External IRB Submission Process in myRESEARCH

- Advarra and NCI-CIRB are currently in the system
- Other sites may be requested by emailing ovpr_myresearchirb@stonybrook.edu
- External IRB Continuing Renewal Submissions must be submitted as a NEW STUDY in myRESEARCH
Step 1 page 1: CREATE NEW STUDY
Step 1 Page 2: External IRB Information

**Basic Information**

1. **Title of study:**
   - Full title of Study that matches external IRB title

2. **Short title:**
   - Name of external IRB; Sponsor; Protocol #

3. **Brief Lay Description:**

4. **Principal Investigator:**
   - PI On

5. **Will an external IRB act as the IRB of record for this study?**
   - Yes □ No □ Clear

6. **What kind of study is this?**
   - Multi-site study (More than one site will conduct the entire study)
   - Collaborative study (Each site will conduct a portion of the study)
   - Single-site study □

7. **Attach the protocol:**
   - Add □

- **Full title should Match external IRB title**
- **Ex:** Advarra; Friendly Pharmaceuticals; 7V34986
- *****If this is a continuing review include CR before external IRB name**
  EX: CR: Advarra; Friendly Pharmaceuticals; 7V34986
- **Must □ YES for external IRB**
- **Add external study protocol -**
Use drop down menu to add the IRB of record. If the IRB does not appear, email ovpr_mresearchirb@stonybrook.edu to request site addition.

Currently available sites: Advarra, NCI (adult), NCI (pediatric)

Same as Short Title

FDA regulated research  ✓ Pre-2018 requirements
Non FDA regulated research  ✓ 2018 requirements

Answer questions 3-12 as applicable
Add Applicable Funding Information: If choose unsponsored option, more inquiry fields will open
All study scope questions MUST be answered. More inquiries may appear based on answer given.
Step 1 Page 6: Drug Information

#1. Click ‘add’ for pop up window to add all study items

#2. Window will pop up to add IND information (number and holder)

#3. Only attach listed forms if the INVESTIGATOR holds the IND
Click FINISH and move on to STEP 2
Step 2 Page 1: Add Local Site Information

**MUST click to add local site information or will be unable to submit**

EDIT site
Step 2 Page 2: Basic Information

Basic Information

1. * Title of site:
   Site for Full Title of Study that matches external IRB title

2. * Short title:
   Site for Name of external IRB, Sponsor; Protocol #

3. * Brief description:
   TEST

4. * Principal Investigator:
   PI One

This is duplicate of study information, Titles will auto populate from previous screen
Step 2 Page 3: Funding

Funding Sources

1. If you have funding, or are seeking funding for this activity, add the name of the funding, or potential funding, source, and provide the information requested. If funding is pending, reply 'UNK' if information is unknown.

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor's Funding ID</th>
<th>Oracle Project/Award/Task Number</th>
<th>Attachments</th>
</tr>
</thead>
<tbody>
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There are no items to display

2. * Is this project sponsored but unfunded? (Reminder: unfunded agreements need to be executed by the Office of Sponsored Programs.)
   - Yes
   - No

3. * Is this research project unsponsored?
   - Yes
   - No
Step 2 Page 4: Add the Study Team

Hover to see which training was completed and expiration dates to verify all training requirements have been met.

Click to add study team members and define their role.

1. Add all individuals, including the Principal Investigator, who will interact or intervene with research subjects or their identifiable data or tissue.

   - Name: [Name]
   - Role: [Role]
   - Involved in Consent: [Yes/No]
   - IRB Training: [Completed/Not Completed]
   - Last CDI Submitted: [Date]

2. List external (non-SBU) study team members. Only include individuals who are unaffiliated with SBU, but who are interacting/intervening with research subjects or their identifiable data/tissue as part of a Stony Brook-specific study. (Note: this is not for collaborations.)

   - Name: [Name]
   - Institution Name: [Institution]
   - Position Held: [Position]
   - Role in Research: [Role]
   - Involved in Consent: [Yes/No]
Step 2 Page 5: List all NON SBU Research Locations

Research Locations

1. Identify research locations outside the institution where the investigator will conduct or oversee the research:

<table>
<thead>
<tr>
<th>Location</th>
<th>Contact</th>
<th>Phone</th>
<th>Email</th>
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There are no items to display
**Step 2 Page 6: Add Stony Brook Documents**

Local Site Documents (Upload the Application for Approval to Conduct Research Activities at Stony Brook University Hospital, (see "For Investigators" library), if applicable)

1. **Consent forms (or Request for Waiver):** Include an HHS-approved sample consent document, if applicable.

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<tr>
<th>Document</th>
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<th>Date Modified</th>
<th>Document History</th>
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   Refer to the following templates and instructional documents:
   - SBU-INV - Assent Form Template for Minor Subjects (English, Long Form)
   - SBU-INV - Assent Short Form Template for Minors (English)
   - SBU-INV - Assent Short Form Template for Minor (Spanish)
   - SBU-INV - Consent Form Addendum (For Enrolled Subjects To Receive New Information)
   - SBU-INV - Consent Form Template and Instructions for Adult Subjects
   - SBU-INV - Consent Short Form Template for Adult Subjects (English)
   - SBU-INV - Consent Short Form Template for Adult Subjects (Spanish)
   - SBU-INV - Parent Permission Form Template and Instructions for Minor Subjects
   - SBU-INV - Supplemental Form G - Consent Waivers for Attraction Documentation

2. **Recruitment materials:** (Add all material to be seen or heard by subjects, including ad

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3. **Other attachments:**

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**Consents, recruitment materials, I/E Checklist, etc.**
Determine Required Ancillary Reviews that apply to the project and request on next two screens.
**If not automatically routed to manage ancillary review/submission page, MUST click on Link.**
STEP 1: Add all necessary ancillary reviews.

STEP 2: Once Department Chair has approved the package, Submit to the IRB.
Step 2 Page 10: Success! Study has been submitted to the IRB

If Pre-Review box is highlighted, study has been successfully submitted to the IRB.