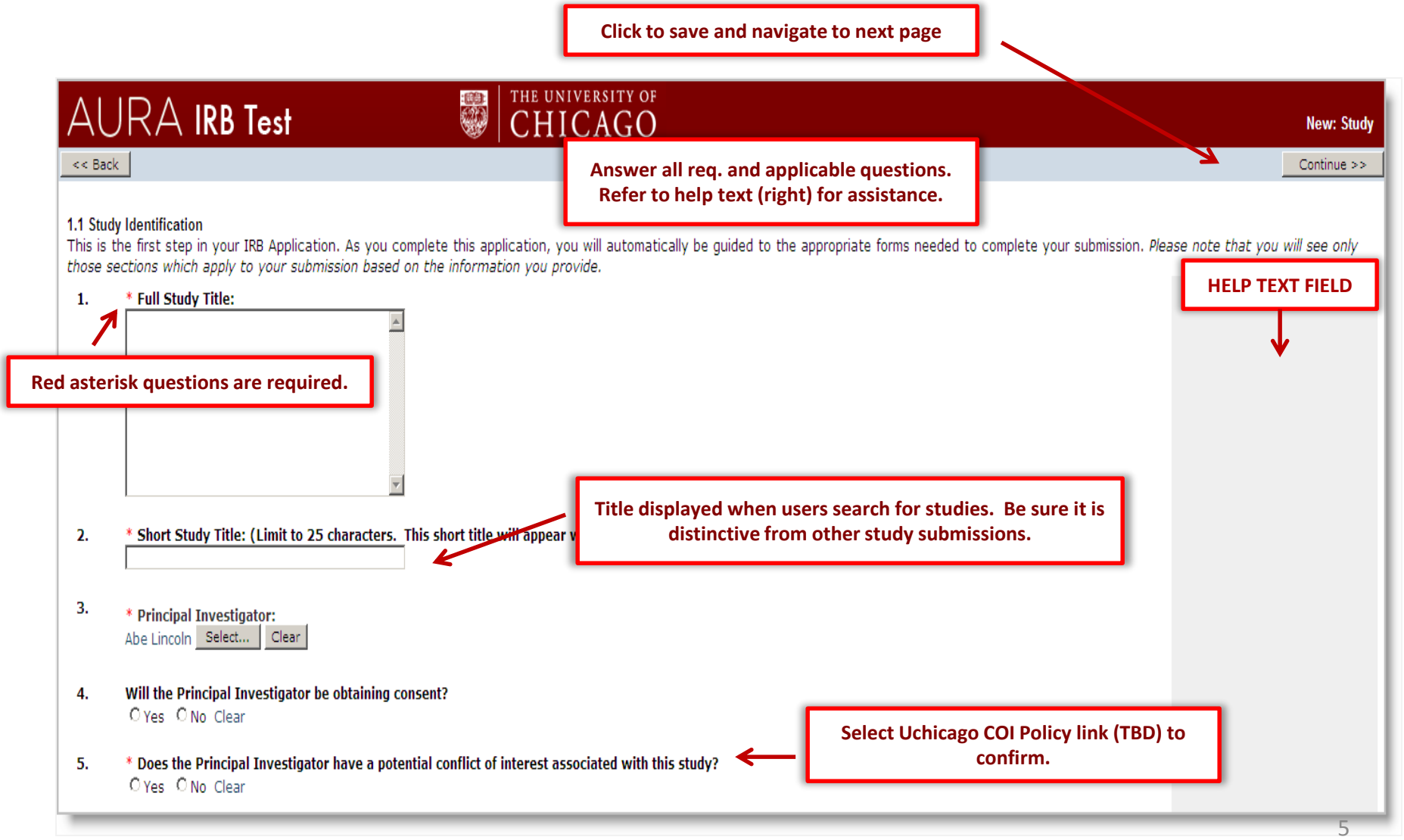
Initial Submission

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



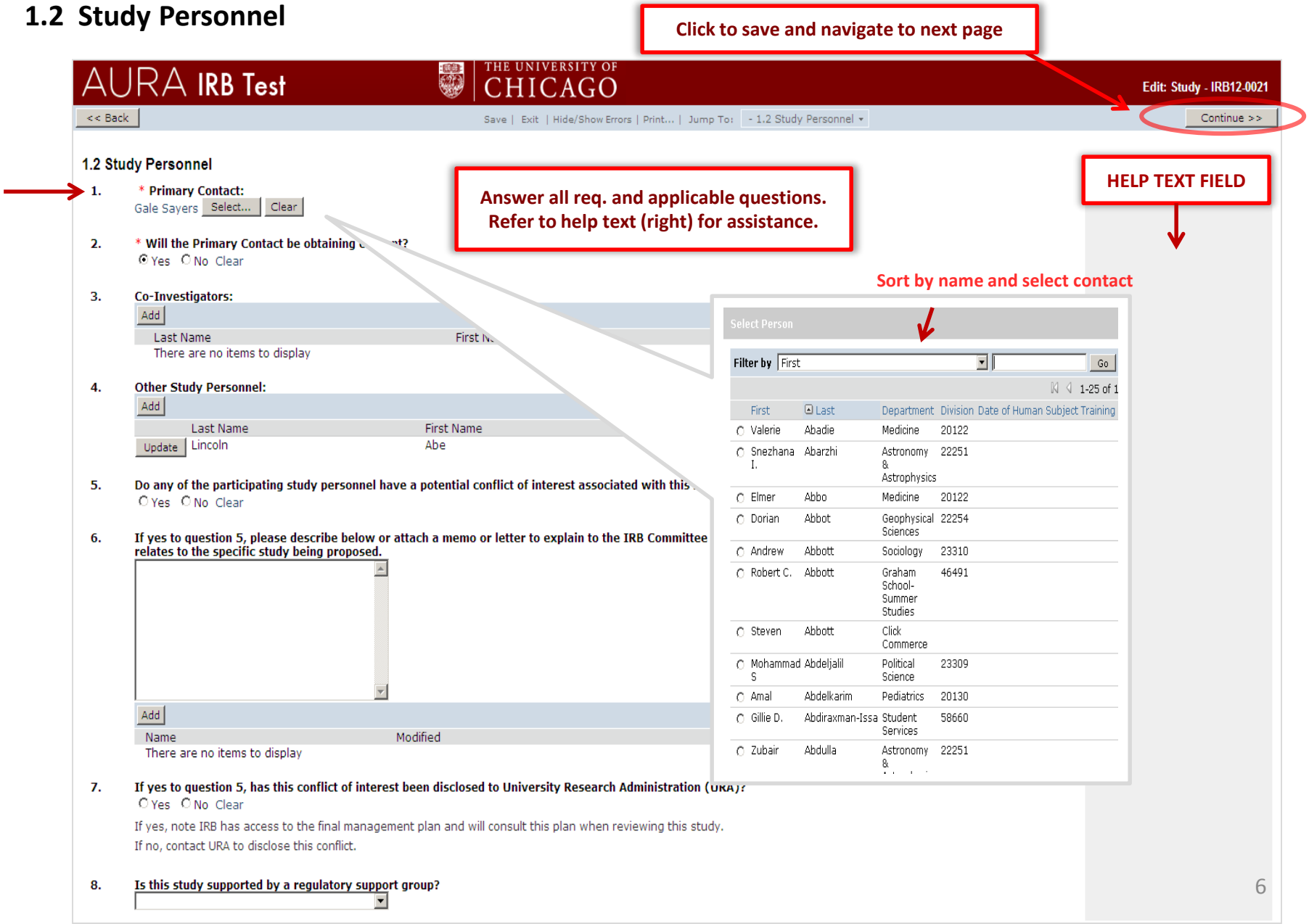
Initial Submission

1.1 Study Identification



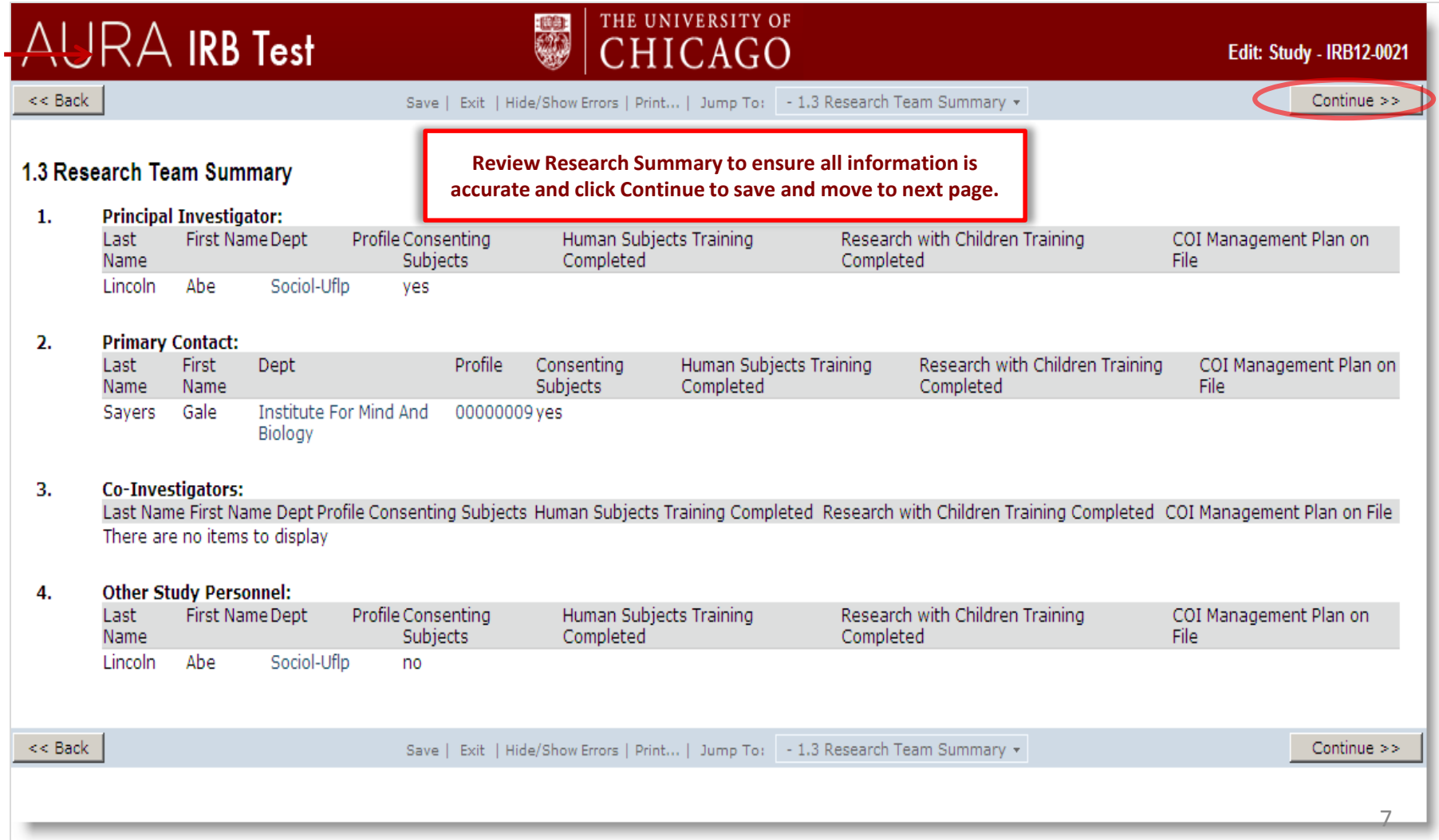
Initial Submission

1.2 Study Personnel



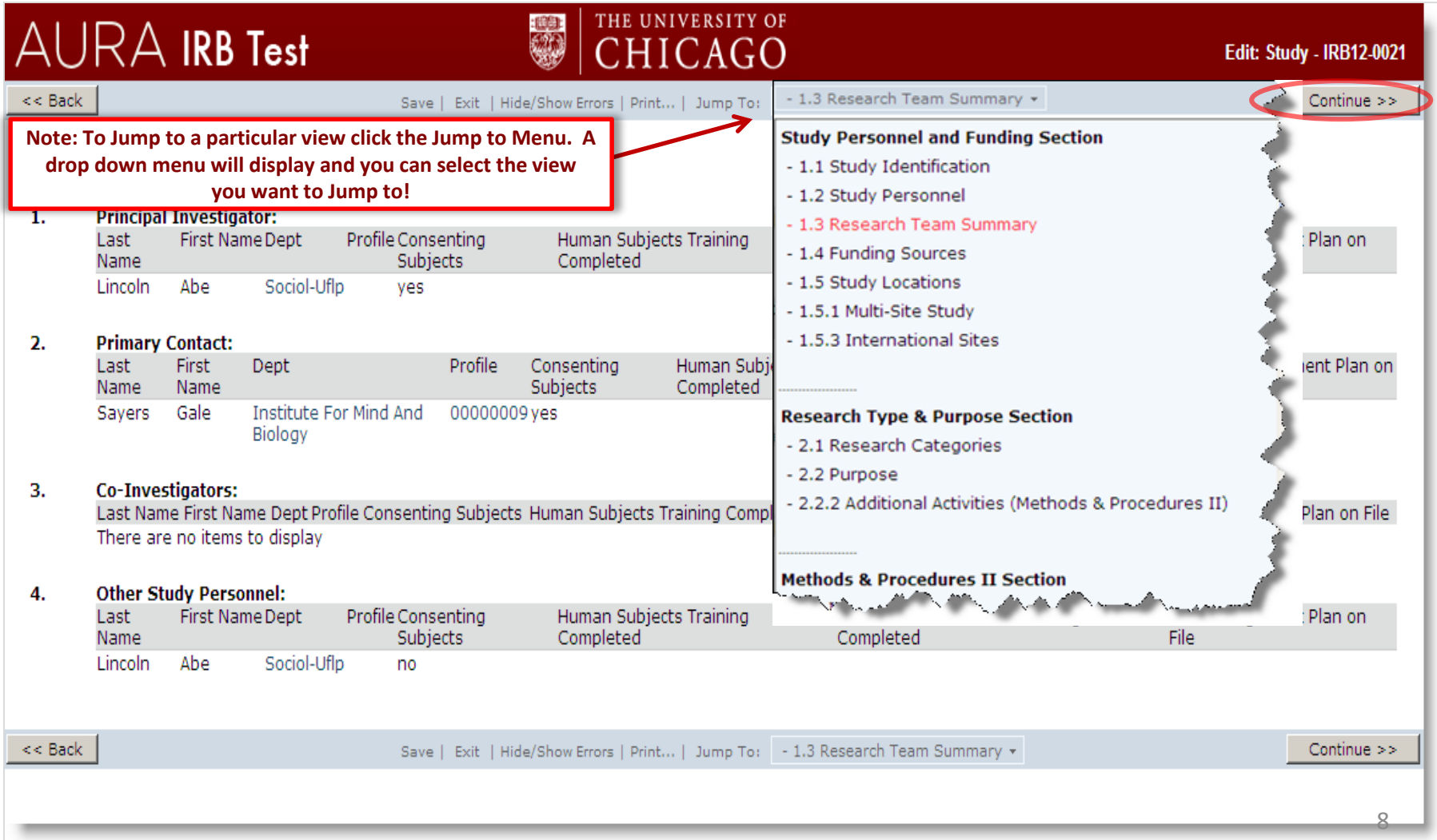
Initial Submission

1.3 Research Team Summary



