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IRB 7.2 User Training

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Human Subject Research Office

IRB 7 NAVIGATION

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"My Inbox"

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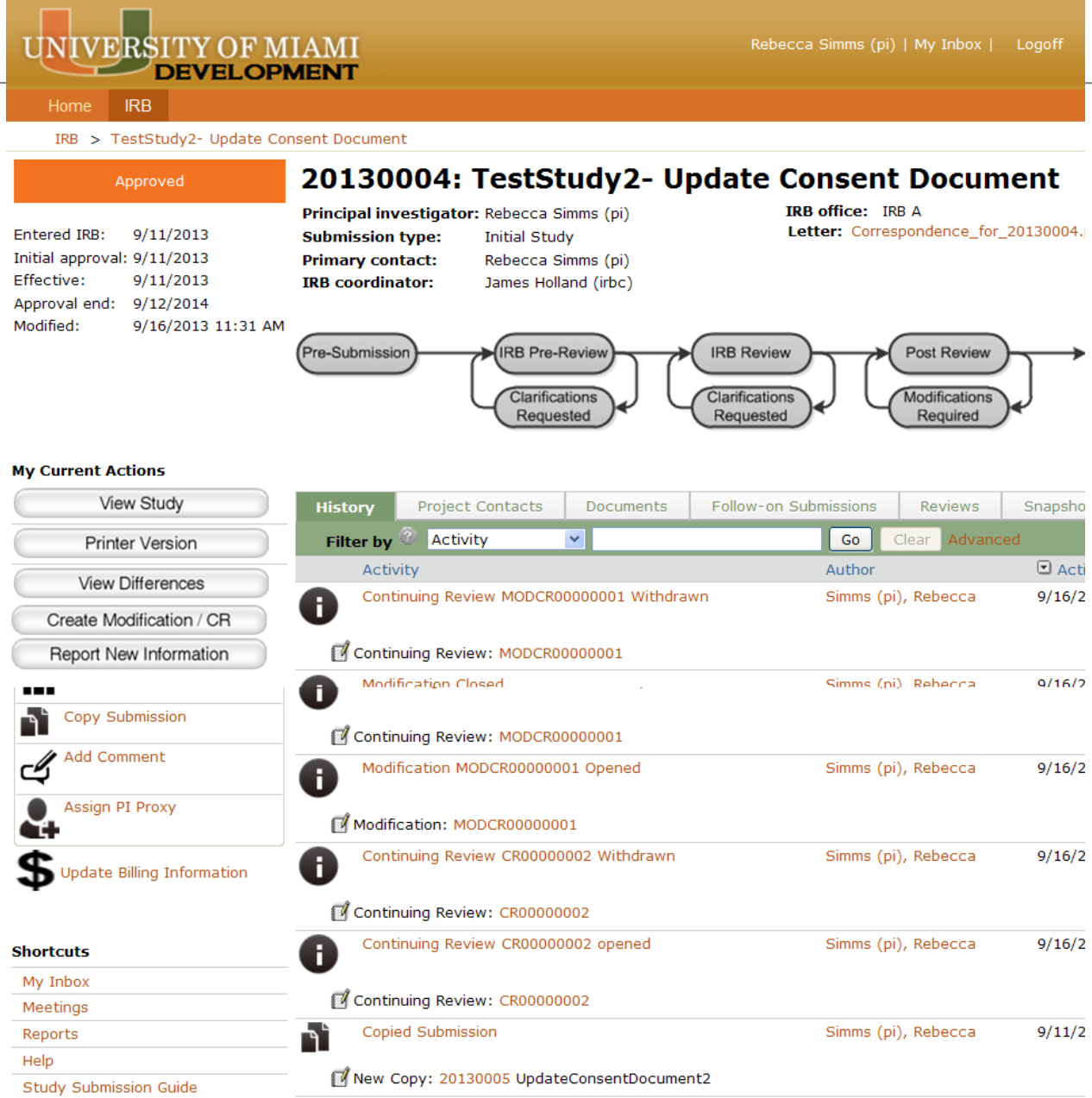
THE IRB PAGE



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THE STUDY WORKSPACE

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THE NEW STUDY APPLICATION

Creating a New Study

- New study information is entered into a series of online forms, the number of which may change based on the answers you provide
  - Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study
- Before you begin, gather files and information about your study such as:
  - Supporting information files
  - Financial interest status for each of your study team members
  - Contact information and IRB oversight information for external sites involved in the study

If you regularly create studies with a similar set of team members, you can save time by defining the default team members to be added to each study you create.

You can save time by defining the default list of ancillary reviewers to be added to each study you create.

