REQUIREMENTS FOR USE OF CENTRAL IRBs

For studies which would otherwise be reviewable[1] by the MLH IRB, the MLH Institutional Official, through the MLH IRB and the Office of Research Protections (ORP) maintains authority to determine which studies may be reviewed by a Central IRB.

Please note the following items:

- The Central IRB must be accredited by the Association for the Accreditation of Human Research Protection Program (AAHRPP)
- The Central IRB must agree to the division of responsibilities as required by MLH IRB and enter into an IRB authorization agreement and/or contract as required.
- The MLH IRB reviews the MLH Conflict of Interest (COI) Disclosure Forms for the PI, determines if COI language is required in consent forms.
- An MLH IRB processing fee of $850.00 for the Abbreviated IRB Application should be negotiated in all clinical trial agreements with the sponsor. This is a one-time fee to be billed at the beginning of a study.
- The MLH IRB, acting as the MLH Privacy Board reviews and approves HIPAA Authorizations and grants waivers (when applicable).

The study may not begin until a FINAL MLH IRB Permission letter is issued by the MLH IRB and approval from the Central IRB Approval has been obtained. Research Subjects may not be screened or enrolled in a study approved at a Central IRB until the MLH IRB permission letter is issued.

Required Documentation Table for Abbreviated MLH IRB Application

Form	Number of Copies	Additional Information
Form 002 (Initial Submission Form)	1	A complete and accurate form is required. ***Note: All research staff must complete and remain current with the MLH IRB training requirements. Refer to the IRB Training Requirements link on the ORP website at: mainlinehealth.org/research/office-of-research-protections/educational-training*** *It is the responsibility of the Principal Investigator to ensure that research staff complete all required training.*
Conflicts of Interest Forms	1	All research staff/individuals responsible for the design, conduct or reporting of a study are required to complete an MLH IRB Conflict of Interest Form. Following review, an email is sent to the coordinator when COI language is to be inserted into the consent form. Individual researchers with a COI requiring a management plan will be contacted directly.
Protocol	1	Provide most current version of the protocol.
Consent Form	1	Provide most current version of the template consent.
MLH IRB HIPAA Authorizations	1	MLH IRB will stamp an approved HIPAA authorization form to be used with subjects, or alternative when applicable.
Waiver of HIPAA Authorization HIPAA authorization	1	The MLH IRB maintains the authority to grant HIPAA waivers of authorization. These can not be approved or granted by the Central IRB.
MLH Transmittal Form	1	A completed form with all appropriate signatures is required for ALL studies (funded and un-funded).

[1] Refer to the MLH IRB Policy and Procedure on Jurisdiction over Clinical Research (Policy XXXIII) for more information.