Initial Submission

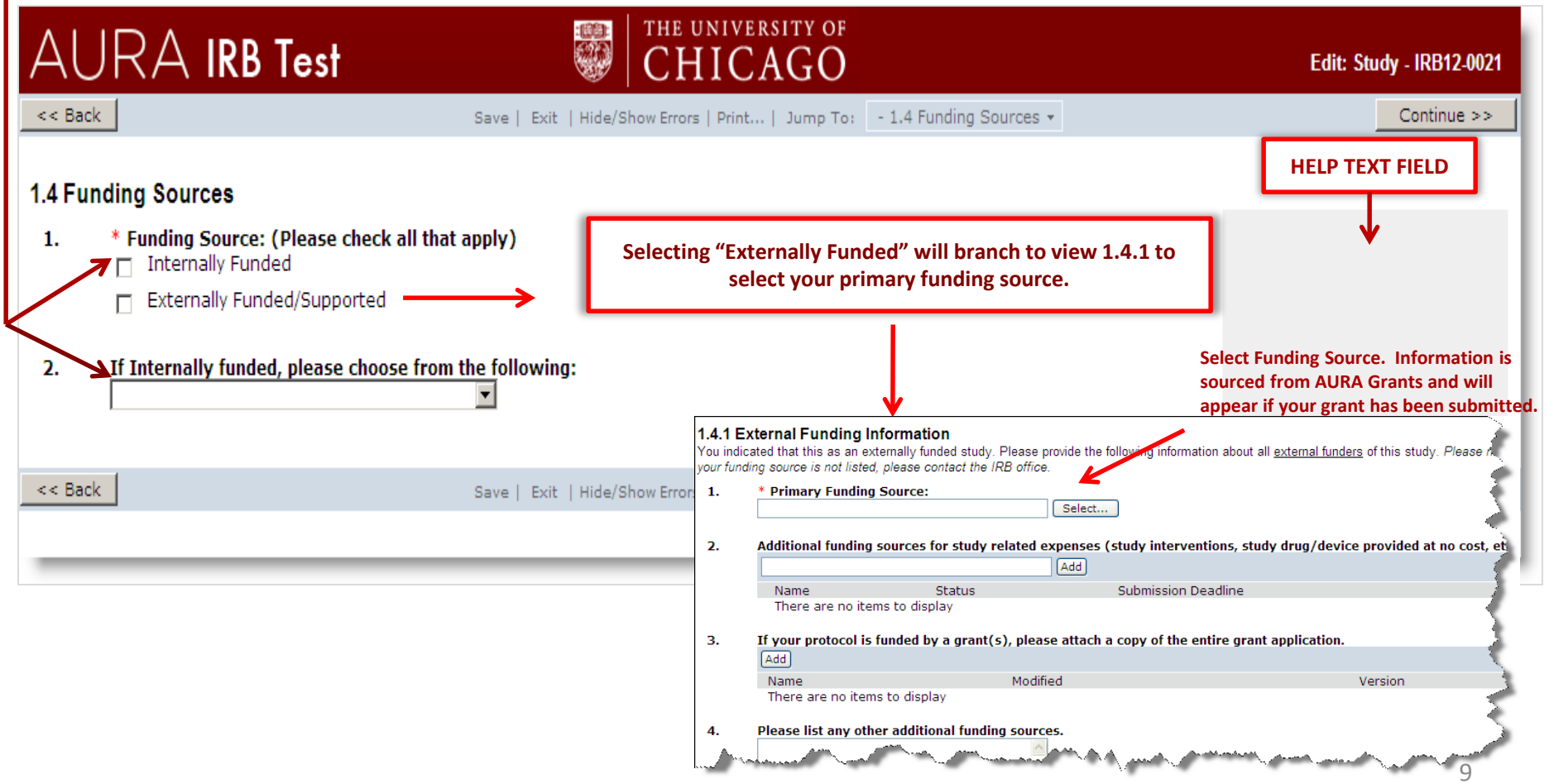
JUMP TO MENU



Initial Submission

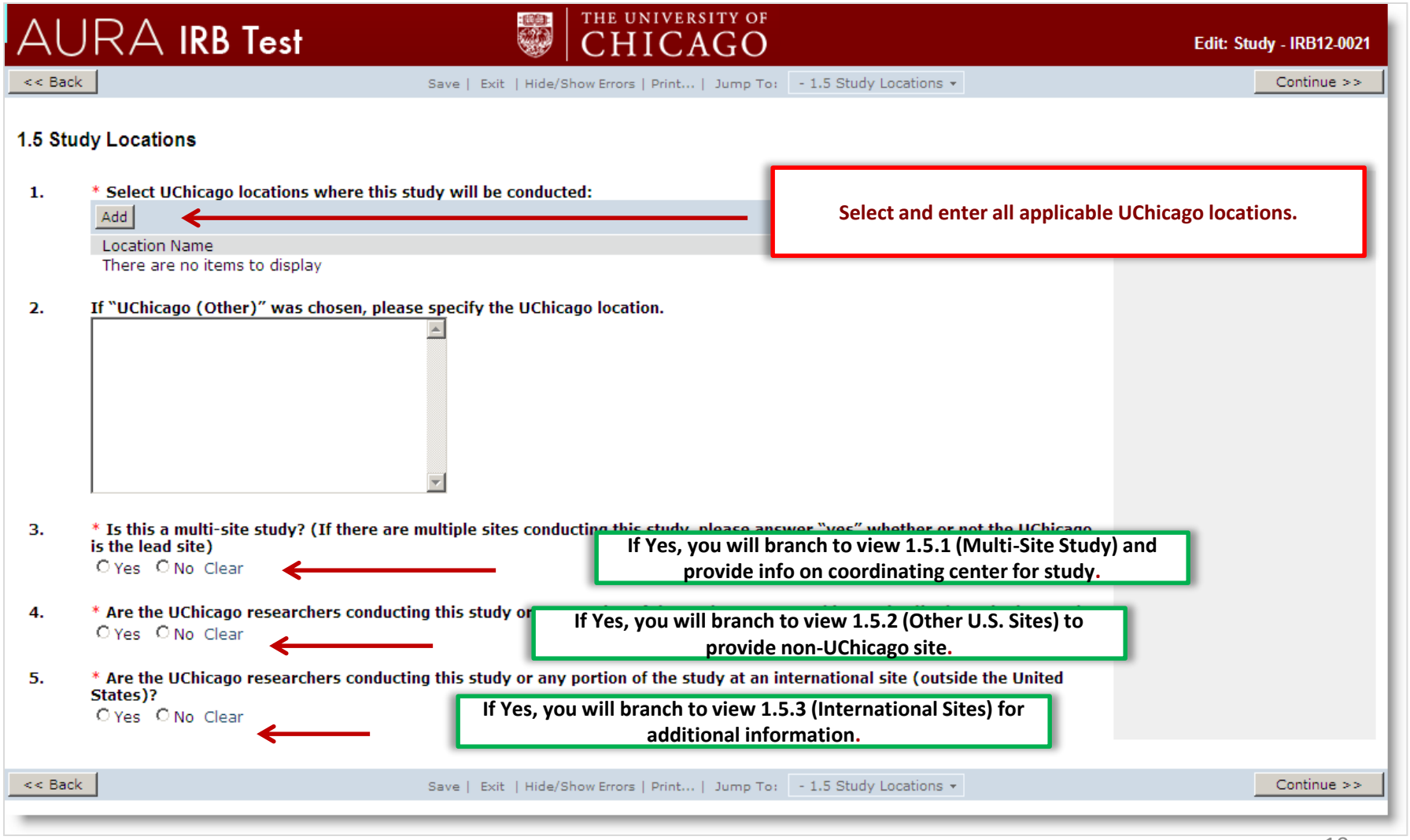
1.4 Funding Resources

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



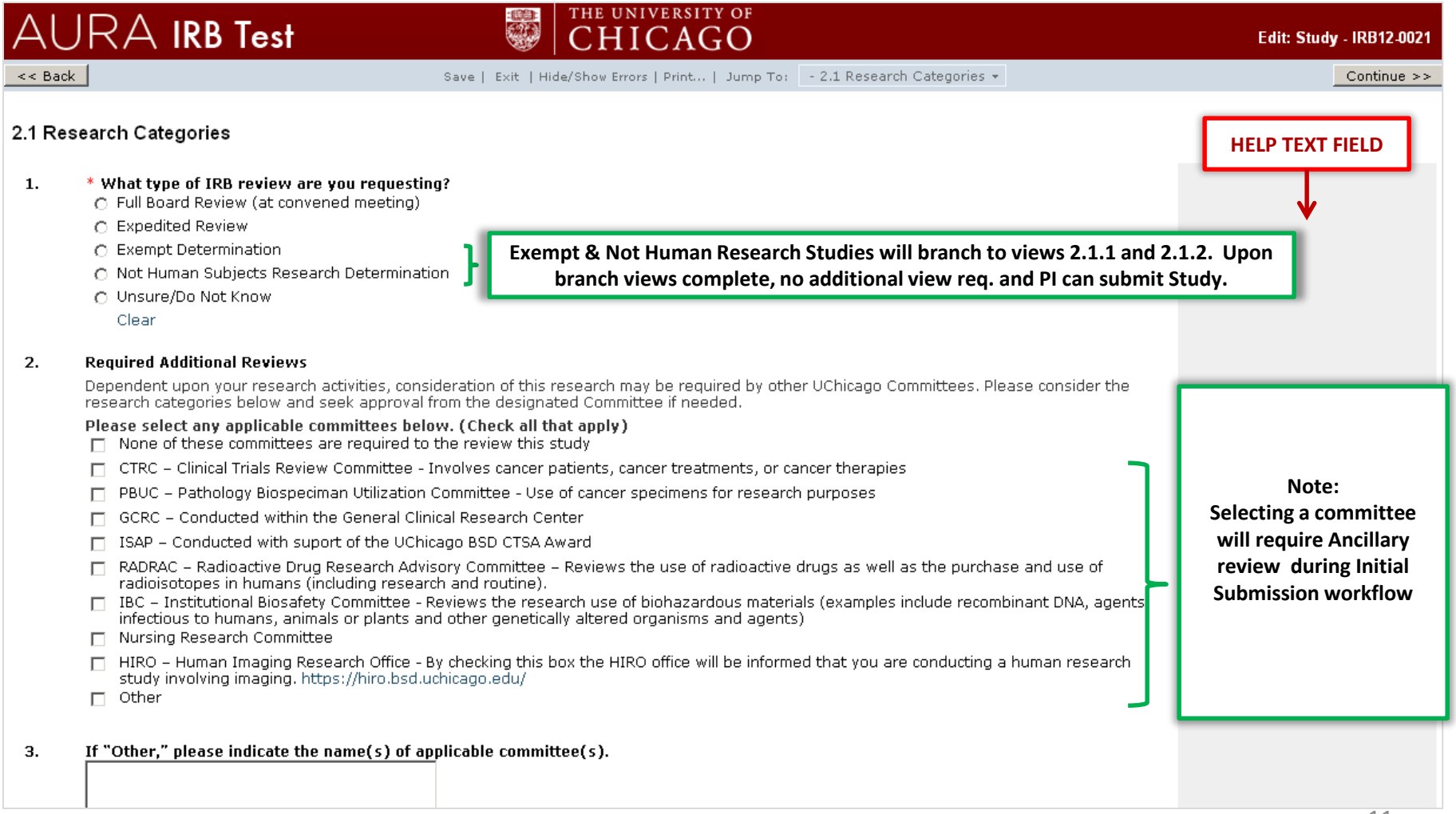
Initial Submission

1.5 Study locations



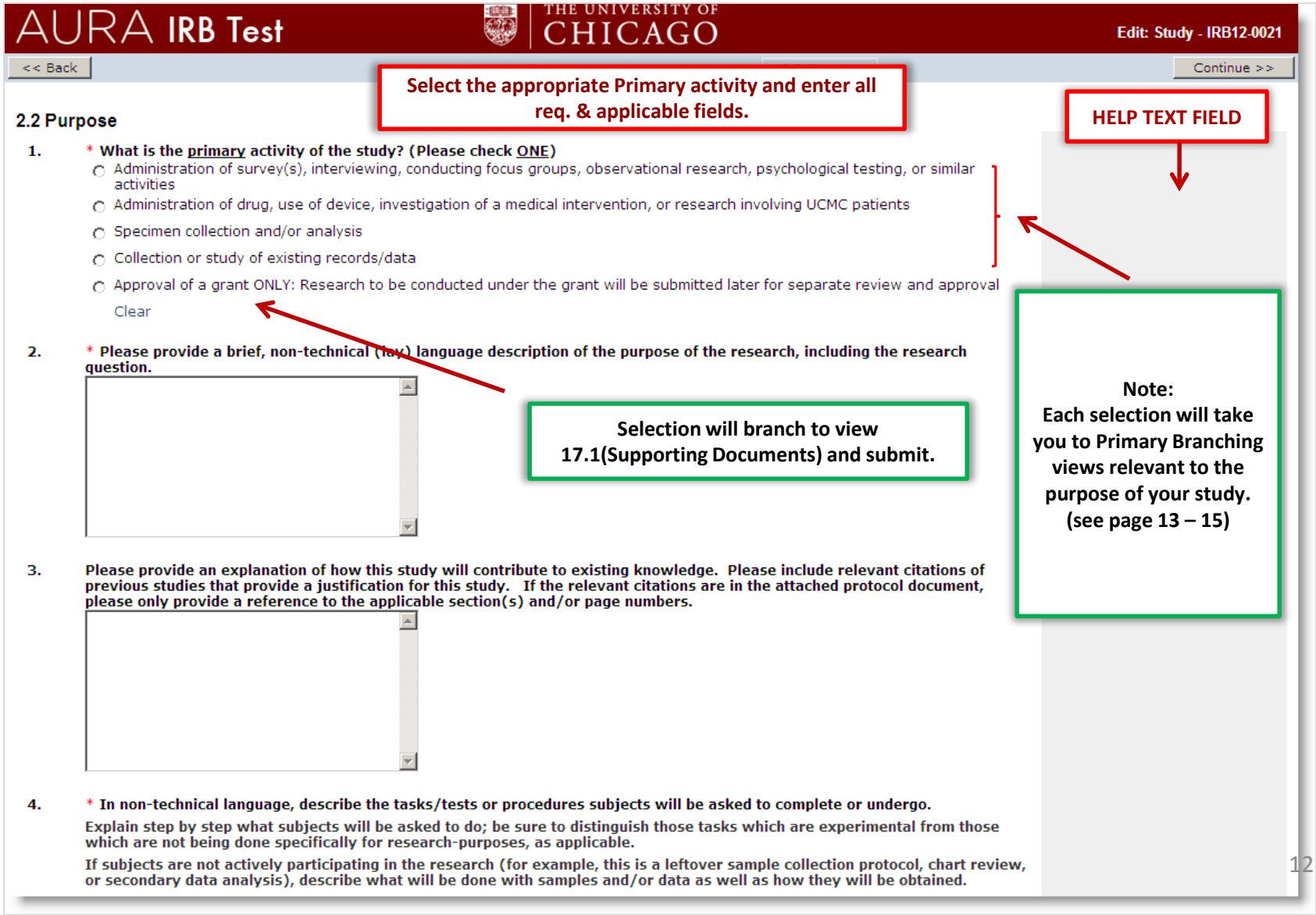
Initial Submission

2.1 Research Categories



