Relying on an Outside Institution’s IRB: Step 1 reliance agreement (IAA)

- **Study Team**
  - Initiate process
  - Add any applicable language to draft consent form
  - Compile all documents and local approvals
  - Go to PAGE 2

- **Outside IRB**
  - Provide draft IRB Authorization Agreement, responses to UF’s “sIRB Request: Information about Outside IRB” form, and any other pertinent information
  - Will they serve as Privacy Board?
    - Yes
      - PI & Outside IRB address Issues
    - No
      - PI will need to submit UF Authorization and Waivers for consideration to IRB-01

- **UF IRB, OR, and GC**
  - Assess Request, negotiate agreement
  - Issues?
    - Yes
      - PI & Outside IRB address Issues
    - No
      - Sign IAA

- **Other UF Offices**
  - Obtain applicable approvals: RAC, IBC, HURRC, COI, etc.
Relying on an Outside Institution’s IRB: **Step 2 Local Context & Notifications**

<table>
<thead>
<tr>
<th>Study Team</th>
<th>UF IRB, OR, and GC</th>
<th>Outside IRB</th>
<th>Other UF Offices</th>
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</thead>
<tbody>
<tr>
<td>Email UF IRB with pertinent documents for local context review and tracking</td>
<td>Conduct local context review, enter in database for tracking, verify local requirements completed.</td>
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<td>Study team must address deficiencies</td>
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<td>Submit final documents to Outside IRB</td>
<td>Provide local context assessment to PI</td>
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<td>UF approved for study?</td>
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<td>Yes</td>
<td>Notify UF IRB + UF PI of:</td>
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<td>No</td>
<td>- Initial &amp; continuing approvals</td>
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<td>- Unanticipated problems involving UF researchers, patients, or facilities</td>
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<td>- For cause audits</td>
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<td>- Study suspension or termination</td>
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<td>Notify applicable offices as appropriate</td>
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<td>Study revised?</td>
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<td>Serious issues?</td>
<td>Yes</td>
<td>Notify UF IRB</td>
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<tr>
<td>Study completed?</td>
<td>Yes</td>
<td>Notify UF IRB</td>
<td></td>
</tr>
</tbody>
</table>

All applicable language in consent?

Yes

No

All local requirements completed?

Yes

Study team must address deficiencies

No

Submit final documents to Outside IRB

UF approved for study?

Yes

Study team must address deficiencies

Update sIRB database with study approval/expiration dates

Notify UF IRB + UF PI of:
- Initial & continuing approvals
- Unanticipated problems involving UF researchers, patients, or facilities
- For cause audits
- Study suspension or termination

Notify applicable offices as appropriate

Notify UF IRB

Notify UF IRB

Notify UF IRB + UF PI of:
- Initial & continuing approvals
- Unanticipated problems involving UF researchers, patients, or facilities
- For cause audits
- Study suspension or termination

Notify applicable offices as appropriate