Instructions for Creating Model Consent Documents for Multi-Sites Studies

For multi-site/cooperative research studies where MU is the lead site, and the external sites will conduct most/all of the protocol (this includes studies needing approval for site-specific changes/documents and/or consenting participants at their site(s)), you may need to create model documents (consent forms, assent forms, recruitment materials) to distribute to external sites so they can create their own site-specific documents. You must first obtain IRB approval for the MU site and MU-specific documents. At this time, you will also submit model documents that follow MU documents exactly but show editable areas for the external sites to enter their site-specific information.

Once approved, the model documents should be shared with the external site to add their site-specific information, which should then be submitted for approval to MU IRB on the Amendment for External Sites form. (Make sure highlighting/instructions are removed from clean version prior to submitting. A tracked version should also be submitted with the clean version so we can ensure only editable areas were modified).

Note: If all sites use the exact same consent/document (there is no need to insert site-specific content), then a model consent/document is NOT required.

Model Consent Editable Areas (apply as needed): Any deviations from the editable areas indicated below should be indicated and justified on the Local Context Form. Please make sure model documents are in alignment with the local context form. **External sites should only be editing content in the highlighted areas unless specified more changes in the local context form.**

- Letterhead
- Principal Investigator Name - Typically external site PI names should be listed in place of the MU PI name. MU PI can be listed as a co-investigator.
- Conflict of Interest - This must be disclosed on the Local Context Form.
- Compensation – This may be editable if the external site has different methods of payment or different institutional policies to follow. This must be disclosed on the Local Context Form.
- Costs – Any changes must be disclosed on the Local Context Form.
- Injury Language – Greater than minimal risk studies should insert their institution's injury language.
- HIPAA Authorization - Use of the HIPAA authorization must be indicated on the Local Context Form. It should be highlighted in the model consent if:
    - The external site has specific HIPAA language that must be used because it's different than what is already included in the model document (this language will be shared with the MU IRB to be approved for the site).
    - The external site will remove the MU HIPAA authorization language from the consent because they will use their own separate HIPAA authorization Form. *The separate form does not need to be submitted to the MU IRB for approval.*
- Contact Information – Typically external site PI name and contact information will be listed in place of MU PI contact information.
- IRB information – **The MU IRB information should NOT be highlighted as it must stay**, however, if an external site wants to insert their own IRB information after the MU IRB information, they may do so.
- Research Participant Advocacy (RPA) information – External sites can replace with their own RPA information, if available. If they don't have their own, it should remain in the site-specific consent form.