Initial Submission

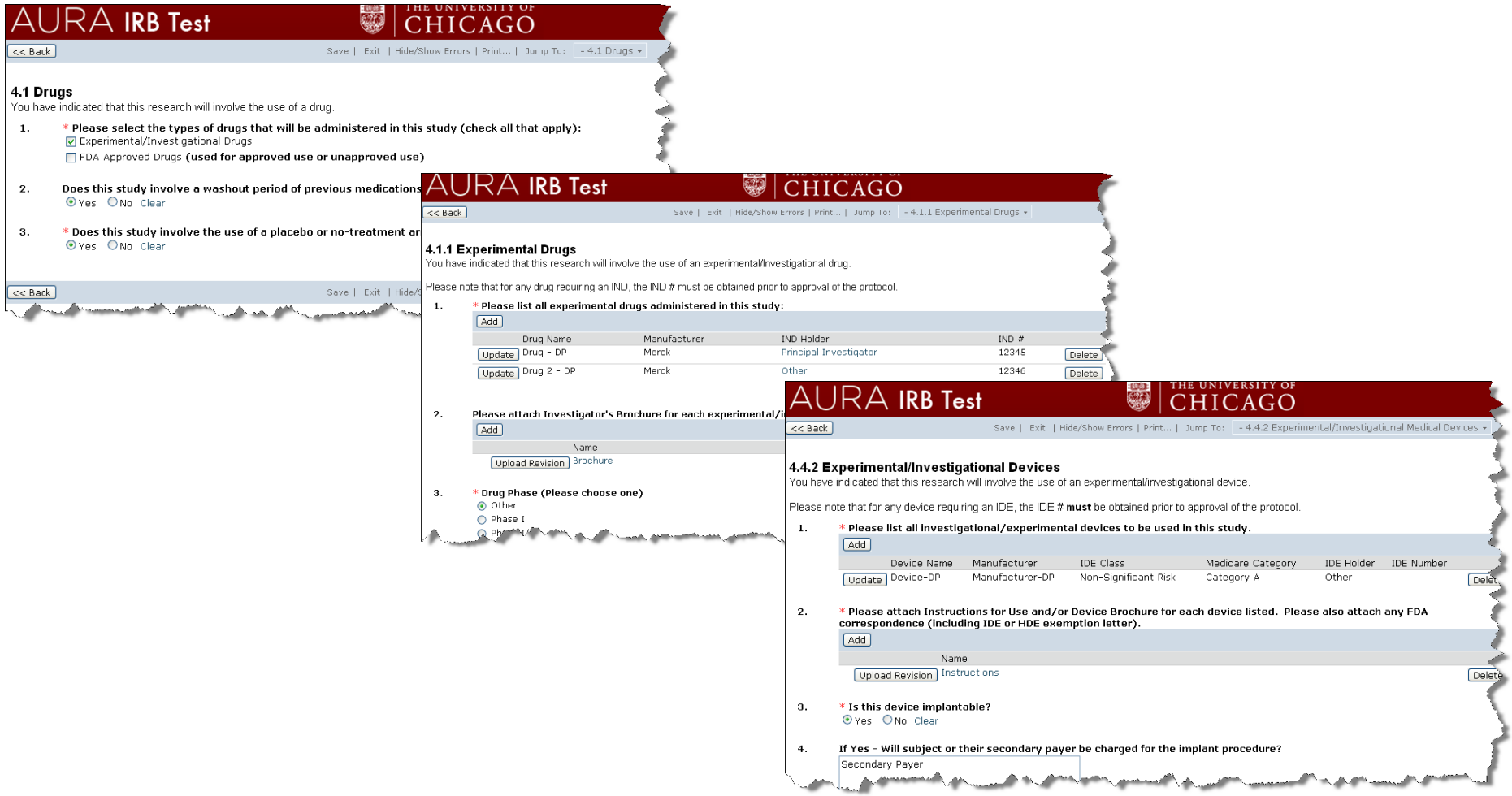
2.2 Purpose



Initial Submission

4.1 – 4.4.2 Drugs and Medical Devices

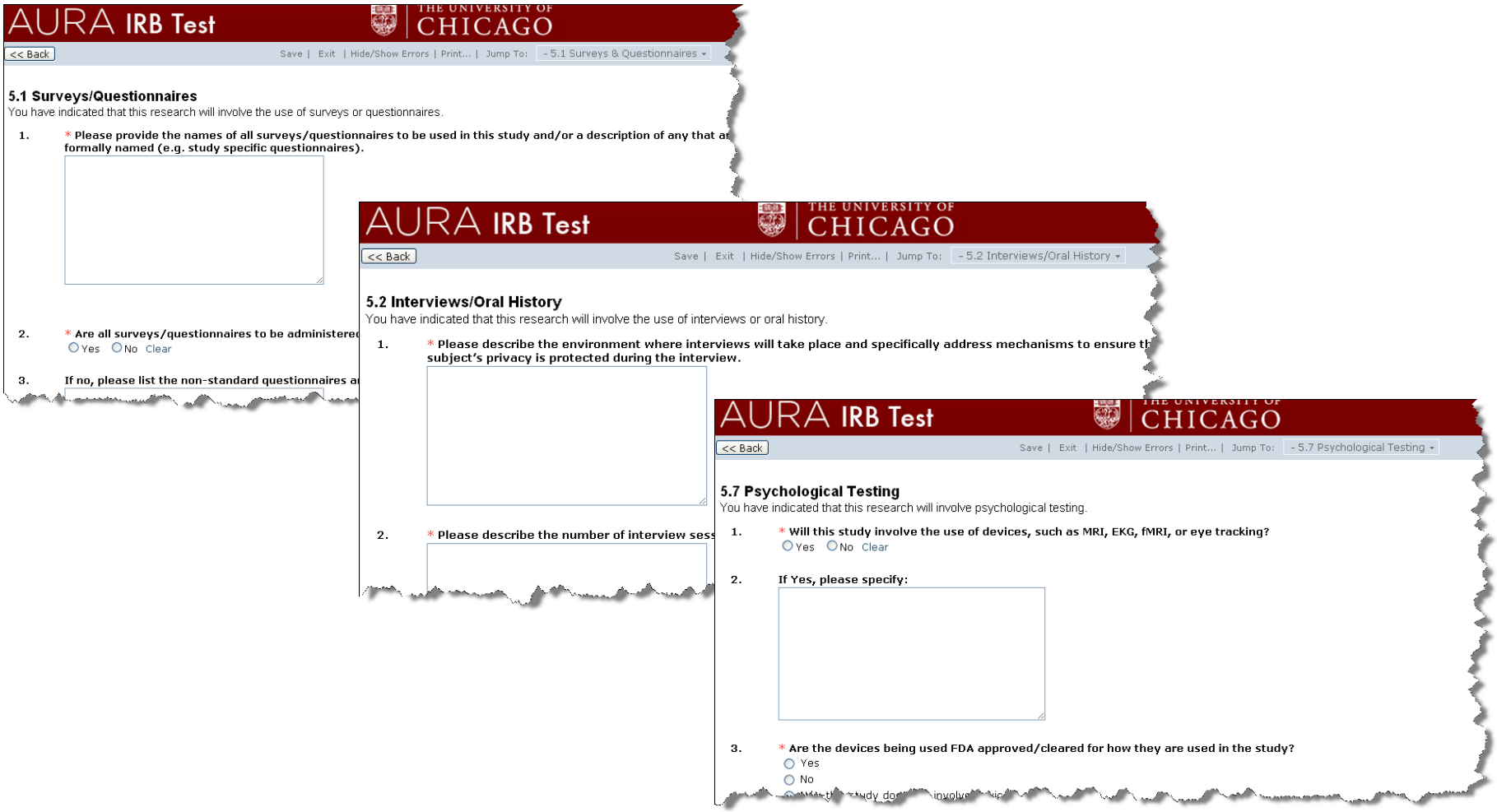
If the MAIN purpose of your study is to Administer drug(s) , Test device(s) , and/or compare or conduct a medical intervention you will prompted to answer questions in section 4 and subsections. *Note:* All views in section 4 are not shown .



