**IRB Authorization Agreement – External Reliance**

1. Upon receiving a request for an IRB Authorization Agreement, determine what is being requested:
   1. Is the Institution requesting that Georgia Tech rely on them as the IRB of record; or
   2. Is the institution requesting to rely on Georgia Tech as the IRB of record?
2. If GA Tech wishes to rely on another institution, or another institution has requested that Georgia Tech rely on them as the IRB of record, follow the below steps.
   1. Determine if GA Tech is engaged in Human subjects research:
      1. Inquire about what specific roles Georgia Tech or Georgia Tech researchers are playing in the research
         1. Will Georgia Tech personnel be consenting subjects?
         2. Will Georgia Tech personnel have access to or be analyzing identifiable data?
         3. Will Georgia Tech be interacting with human subjects in any way? If so, request the specifics of this interaction
            1. If it is determined that GA Tech personnel are not engaged in Human Subjects research, an agreement will not be necessary and no further action is required

Inform the inquiring institution or requesting Georgia Tech personnel that an IAA is not necessary because Georgia Tech Personnel are not engaged in human subjects research

* 1. If it is determined that Georgia Tech personnel are engaged in human subjects research, check to see if Georgia Tech has a pre-existing reciprocity agreement with said institution
     1. If so, given the details of Georgia Tech's specific level of engagement in the project, does the reciprocity agreement cover it?
        1. If it does If it does, inform the inquiring institution (or individual), that there is a pre-existing agreement in place and no new agreement is needed. There may be updates or submissions required at the reviewing institution.”
  2. If there is no pre-existing agreement, or there is a pre-existing agreement but it does not cover Georgia Tech's level of engagement in the research project, proceed to process a new IAA.
  3. Request that the Georgia Tech principle investigator create a "shell protocol" in our IRBWISE system:
     1. Things that the shell protocol should include:
        1. Study title
           1. The study title should lead with the name of the institution Georgia Tech plans on relying on (E.g. Harvard - Single Ventricle Surgical Planning: Assessing Proposed Options and Post-operative Results)
        2. All study personnel
        3. A description of Georgia Tech personnel's proposed role and involvement in the research, i.e. what research activities will Georgia Tech personnel be engaged in?
        4. Funding information, if applicable
           1. If Georgia Tech is not receiving any funding for the research, this section can be left blank
        5. Documentation of approval
           1. Copies of the approved protocol, consent forms, and the other institution’s letter of approval should be uploaded in the "documents" section of the shell protocol
     2. Note: This shell is not being created for the purposes of approval, but rather, it is being created for the purposes of storing and maintaining a record of Georgia Tech's reliance upon the other institution
  4. Upon the submission of the shell protocol, accept and assign the submission to the responsible administrator. Upon determining that conditions are such that it is appropriate for Georgia Tech to rely on the other institution as the IRB of record, you can begin to draft the reliance agreement
     1. Ask the institution if they would like us to use their reliance agreement document, or if they would rather us draft the agreement
        1. If they would rather Georgia Tech draft the agreement, follow these steps:
           1. Open up the IAA Template sheet and fill out and complete the as much of the document as you can

Directions to the IAA template sheet: Click on the "Grand Central" folder on the desktop-->ORIA-->IRB-->IRB Reliance Agreements-->Agreement Templates-->IAA Template (external reliance)

* + - 1. If the other institution prefers to use their agreement template, review the agreement to ensure it complies with the GA Tech institutional policies. If needed, consult with the IRB Legal Advisor for review of the agreement.
         1. Specifically, red flags include indemnification language, fees for reliance (we do not pay for reliance) and other clauses that would limit GA Tech or hold us to other state/local laws that we can’t conform to.
      2. After the agreement template has been completed as much as possible, send the IAA draft to the other institution's IRB to enter their institutional details (e.g. IRB registration number, FWA, Protocol number for their institution, IO information, etc). When sending the draft IAA to the other institution, request they send the finalized draft to you for review prior to beginning signatures.
      3. After the final draft is agreed upon, they should have their Institutional Officer sign and date the IAA document and then resend the signed document to us.
      4. Once we receive the document, have the Georgia Tech Institutional Official (Jilda Diel Garton) sign the IAA. This final signed document constitutes an executed agreement between Ga Tech and the other institution.
      5. Scan the executed IAA document and save the document in the "IRB Authorization Agreement files" folder.
         1. If there is not a folder already made for the institution we are relying on, create one and store the document within that folder

Directions to the "Agreement files" folder: Click on the "Grand Central" folder on the desktop-->ORIA-->IRB-->IRB Reliance Agreements-->IRB Authorization Agreement files

* + - 1. Send the finalized IAA to the other institution's IRB for their records
      2. Process the "shell protocol:"
         1. Submit a review:

Provide details regarding the circumstances of the IAA

* + - * 1. Select “Exempt NL” as the Review and Study Type in IRBWISE.
        2. Select “Central Institutional Review Board #1” as the Committee Assigned in IRBWISE.
        3. Change the Current Status to “Approved” and select “Indefinite” for the expiration.
        4. Complete a deferral letter and upload it into the study and also email it to the Georgia Tech PI.