A red asterisk (*) marks each required question. If you do not answer the question initially, you must answer it before you can submit the study for review

Tips & Time Savers

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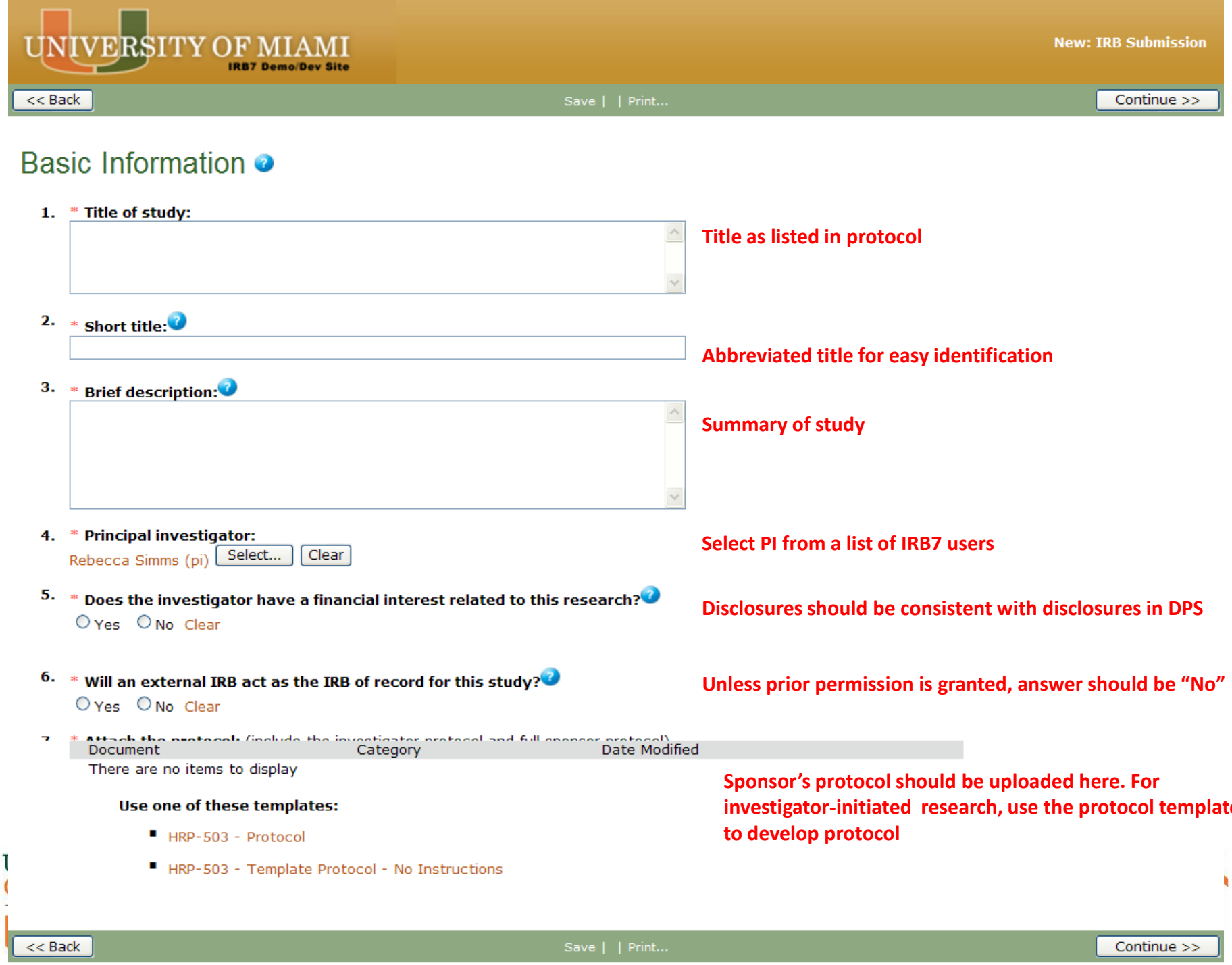
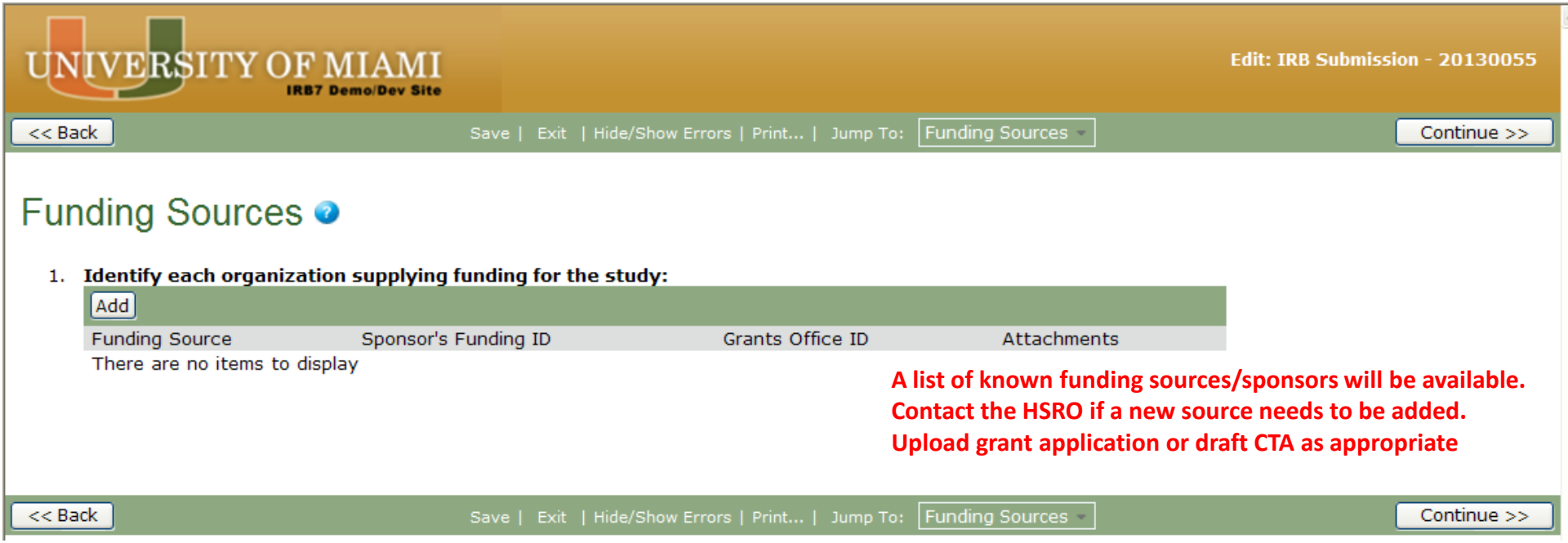
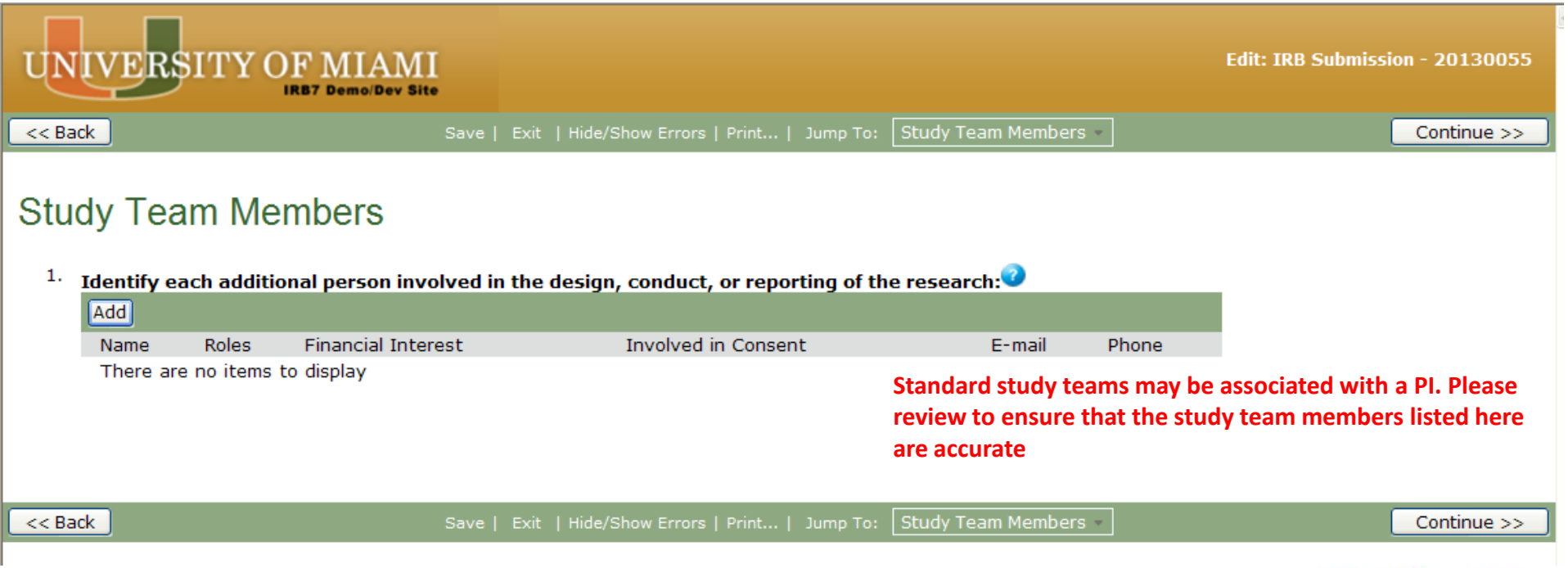
Completing the Smart Form