Initial Submission

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

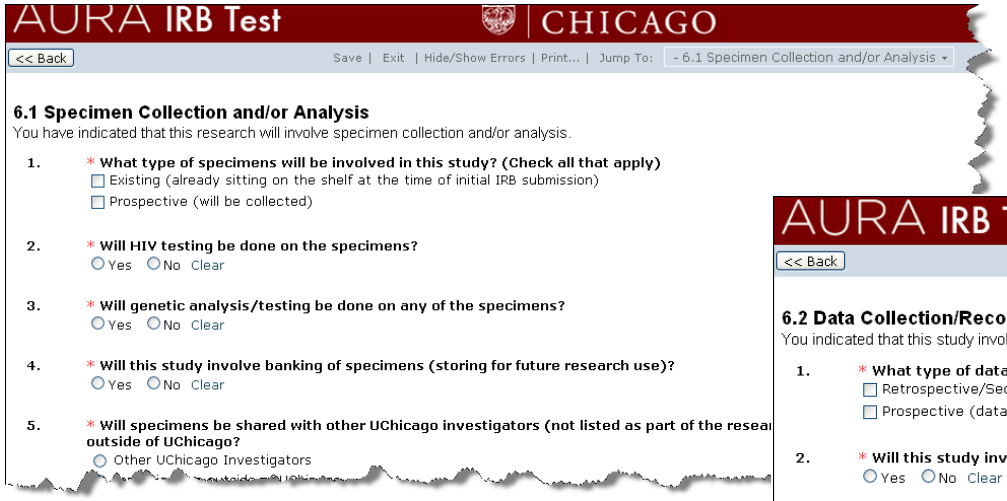
If the MAIN purpose of your study is to Conduct a surveys, interviews, focus groups, psychological testing you will be prompted to answer questions in section 5 and subsections. *Note:* All views in section 5 are not shown.

