1. PURPOSE
   1. The purpose of this process is to conduct pre-review for submissions where this institution is being asked to rely on an external IRB, or where this institution is asked to assume IRB oversight of external Participating Sites (pSite).
   2. This process begins when a request to rely or cede oversight is submitted for pre-review.
   3. This process ends when reliance on the external IRB is confirmed or this institution confirms it will assume oversight for external Participating Sites (pSite).
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. The TAMU HRPP reserves the right to determine on an individual study basis whether or not to accept an External IRB review. The HRPP will evaluate for the institution the external IRB and the circumstances of the request.
   2. TAMU investigators may not initiate or engage in any human research activities until the TAMU HRPP has evaluated and acknowledged a new study application in the electronic system regardless of any External IRB approval.
   3. Any institution located in the United States that is engaged in federally-funded cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.
   4. An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the [NIH Single IRB policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html) and/or the revised Common Rule cooperative research provision ([§46.114](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1114)  [Link to Non-U.S. Government Site - Click for Disclaimer](https://grants.nih.gov/grants/disclaimer.htm) ).
   5. .
4. RESPONSIBILITIES
   1. The IRB Staff generally carries out these procedures.
5. PROCEDURE
   1. If the item is a submission of approval documents for a study already reviewed by and approved by an external IRB[[1]](#footnote-1).
      1. Check the submission materials for completeness. This includes:
         1. HRP-811 - FORM - Basic Site Information or equivalent form or electronic form..
         2. Study related documents, if this is a multi-site or collaborative study relying on an external IRB.
         3. Local site documents, if this is a single-site study relying on an external IRB.
      2. Use HRP-309 - WORKSHEET - Ancillary Review Matrix to identify any ancillary reviews that are needed before reliance can be confirmed.
      3. Review for local context to determine whether local requirements are satisfied.
      4. Note any missing materials in HRP-401 - CHECKLIST - Pre-Review or equivalent form or electronic form and return the submission to the study team.
      5. Refer to HRP-804 - SOP - External IRB Post-Review.
   2. If the item is a request for this institution to rely on another IRB[[2]](#footnote-2):
      1. Identify the external IRB.
      2. Consult Institutional Profiles to determine whether there is sufficient information about the external IRB to confirm reliance.
      3. If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and add to Institutional Profiles.
      4. Once the required information is obtained and the necessary agreements are in place, check the submission materials for completeness. This includes:
         1. HRP-811 - FORM - Basic Site Information or equivalent.
         2. Study related documents, if this is a multi-site or collaborative study relying on an external IRB.
         3. Local site documents, if this is a single-site study relying on an external IRB.
      5. Consult HRP-309 - WORKSHEET - Ancillary Review Matrix to identify the ancillary reviews that must be completed prior to submission to an external IRB.
      6. Review for local context to determine whether local requirements are satisfied.
      7. Note any missing materials in HRP-401 - CHECKLIST - Pre-Review or equivalent form or electronic form and return the submission to the study team.
      8. Refer to HRP-804 - SOP - External IRB Post-Review.
   3. If the item is a request for this institution to serve as the single IRB of record (sIRB) for an external pSite:
      1. Review the submission and identify all pSites (Note: pSites can only be approved after the approval of the main study).
      2. Consult Institutional Profiles to determine whether an existing Authorization Agreement covers the study activities for each pSite identified.
      3. If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and add to Institutional Profiles.
      4. Once all the information is complete and the authorization agreement has been executed, use HRP-851 - LETTER - Invitation Decision or equivalent correspondence to notify the pSite that this institution will serve as the IRB of Record for their participation in the study and that site-specific materials can be prepared from the approved main study documents and templates.
      5. Notify the assigned IRB coordinator that this institution will serve as the sIRB for each pSite and can proceed with Pre-Review using HRP-021 - SOP - Pre-Review.
6. MATERIALS
   1. HRP-031 - SOP - Non-Committee Review Preparation
   2. HRP-309 - WORKSHEET - Ancillary Review Matrix
   3. HRP-401 - CHECKLIST - Pre-Review
   4. HRP-801 - SOP - Establishing Authorization Agreements
   5. HRP-804 - SOP - External IRB Post-Review
   6. HRP-851 - LETTER - Invitation Decision
7. REFERENCES
   1. None.

1. This includes, per institutional policy, external IRB studies for which local confirmation of reliance is not required prior to submission to the IRB of record. This would also include NCI CIRB submissions. [↑](#footnote-ref-1)
2. This includes, per institutional policy, external IRB studies for which local confirmation of reliance is required prior to submission to the IRB of record. [↑](#footnote-ref-2)