1. From My Inbox, click Create New Study.
   - *Note: If you do not see the Create New Study button, click the My Inbox link (upper right).*
2. Fill in the applicable boxes and answer the questions.
3. Click Continue to move to the next form.
4. When you reach the final page, click Finish to exit the study.
   - ***IMPORTANT! The study has not been submitted for review yet!***
   - *You can continue to edit the study until you submit it for review.*


UNIVERSITY OF MIAMI
IRB7 Demo/Dev Site
New: IRB Submission
<< Back
Save | | Print...
Continue >>
Basic Information
1. * Title of study:
Title as listed in protocol
2. * Short title:
Abbreviated title for easy identification
3. * Brief description:
Summary of study
4. * Principal investigator:
Rebecca Simms (pi) Select... Clear
Select PI from a list of IRB7 users
5. * Does the investigator have a financial interest related to this research?
Yes No Clear
Disclosures should be consistent with disclosures in DPS
6. * Will an external IRB act as the IRB of record for this study?
Yes No Clear
Unless prior permission is granted, answer should be "No"
Document Category Date Modified
There are no items to display
Use one of these templates:
HRP-503 - Protocol
HRP-503 - Template Protocol - No Instructions
Sponsor's protocol should be uploaded here. For investigator-initiated research, use the protocol template to develop protocol
<< Back
Save | | Print...
Continue >>