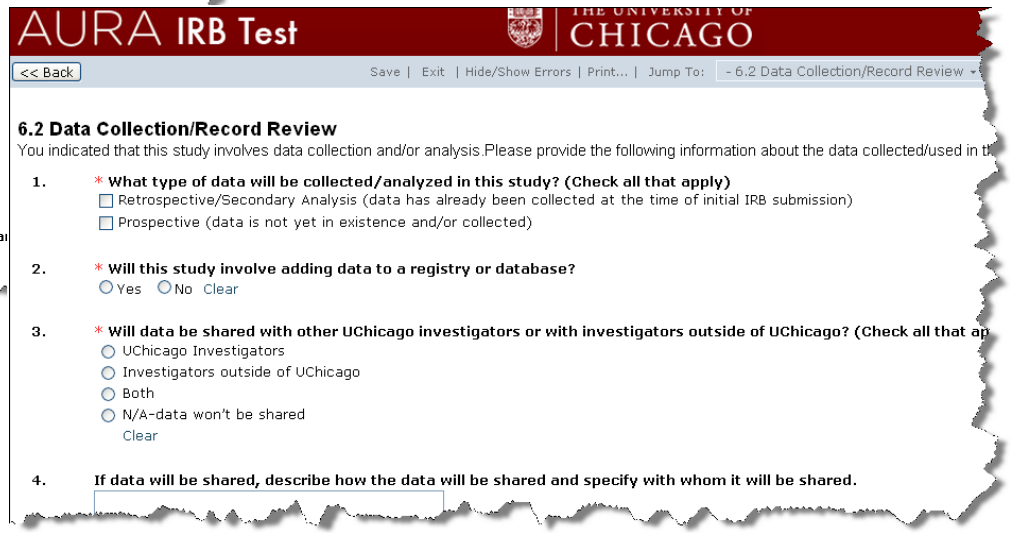


Initial Submission

6.1 – 6.2 Analyze data and/or specimens

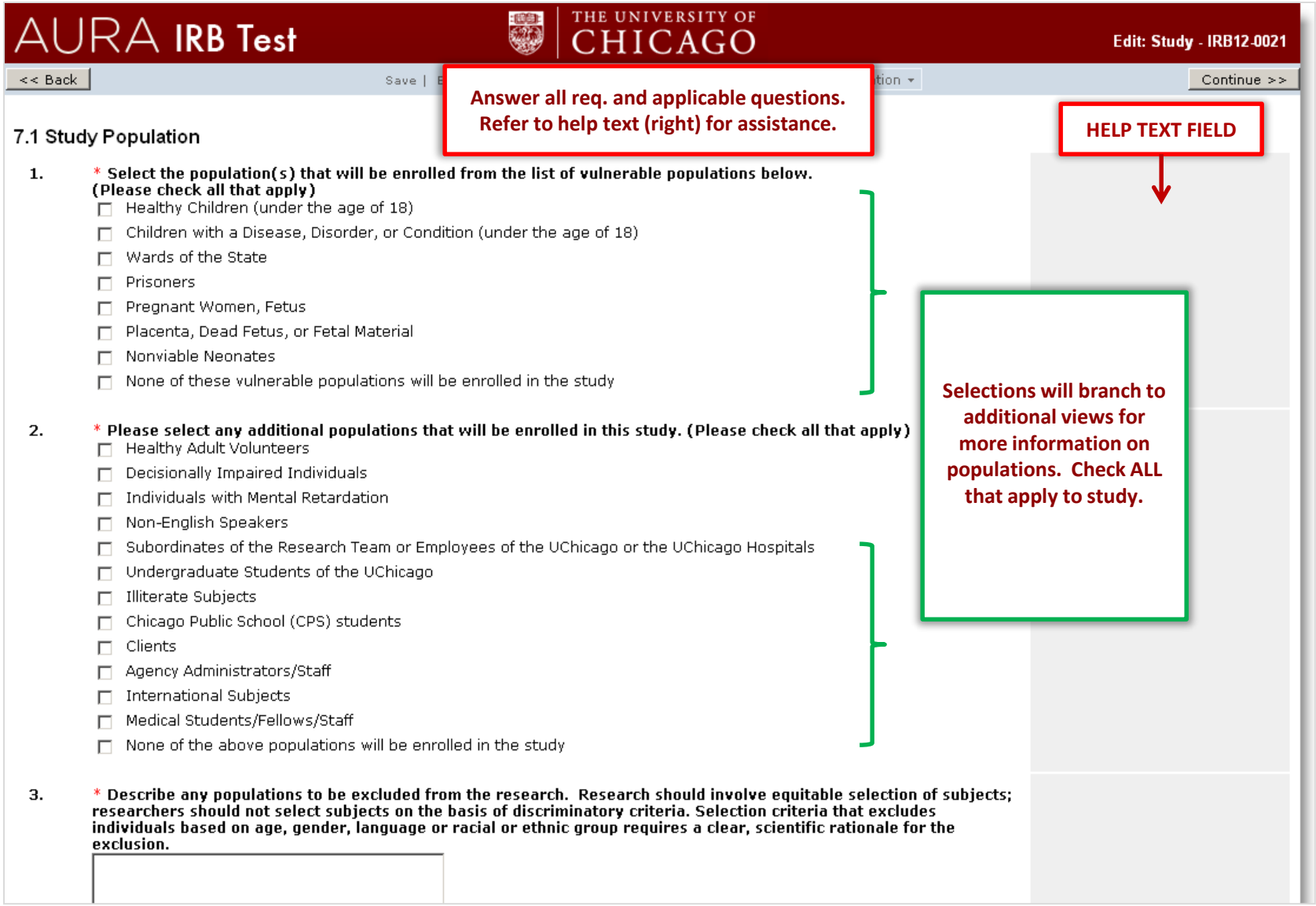
If the MAIN purpose of your study is to gather or analyze data and/or specimens (such as a chart review or secondary analyses you will be prompted to answer questions in section 6 and subsections. *Note:* All views in section 6 are not shown.





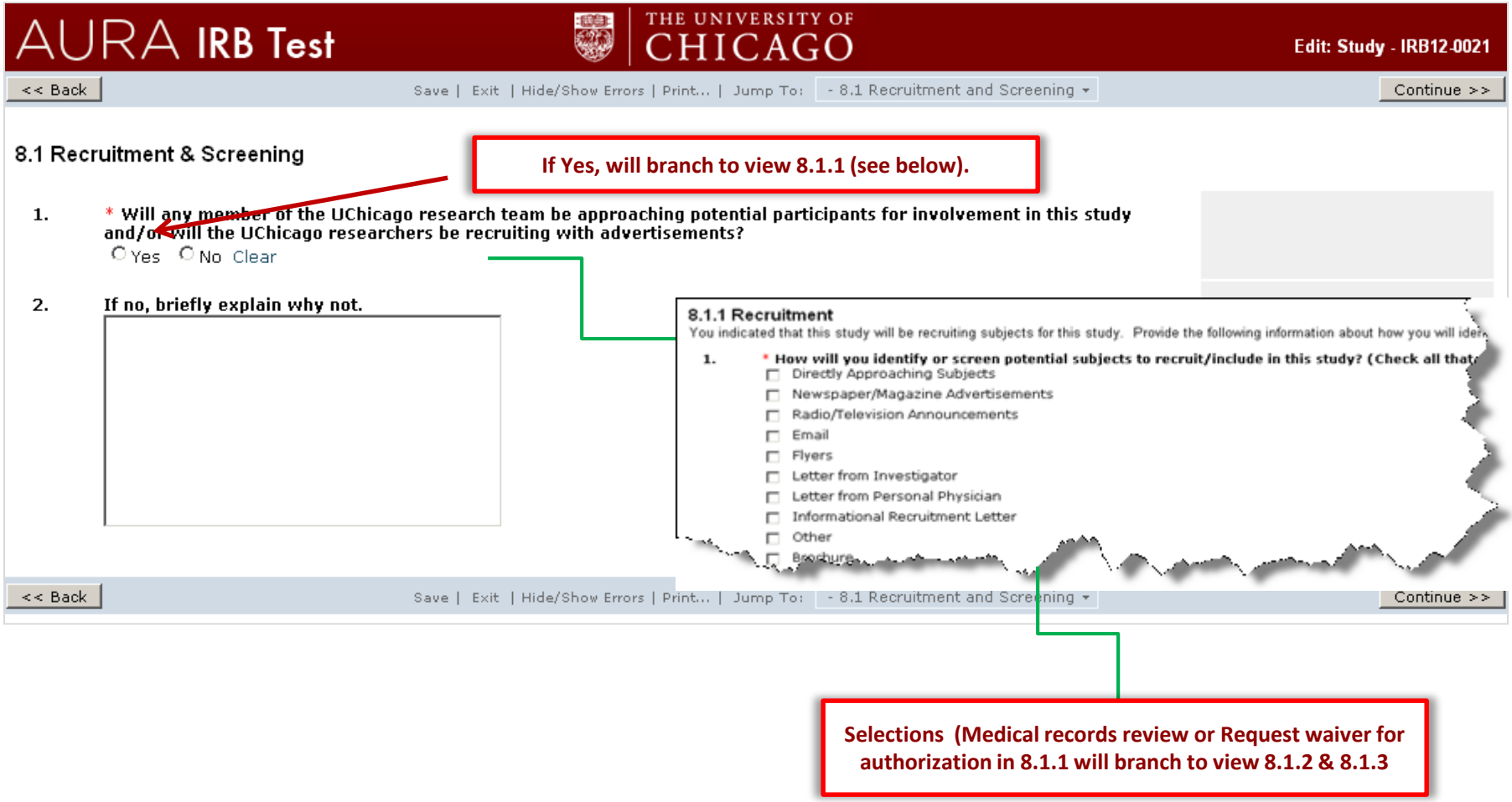
Initial Submission

7.1 Study Population



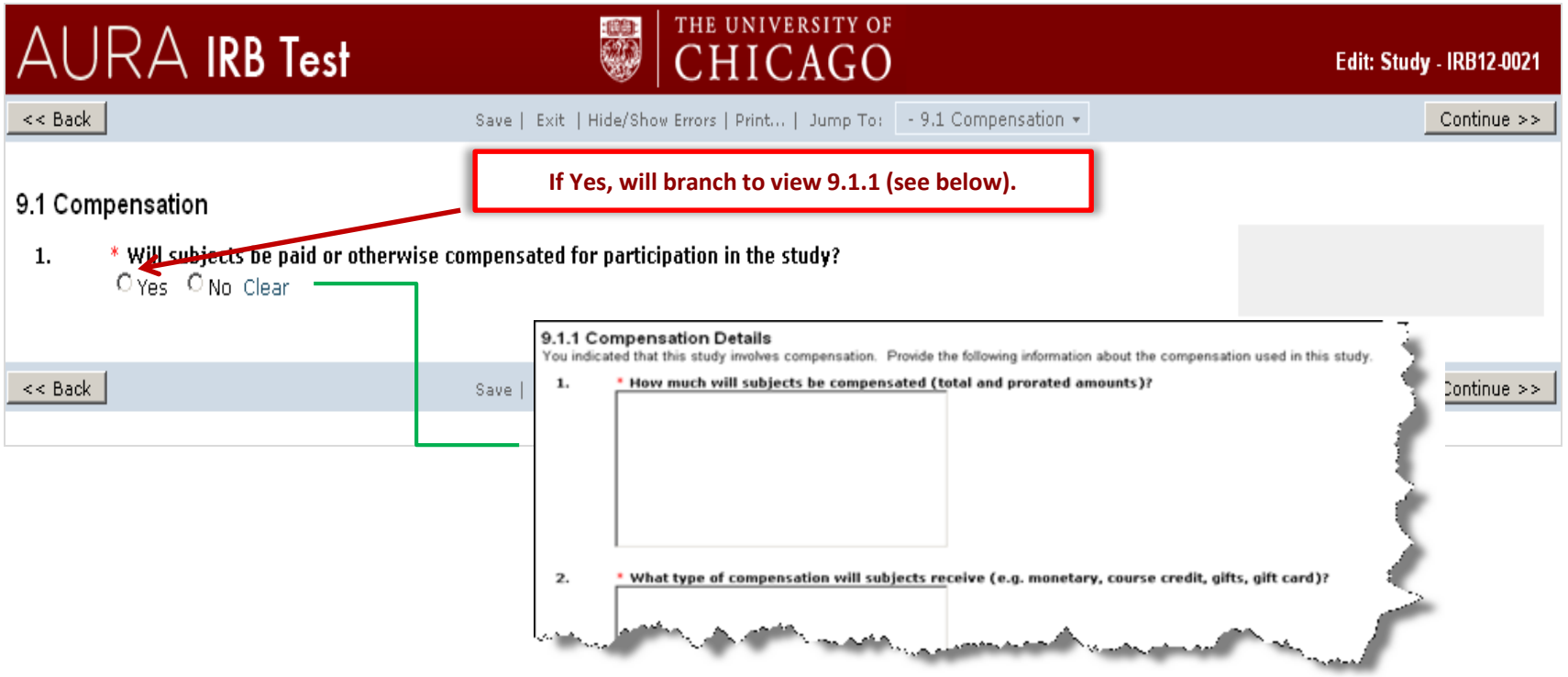
Initial Submission

8.1 Recruiting and Screening



Initial Submission

9.1 Compensation



Initial Submission

10.1 Risk Assessment

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

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: - 10.1 Risk Assessment | Continue >>

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.)

