**IRB Authorization Agreement – Georgia Tech as IRB of Record**

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 for another institution rely on them, or another institution has requested that Georgia Tech became the IRB of record, follow the below steps:
   1. Determine to what extent GA Tech is engaged:
      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. Where will the majority of research be conducted? Will most of it be conducted at Georgia Tech and by Georgia Tech personnel?
         4. 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 that an IAA is not necessary because Georgia Tech Personnel are not engaged in human subjects research

* 1. Determine to what extent the other institution is engaged?
     1. Inquire about what specific roles the other institution’s personnel will play in the research
        1. Will the other institution's personnel have access to or be analyzing identifiable data?
        2. Where will the majority of research be conducted? Will most of it be conducted at the other institution and by their personnel?
        3. Will the other institution be interacting with human subjects in any way? If so, request the specifics of this interaction
           1. If it is determined that the other institution's personnel are not engaged in Human Subjects research, an agreement will not be necessary and no further action is required

Inform the inquiring institution that an IAA is not necessary because their personnel are not engaged in human subjects research

* 1. If it is determined that both Georgia Tech and the other institution is engaged in human subjects research, check to see if Georgia Tech has a pre-existing umbrella reliance agreement with said institution
     1. If so, given the details of Georgia Tech's specific level of engagement in the project, does the umbrella agreement cover it?
        1. 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, however.
  2. If there is no pre-existing agreement, or there is a pre-existing agreement but it does not cover the particular circumstances of the research project, proceed to process a new IAA.
  3. Request that the Georgia Tech principle investigator create and submit an amendment in our IRBWISE system:
     1. Things that the amendment should include:
        1. Personnel from the other institution needs to be added to the study roster
           1. They may need IRBWISE accounts in order to add them, so make sure the PI understands this
           2. We will need their CITI certifications and update them into our system
        2. The study team should provide a detailed account of what each new team members role is in the study:
           1. Are they interacting with subjects?
           2. Are they consenting subjects or seeing identifiable data?
           3. Are they participating in the implementation of any study related interventions?
  4. Upon the submission of the amendment, accept and assign the submission to the responsible administrator. Upon determining that conditions are such that it is appropriate for the other institution to rely on Georgia Tech as the IRB of record, you can begin to draft the reliance agreement
     1. Open up the IAA Template sheet and fill out and complete as much of the document as you can
        1. 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)
  5. After the document has been filled out as much as possible, send the IAA document to the other institution's IRB so that they can complete their side of the form (e.g. IRB registration number, FWA, Protocol number for their institution, etc).
  6. After they've filled out the form they should have their Institutional Officer sign and date the IAA document and then resend the signed document to us.

1. Once we have received the document, have the Institutional Officer (Jilda Diel Garton) sign and finalize the IAA document.
2. Scan and email the finalized IAA document to yourself and store the document in the "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
      1. Directions to the "Agreement files" folder: Click on the "Grand Central" folder on the desktop-->ORIA-->IRB-->IRB Reliance Agreements-->Agreement files
3. Send the finalized IAA to the other institution's IRB for their records
4. Process the amendment:
   1. Submit a review:
      1. Provide details regarding the circumstances of the IAA
   2. Approve the amendment
      1. If the amendment only included the addition of the other study site and personnel, you only need to write a deferral letter. Upload the deferral letter into the amendment and then email it the Georgia Tech PI like you normally would.
      2. If the amendment included additional changes (e.g. new surveys, additional interventions, a new device, etc), you must complete both an approval letter and a deferral letter. These should both be uploaded into the amendment and then emailed to the Georgia Tech PI.