UNIVERSITY OF MIAMI
IRB7 Demo/Dev Site
Edit: IRB Submission - 20130055
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Funding Sources
Continue >>
Funding Sources
1. Identify each organization supplying funding for the study:
Add
Funding Source
Sponsor's Funding ID
Grants Office ID
Attachments
There are no items to display
A list of known funding sources/sponsors will be available.
Contact the HSRO if a new source needs to be added.
Upload grant application or draft CTA as appropriate
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Funding Sources
Continue >>


UNIVERSITY OF MIAMI
IRB7 Demo/Dev Site
Edit: IRB Submission - 20130055
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Study Team Members
Continue >>
Study Team Members
1. Identify each additional person involved in the design, conduct, or reporting of the research:
Add
Name
Roles
Financial Interest
Involved in Consent
E-mail
Phone
There are no items to display
Standard study teams may be associated with a PI. Please review to ensure that the study team members listed here are accurate
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Study Team Members
Continue >>

Study Scope

1. * **Are there external sites where the investigator will conduct or oversee the research?**
   Yes No Clear

   Answer "yes" only if the UM PI is responsible for the conduct of this study at external sites

2. * **Does the study do any of the following:**

   - Specify the use of an approved drug or biologic?
   - Use an unapproved drug or biologic?
   - Use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?

   Yes No Clear

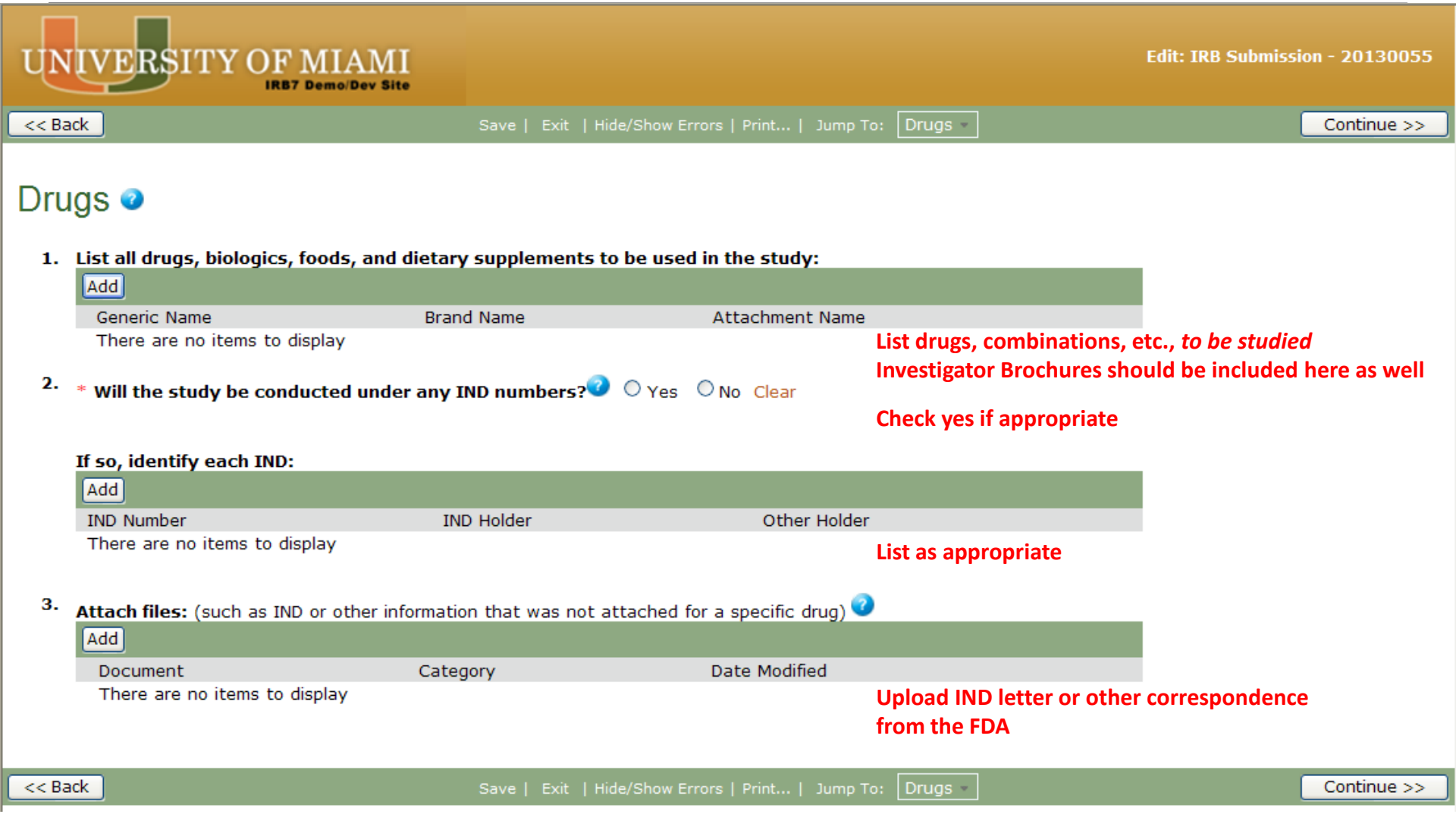
   Used for branching

3. * **Does the study do any of the following:**

   - Evaluate the safety or effectiveness of a device?
   - Use a humanitarian use device (HUD)?