1. * **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.

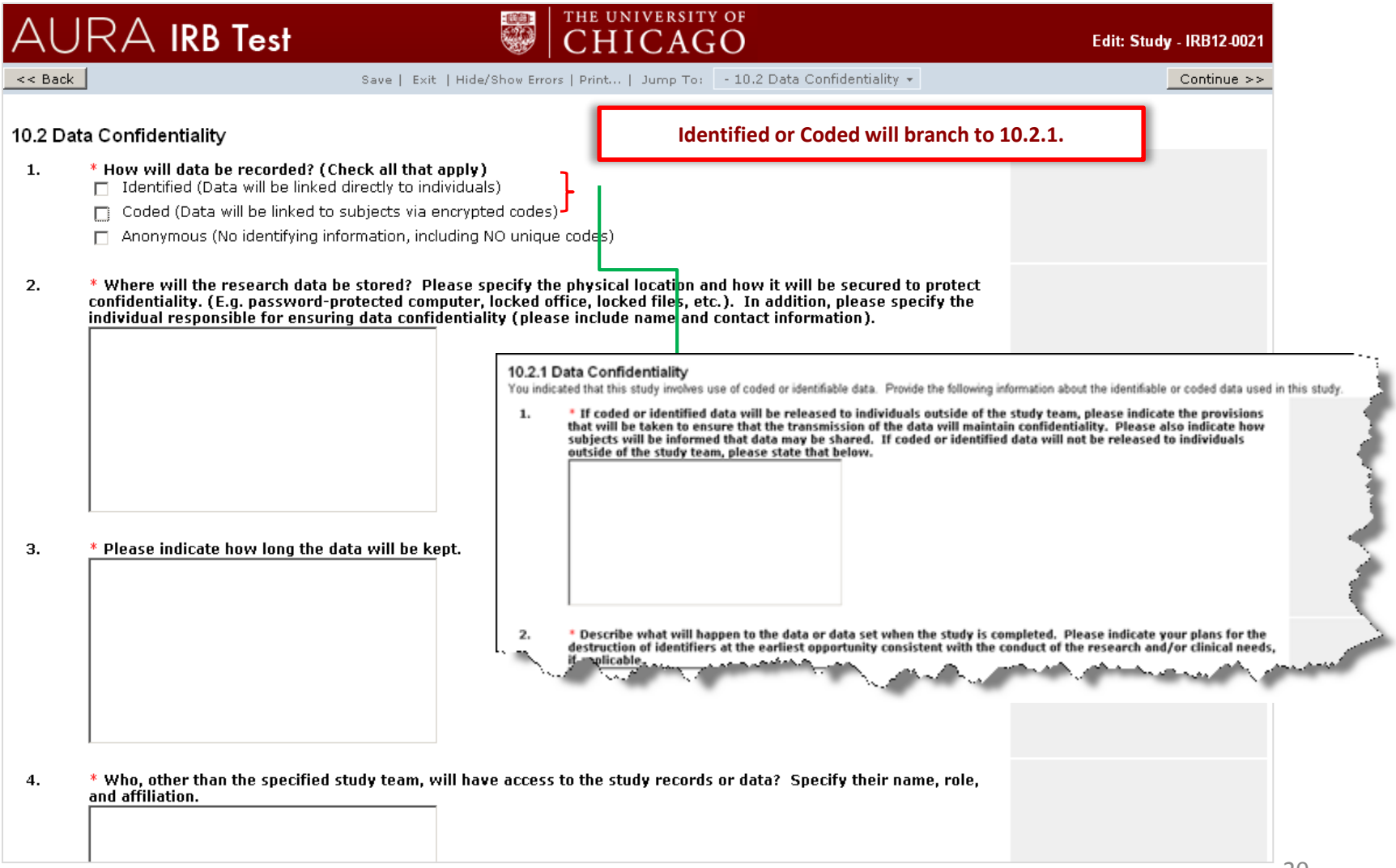
Answer all req. and applicable questions.
Refer to help text (right) for assistance.

