REQUIREMENTS FOR RETROSPECTIVE CHART REVIEWS

Generally, retrospective chart reviews are eligible for expedited review. If your request is not eligible for expedited review, you will be notified and may be requested to provide additional copies of materials below.

Information must be provided on the most current version of the forms available on the ORA website.

Form	Number of Copies	Miscellaneous Information
MLH/LIMR Transmittal Form	1	This form is required for ALL studies (funded and un-funded).All signatures are required as indicated on the form prior to submitting to the Office of Research Affairs. A new protocol will not be reviewed without all appropriate signatures.
Clinical Trials Budget Form	1	This form is required for ALL funded/sponsored studies.
Form 001 (Protocol Submission Form)	1	A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time.
Form 002 (Initial Submission Form)	1	A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time.
Protocol	1	Please refer to the *MLH Protocol Preparation Guide* for assistance.
Waiver of Informed Consent /HIPAA Authorization	1	In studies not regulated by the FDA, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 45 CFR 46.116 (a) and (b), or waive the requirements to obtain informed consent under 46.116 (c). In addition, your study may qualify for a waiver of HIPAA Authorization. In order to determine if your study could qualify for a waiver, refer to the following policies from the MLHIRB Policies and Procedure Manual: Policy XV: Waiver or Alteration of Informed Consent Process (page 38) Policy XXIX: Use of Protected Health Information (PHI) for Research (pages 72-78) Policy I, Section 3: Research Activities Involving Patient Medical Records And Or Patient Charts (page 117) MLH IRB Manual is located at: http://limr.org/doc/Page.asp?PageID=DOC001258 The Principal Investigator must request in writing and provide justification for a waiver of Informed Consent and HIPAA Authorization for studies in which prospective consent will NOT be requested of research subjects and when any protected health information (PHI) is used.
Conflicts of Interest Disclosure Form B for Investigators (COI Form B)	1	All research staff/individuals responsible for the design, conduct or reporting of a study are required to complete a Conflict of Interest Form. This includes all investigators, sub-investigators, staff, coordinators, nurses, etc. involved in the conduct of this study. Please note that the FDA Form 3455 Financial Disclosure may NOT be substituted.
Education and Requirements for All Researchers	N/A	All research staff must complete and remain current with the MLH IRB training requirements. Refer to the *IRB Training Requirements* link on the ORA website. It is the responsibility of the Principal Investigator to ensure that research staff complete all required training.