   Yes No Clear

   Used for branching



This page will only appear if "yes" is selected in question 2 on the Study Scope page

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Devices

1. * **Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

Add

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

List devices *to be studied*
Any documentation, instructions, etc. associated with the use of the device would be uploaded here as well

2. * **Device exemptions applicable to this study:**

- ○ IDE number
- ○ HDE number
- ○ Claim of abbreviated IDE (nonsignificant risk device)
- ○ Exempt from IDE requirements

Clear

Check appropriate radio button

3. **If applicable, identify each IDE and HDE number:**

Add

IDE / HDE Number	IDE/ HDE Holder	Other Holder
There are no items to display		

List as appropriate

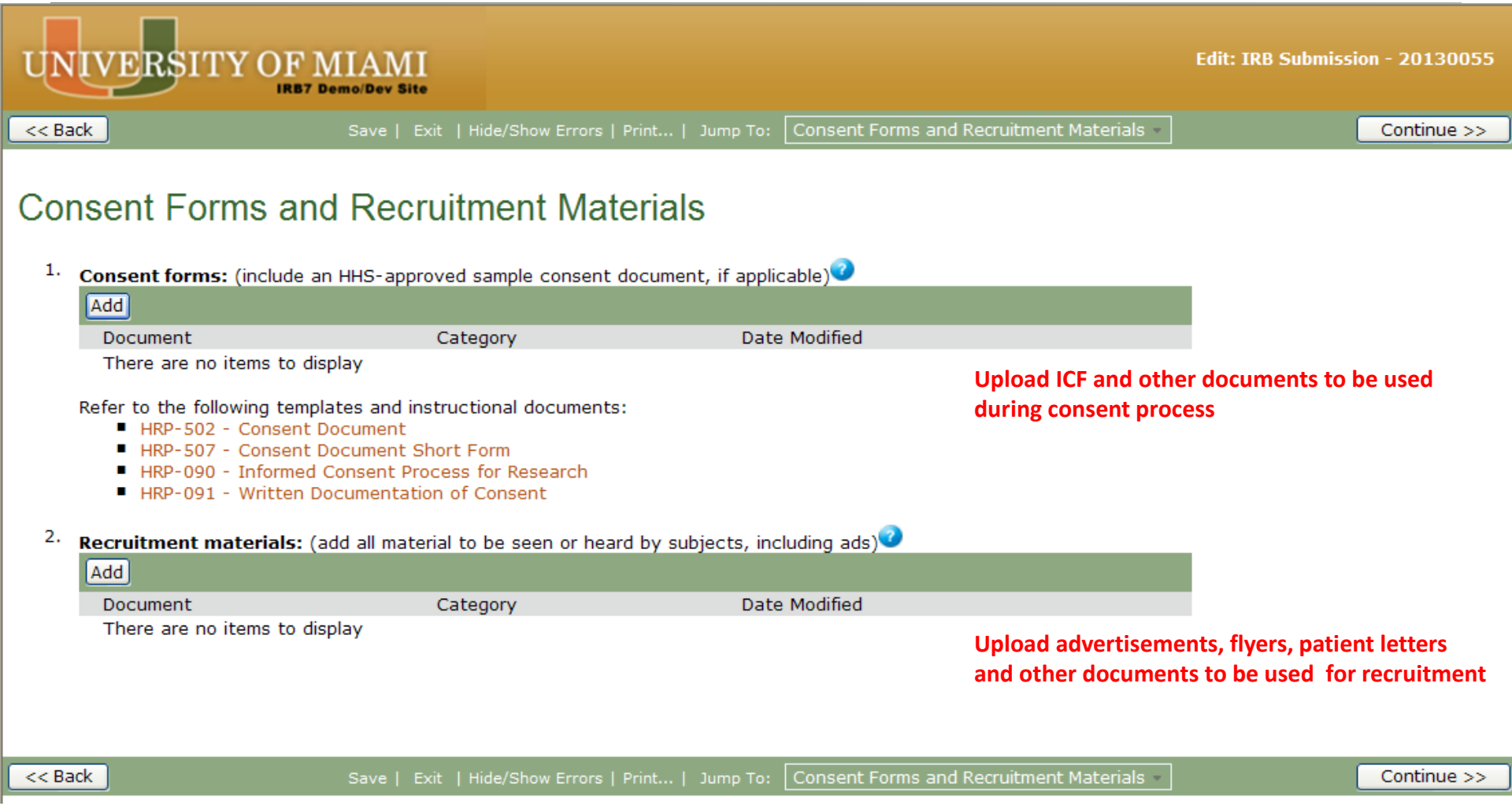
4. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)

Add

Document	Category	Date Modified
There are no items to display		

Upload IDE letter or other correspondence from the FDA

This page will only appear if "yes" is selected in question 3 on the Study Scope page


UNIVERSITY OF MIAMI
IRB7 Demo/Dev Site
Edit: IRB Submission - 20130055
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Consent Forms and Recruitment Materials
Continue >>
Consent Forms and Recruitment Materials
1. Consent forms: (include an HHS-approved sample consent document, if applicable)
Add
Document
Category
Date Modified
There are no items to display
Refer to the following templates and instructional documents:
HRP-502 - Consent Document
HRP-507 - Consent Document Short Form
HRP-090 - Informed Consent Process for Research
HRP-091 - Written Documentation of Consent
Upload ICF and other documents to be used during consent process
2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)
Add
Document
Category
Date Modified
There are no items to display
Upload advertisements, flyers, patient letters and other documents to be used for recruitment
<< Back
Save | Exit | Hide/Show Errors | Print... | Jump To: Consent Forms and Recruitment Materials
Continue >>