2. * **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.**

3. * **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.**

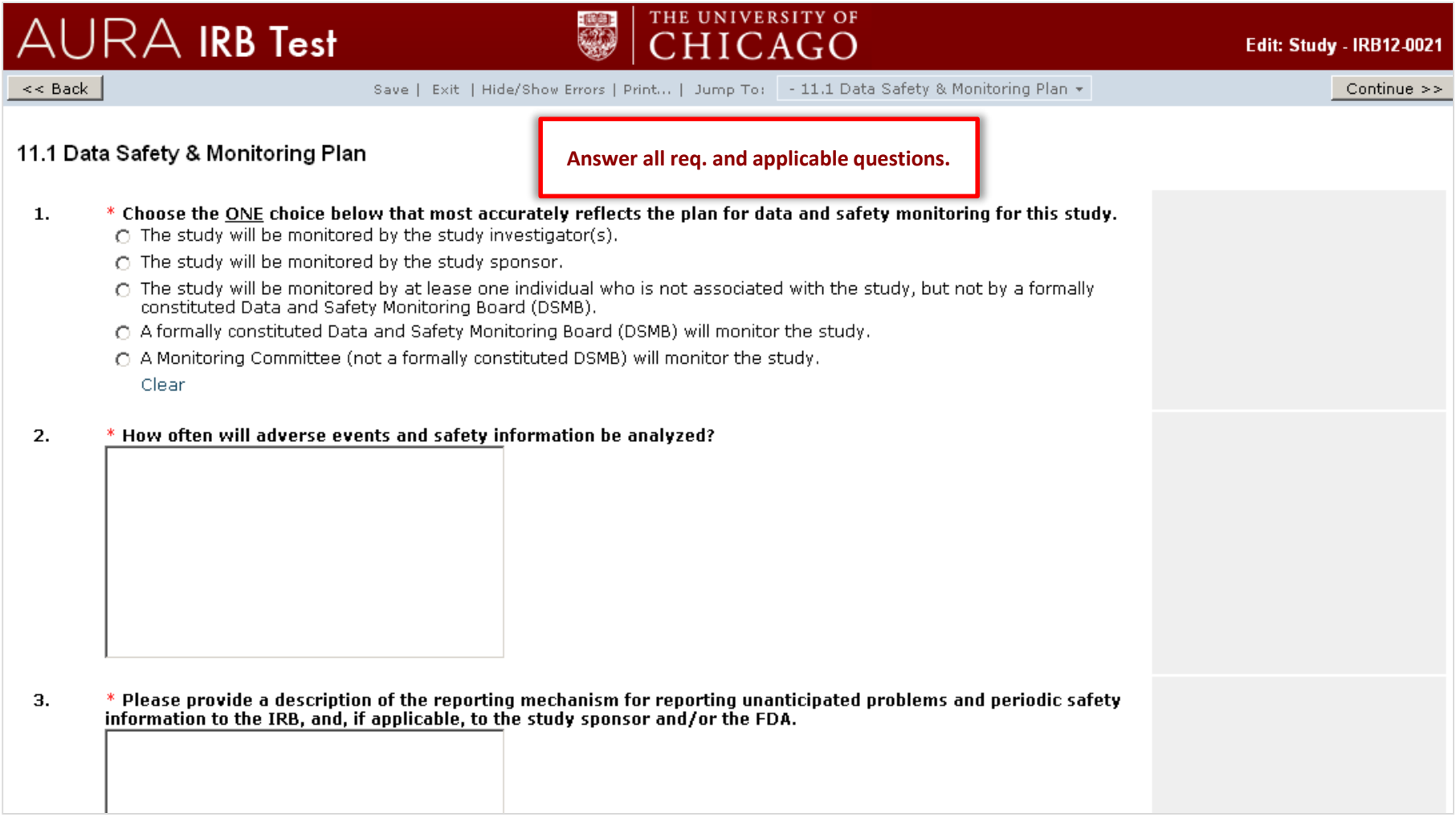
Initial Submission

10.2 Data Confidentiality



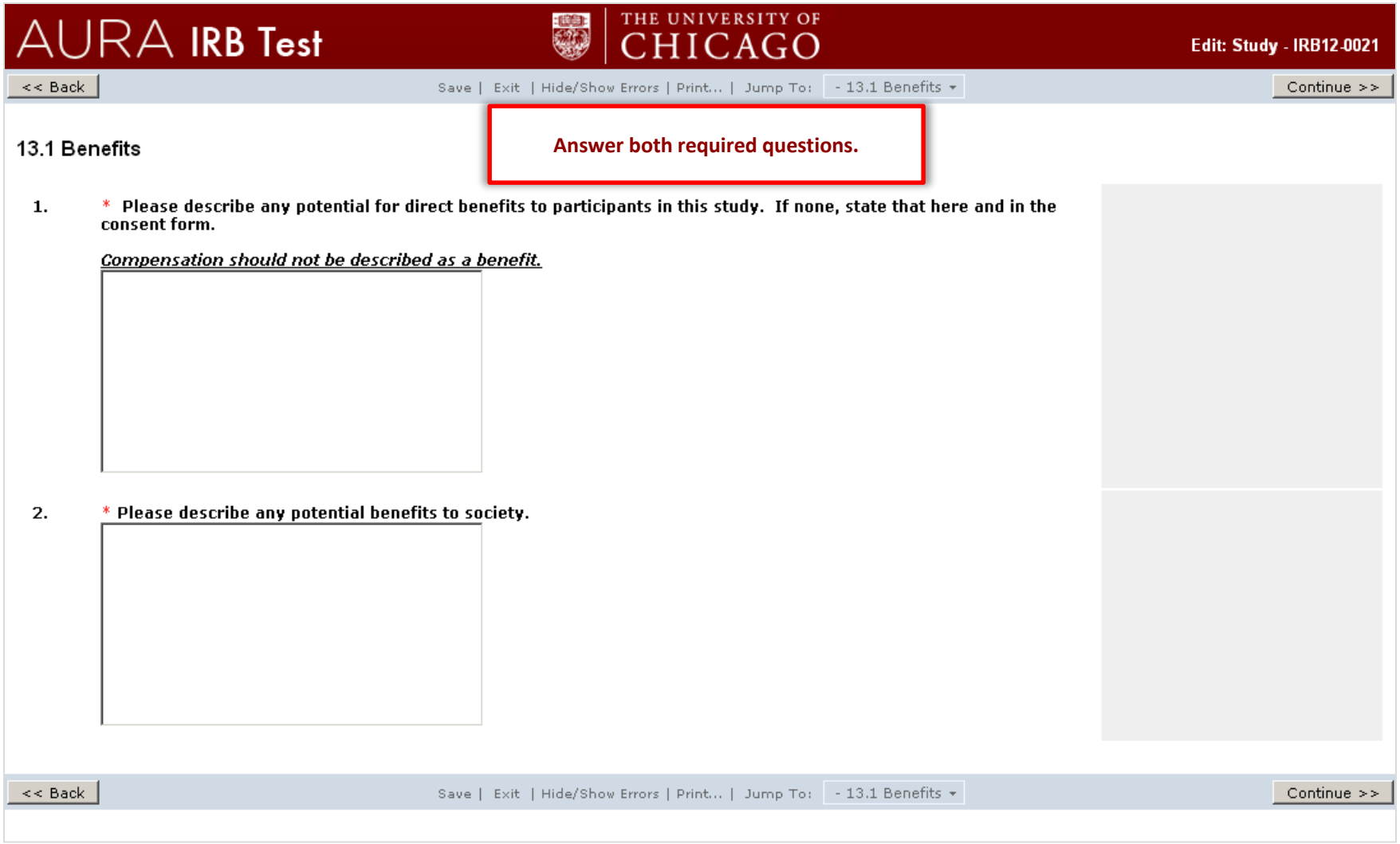
Initial Submission

11.1 Data Safety & Monitoring Plan



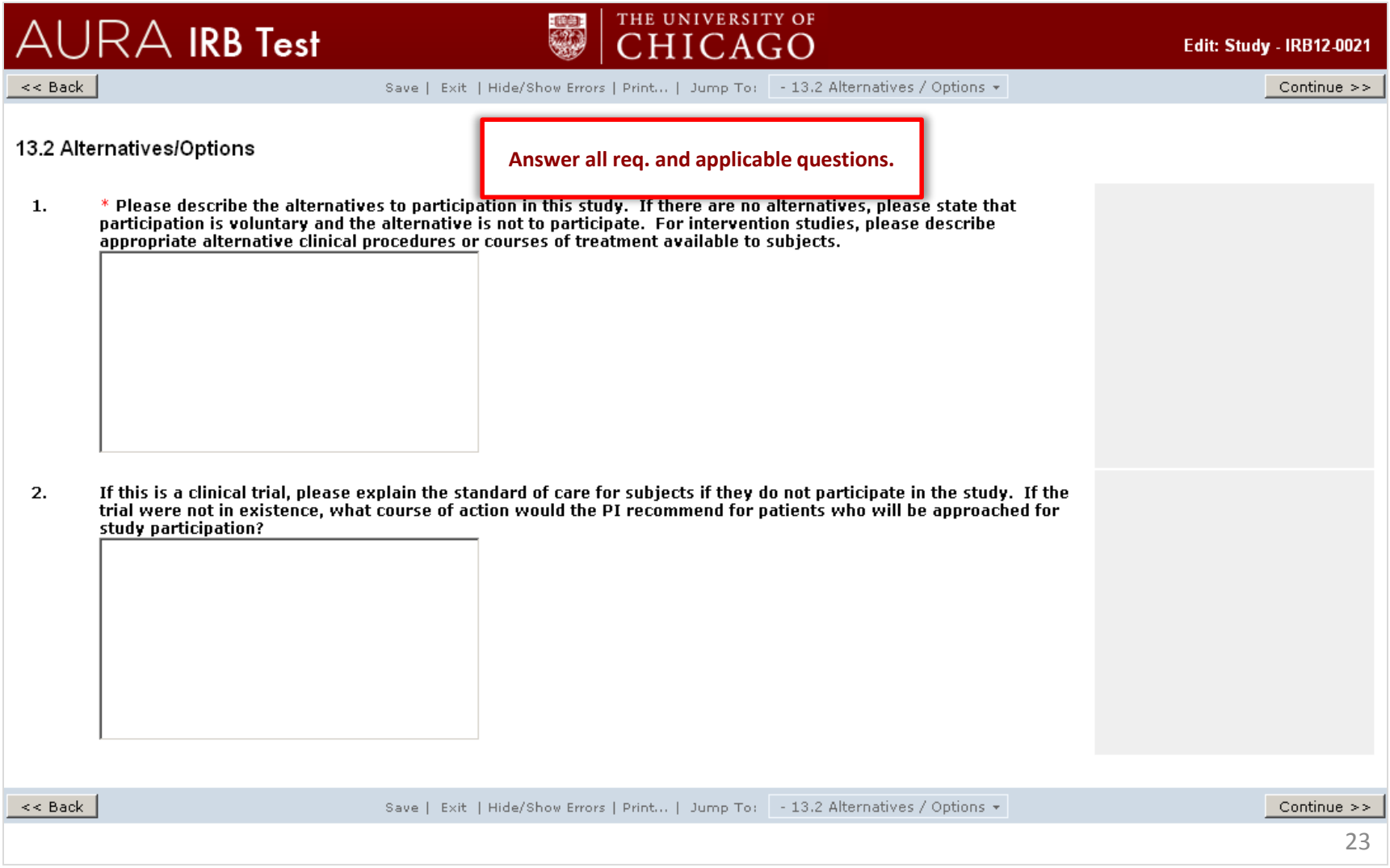
Initial Submission

13.1 Benefits



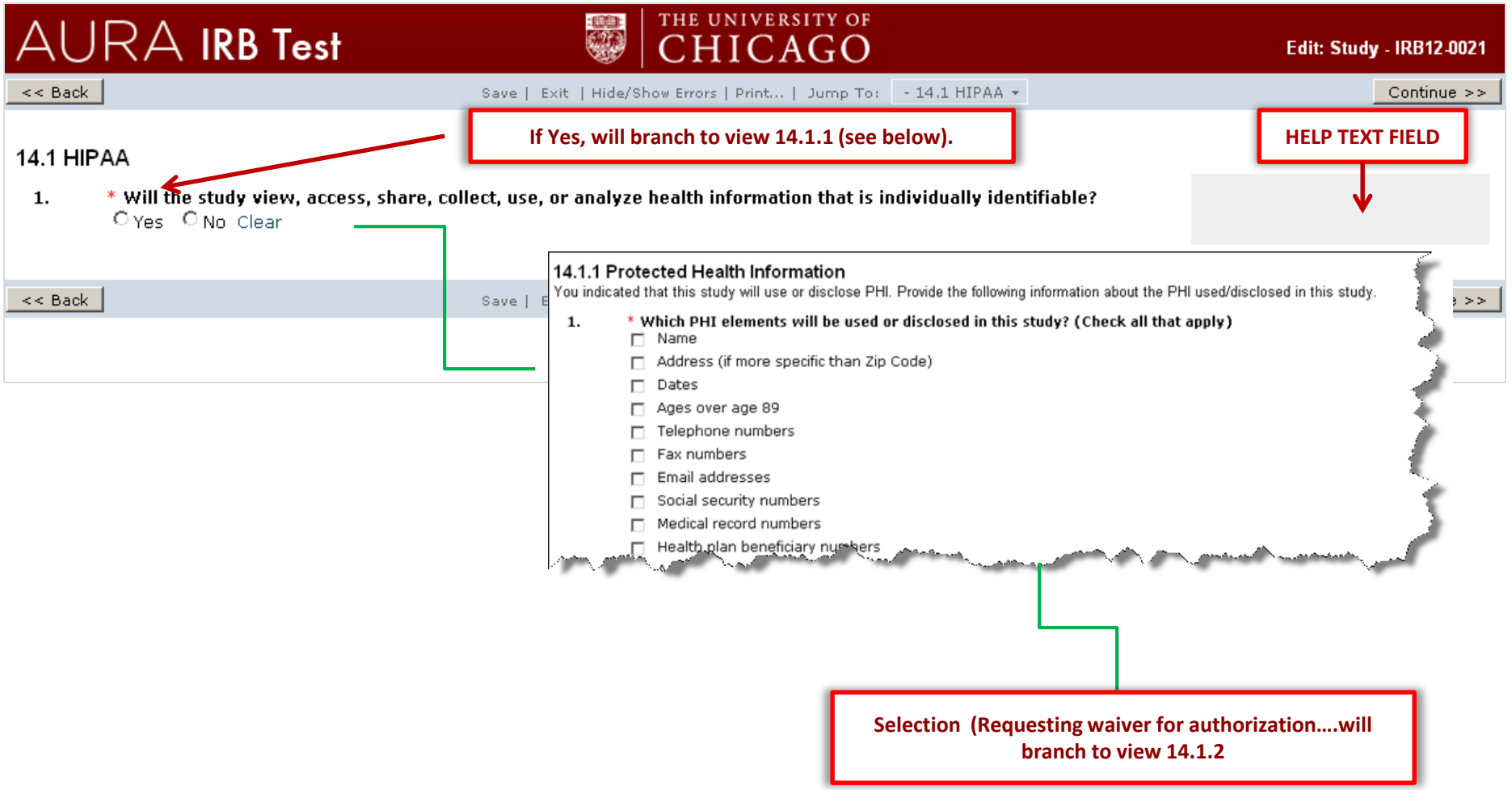
New Study Pre-Submission