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IRB7 Demo/Dev Site

Edit: IRB Submission - 20130055

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

Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter:

Add

Document	Category	Date Modified
There are no items to display		

Upload any other documents not already included

Suggested attachments:

- Conflict of Interest Committee's determination for any financial interest related to the research
- Complete checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

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

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IRB7 Demo/Dev Site

Edit: IRB Submission - 20130055

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: | Finish

Final Page

NOTE: Clicking "Finish" does not submit the study. The PI must log in and click on the submit study link. NOTE: Only the PI may submit the study.

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, the principal investigator must click **Submit** on the next page.

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: | Finish

CHECKING THE STUDY FOR ERRORS

- ***Automatic system error checking*** identifies omitted answers to required questions on the form when you click Continue
- ***Visually inspect the form*** to see if you missed:
  - Questions that are relevant to your study but not usually required
  - Documents that should be attached
- Use ***the Hide/Show Errors option*** to find and correct all errors before submitting the study
  - IRB 7.2 automatically checks for errors when PI attempts to submit the study
  - If you are filling out the forms on behalf of the PI, check the study for errors before the PI attempts to submit it

Submitting the Study for Review

Important! Only the principal investigator can complete the following steps.

1. Log in to the system.
2. Make sure you are in My Inbox.
3. Click the name of the study to open it.
4. Click **Submit** from the My Current Actions list on the left.
5. Click **OK** to agree to the statement presented on the screen.
6. When prompted, log in again to verify your identity as the study's PI.
7. Click **Submit**.

What to Expect After Submitting

Submitting information to the IRB initiates a series of activities that may include:

- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Any of these may lead to a request for the investigator to take further action, such as providing clarifications or modifying the study. ***Whenever you need to act, you receive an e-mail notification, and the study appears in My Inbox when you log in to the IRB system.***

Checking the Status of Your Study

- You can see a diagram showing the state of your study by opening the study. For example:

- You can easily open your study from one of the following lists (depending on its status):
  - My Inbox
  - IRB In-Review Studies
  - IRB Active Studies

Responding to a Request for Clarifications or Modifications

*The IRB may request clarifications or require changes before research can begin. The PI and the study's primary contact will receive an e-mail and the study will appear in **My Inbox** for each member of the study team.*

To view the details of the request and respond with the changes:

1. From **My Inbox**, click the name of the study to open it
2. Locate the details of the request
3. Edit the study to incorporate changes as needed
4. Click **Submit Changes** to return the study to the reviewers
   - The Submit Changes form gives you space to type a response to the requests and to attach a file
5. Click **OK**. The study will return to the review process

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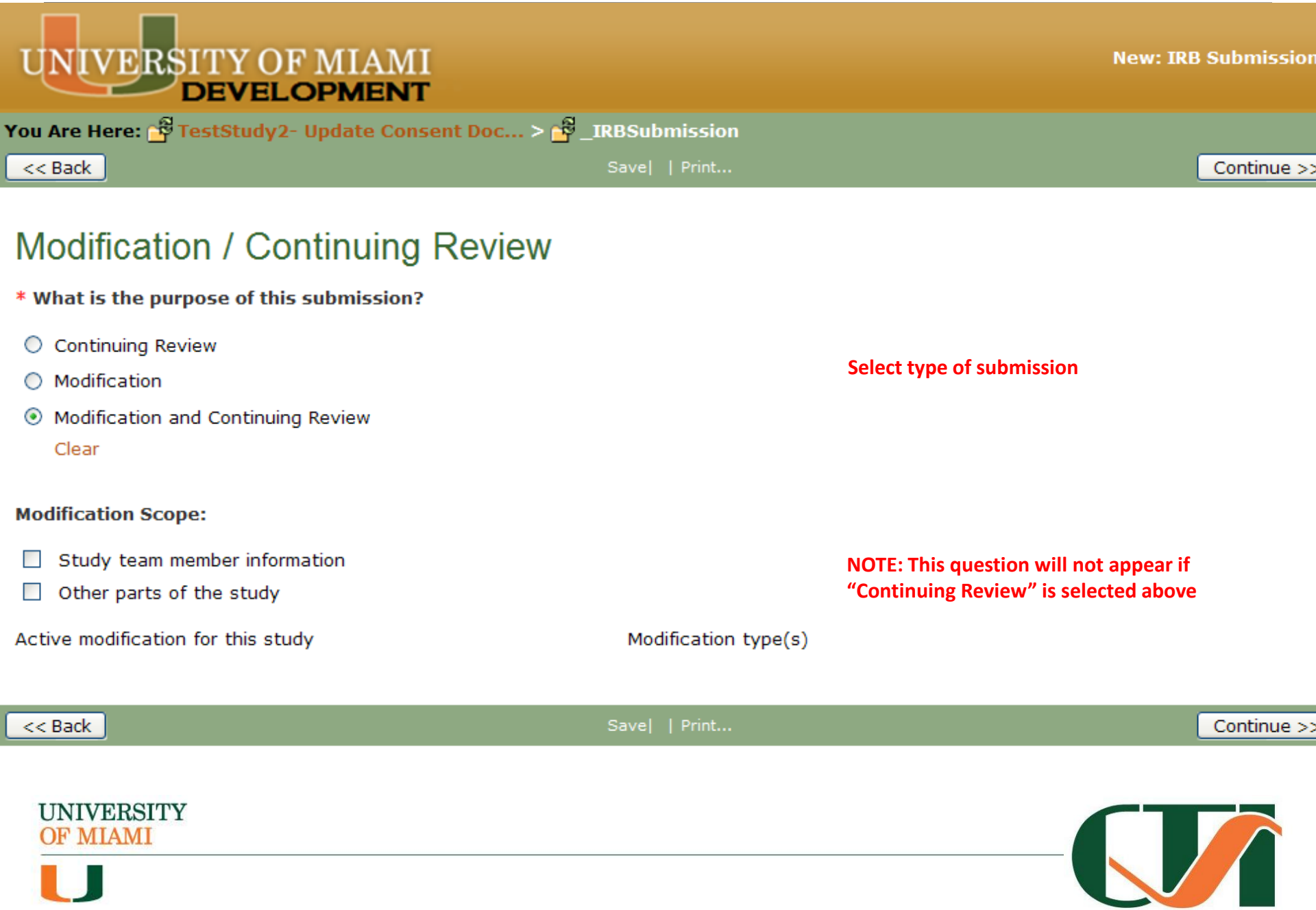
THE MODIFICATION/ CONTINUING REVIEW FORM