13.2 Alternative/ Options



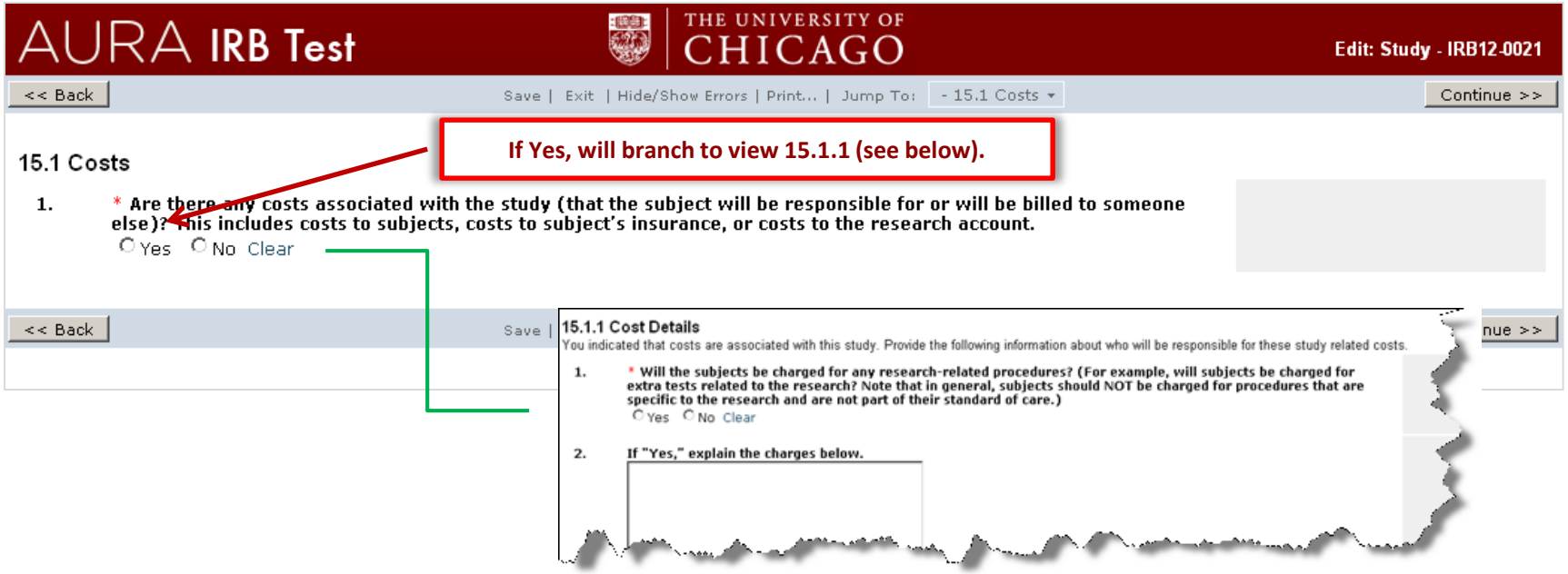
Initial Submission

14.1 HIPAA



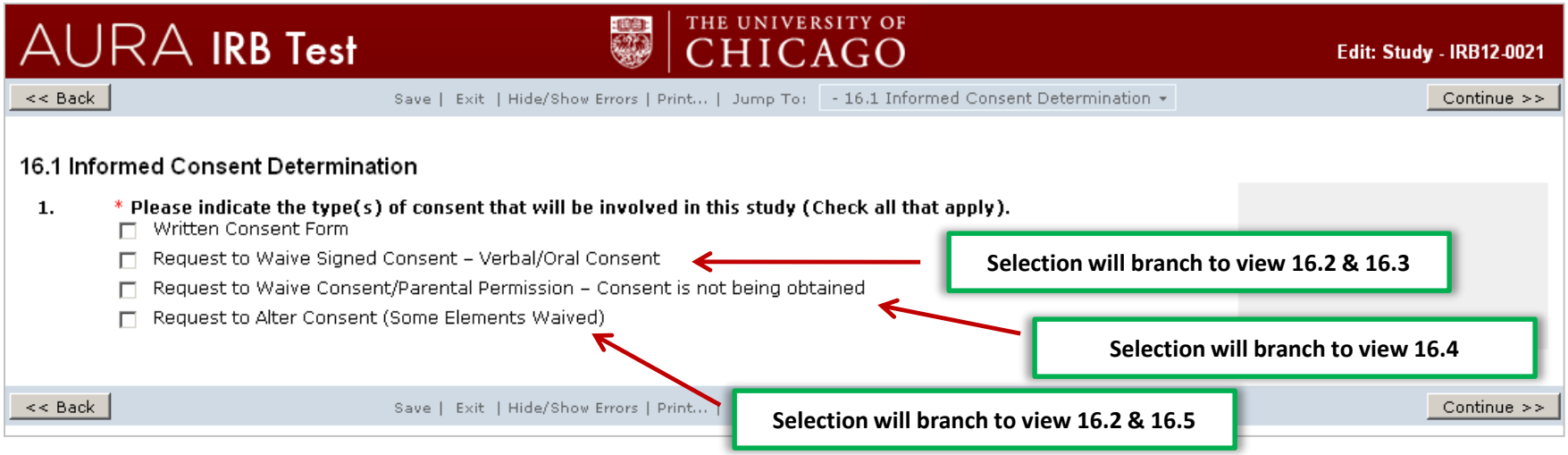
Initial Submission

15.1 Costs



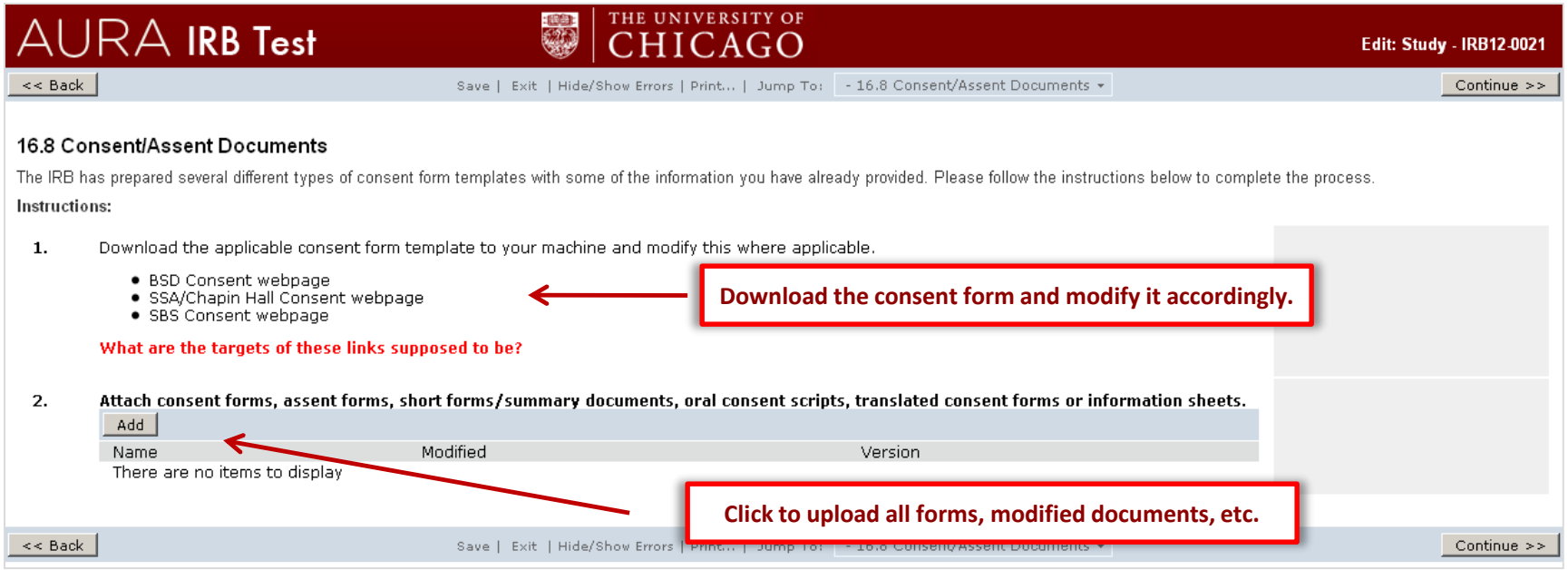
Initial Submission

16.1 Informed Consent Determination



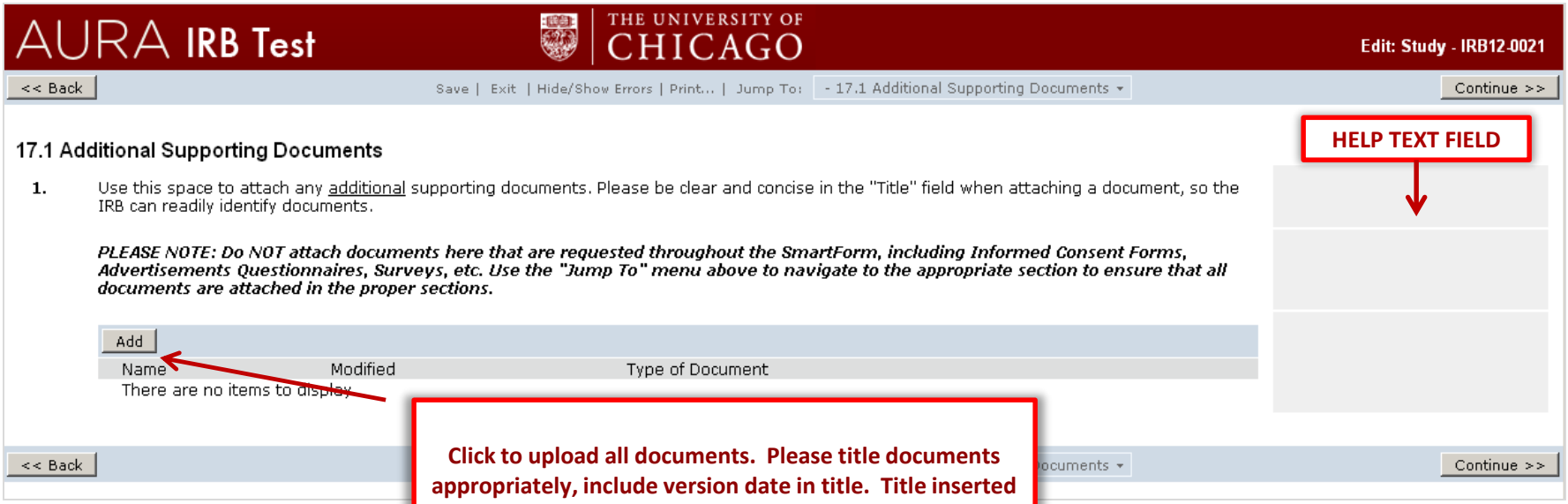
Initial Submission

16.8 Consent/ Assent Documents



Initial Submission

17.1 Additional Supporting documents



Initial Submission

19.1 Final Page