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Continuing Review / Study Closure Information

1. * **Specify enrollment totals:**

Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:		
Study-wide:		

Numbers reported here must be consistent with prior reports and, if applicable, Velos

2. **Research milestones:** (select all that apply)
   - ☐ Study is permanently closed to enrollment
   - ☐ All subjects have completed all study-related interventions
   - ☐ Collection of private identifiable information is complete
   - ☐ Analysis of private identifiable information is complete
   - ☐ Remaining study activities are limited to data analysis
   - ☐ Study remains active only for long-term follow-up of subjects

Indicate current state of the study

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

3. * **Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**

☐ Study remains active only for long-term follow-up of subjects

Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.

3. * **Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?**

If a COI was disclosed at initial submission, or there are no COIs, select "No"

○ Yes ○ No Clear

Select all that apply

- ☐ NO subjects withdrew from the study
- ☐ NO unanticipated problems involving risks to subjects or others
- ☐ NO complaints about the study
- ☐ NO publications in the literature relevant to risks or potential benefits
- ☐ NO interim findings
- ☐ NO multi-center trial reports
- ☐ NO data safety monitoring reports
- ☐ NO regulatory actions that could affect safety and risk assessments
- ☐ NO other relevant information regarding this study, especially information about risks
- ☐ In the opinion of the PI, the risks and potential benefits are unchanged
- ☐ All modifications to the protocol have been submitted to the IRB
- ☐ All problems that require prompt reporting to the IRB have been submitted

5. **Attach supporting documents:** (include an explanation of each item left unchecked above)

Add

Name
There are no items to display

Examples: enrollment summaries, summaries of AEs not requiring immediate reporting, summaries of deviations not requiring immediate reporting, DSMB reports, grant progress reports, sponsor letters re: enrollment, etc.

Modification Information

1. **Study enrollment status:**
   - ☐ Subjects are currently enrolled
   - ☐ Study is permanently closed to enrollment
   - ☐ All subjects have completed all study-related interventions
   - ☐ Collection of private identifiable information is complete

Indicate current state of study

2. **Notification of subjects:** (check all that apply)
   - ☐ Current subjects will be notified of these changes
   - ☐ Former subjects will be notified of these changes

Indicate whether PI intends to notify subjects

Attach files: If notifying subjects, add a description of how they will be notified to the Supporting Documents page.

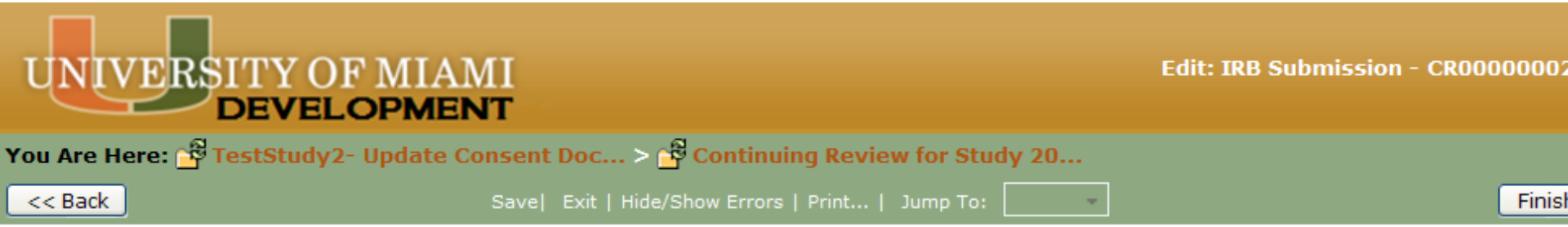
3. * **Summarize the modifications:**

List any changes that are UM-specific

Study-wide modifications that are described in a sponsor's amendment do not need to be included here. Study teams may simply state "Refer to sponsor's summary of changes (or other appropriate document)"

IRB 7 WILL AUTOMATICALLY OPEN A MODIFIABLE VERSION OF THE STUDY FORM

ANY CHANGES LISTED IN THE AMENDMENT FORM SHOULD BE MADE TO THIS VERSION OF THE STUDY FORM



Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, the principal investigator must click **Submit** on the next page.

NOTE: Clicking "Finish" does not submit the continuing review/modification. The PI must log in and click on the submit link. NOTE: Only the PI may submit the continuing review/modification.

<< Back
Save| Exit | Hide/Show Errors | Print... | Jump To:
Finish

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THE REPORTABLE NEW INFORMATION FORM

Reportable New Information

When viewing items in your Inbox or on the IRB Workspace, RNI Short Title will show up under the "Name" column

1. **RNI short title:** (uniquely identify this new information report)

2. * **Date you became aware of the information:**

List date study team became aware of the RNI

3. **Identify the categories that represent the new information:** (check all that apply)

☐ **Risk:** Information that indicates a new or increased risk, or a safety issue. For example:

a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.

c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

f. Any changes significantly affecting the conduct of the research. frequency, and characteristics of the study population.

b. A harm is "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

☐ **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance

RNI includes unanticipated problems, newly identified risks, adverse events (unexpected and probably related), deviations and violations, audit or monitoring results, etc.

RNIs do not include expected or unrelated AEs, IND Safety Reports, Translations, Sponsor Letters without impact on risks, etc.

b. A harm is "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

- ☐ **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
- ☐ **Audit:** Audit, inspection, or inquiry by a federal agency.
- ☐ **Report:** Written reports of study monitors.
- ☐ **Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- ☐ **Confidentiality:** Breach of confidentiality.
- ☐ **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- ☐ **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- ☐ **Complaint:** Complaint of a subject that cannot be resolved by the research team.
- ☐ **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
- ☐ **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Important! Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

4. * **Briefly describe the new information:**

Summary of RNI

5. In the PI's opinion:

5. **In the PI's opinion:**

   a. * **Does this information indicate a new or increased risk, or a safety issue?**
   ○ Yes ○ No Clear

   b. * **Does the study need revision?**
   ○ Yes ○ No Clear

   c. * **Does the consent document need revision?**
   ○ Yes ○ No Clear

Select Yes or No based on PI's review of the RNI

If revisions are required, describe them above and submit a study modification for review.

6. **Related Studies:**

Add

ID	Short Title	Investigator	State	IRB Office
There are no items to display				

You will be able to list as many studies as are affected. *(E.g. PI is involved in multiple studies involving the same drug.)*

7. **Attach files containing supporting information:**

Add

Name
There are no items to display

Upload documents as appropriate

<< Back | Save | | Print... | Continue >>

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THE PROTOCOL TEMPLATE

Using the Investigator Protocol Template

- Guidance to investigators will be italicized and should be deleted
- Certain sections of the template *may not* be applicable
- Indicate in your inclusion criteria the following populations of subjects :
  - Adults unable to provide legally effective consent
  - Individuals who are not yet adults (infants, children, teenagers)
  - Pregnant women
  - Prisoners
- Contact the HSRO for information about:
  - Using a community-based participatory research design
  - Use of community advisory boards
  - Use of participant advocates
  - Partnerships with community-based organizations

Sample Protocol Template Section-By-Section

1. Protocol Title
2. IRB Review History
   - Details of any prior review including IRB name, dates and contact info
3. Objectives
   - Purpose, specific aims and objectives
4. Background
5. Inclusion and Exclusion Criteria
   - Populations with additional requirements: adults unable to consent; infants, children, teenagers; pregnant women; prisoners
6. Number of Subjects
7. Study-Wide Recruitment Methods
8. Study Timelines
9. Study Enpoints
10. Procedures Involved
11. Data and Specimen Banking
12. Data Management
13. Provisions to Monitor the Data to Ensure the Safety of Subjects
14. Withdrawal of Subjects
15. Risks to Subjects
16. Potential Benefits to Subjects

Sample Protocol Template Section-By-Section

17. Vulnerable Populations
18. Multi-Site Research
    - Procedures for communciation among engaged sites
19. Community-Based Participatory Research
20. Sharing of Results with Subjects
21. Setting
22. Resources Available
23. Prior Approvals
    - e.g. schools, external sites, funding agency, laboratory, radiation safety, biosafety
24. Recruitment Methods
25. Local Number of Subjects
26. Confidentiality
27. Provisions to Protect the Privacy Interests of Subjects
28. Compensation for Research-Related Injury
29. Economic Burden to Subjects
30. Consent Process
    - Non-English speaking subjects
    - Waivers or Alternation of Consent Process
    - Cognitively Impaired Adults
    - Adults Unable to Consent
31. Process to Document Consent in Writing
32. Drugs or Devices

Creating a Consent Document

- HSRO will provide a Template Consent Document
- All consent documents must contain all of the required and all additional appropriate elements of informed consent disclosure
  - Standard language for studies that pay $600 or more
  - Standard language for Category B devices
  - Standard language for UHealth studies
- We recommend that you date the revisions of your consent documents to ensure that you use the most recently approved version

THANK YOU!

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305-243-9232

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