REQUIRMENTS FOR NEW PROTOCOL SUBMISSIONS/APPLICATIONS

Refer to the following two tables when planning to submit a new research study. Please note that depending on the type of study, the review process may vary. Only Submissions which are complete will be scheduled for a meeting and will be scheduled on a first-come, first-serve basis.

Full Board Review

For expedited review, refer to Table 2 on page 2.

Information must be provided on the most current version of the forms available on the Office of Research Protections (ORP) website.

Table 1

Form	Number of Copies	*Additional Information and Instructions – Please be sure that all packets are collated. No handwritten materials will be accepted.*
Form 001 – Protocol Submission Form	18	A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time.
Form 002 – Initial Submission Form	18	A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time.
MLH 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 Protections. A new protocol will not be reviewed without all appropriate signatures. **Note: At the time of submission when a contract/funding agreement is finalized, provide a copy of contract funding agreement covering provisions for medical care or other care or services for research-related injury.**
Protocol	18	Please refer to the *MLH Protocol Preparation Guide* for assistance.
Miscellaneous Materials	18	For example, this may include recruiting or advertising materials.
Investigator Brochure, Approved Package Insert or Device User Manual/Guide or Other Device Brochures	4	For all studies involving test articles (drugs, devices, biologics, vaccines, dietary supplements, in-vitro diagnostic or other test articles) for **EACH** test article. **NOTE: Approved Package Inserts or Device User Manual/Guides when approved drugs and devices are used in a clinical investigation.**
IND or IDE Numbers (or Exemption Documentation or Request) for Test Articles	1	For studies involving test articles (drugs, biologics, vaccines, dietary supplements, in-vitro diagnostic or other test articles) which are 1.) investigational agents or 2.) approved test articles provide the following information for **EACH** test article: 1.) IND Number(s): Confirmation of Valid IND number must be provided through one of three ways: a.) the number is imprinted on the sponsor's protocol; b.) the number is noted in written correspondence from the sponsor or c.) the number is noted in written correspondence from the FDA (required if the Investigator holds the IND). ***Note: The Investigator's Brochure may not be used for this purpose.*** 2.) IDE Number(s) a.) the number is imprinted on the sponsor's protocol; b.) the number is noted in written correspondence from the sponsor or c.) the number is noted in written correspondence from the FDA (required if the Investigator holds the IDE). ***Note: The Investigator's Brochure may not be used for this purpose.*** 3.) Documentation of Exemption from IND and IDE requirements 4.) Request for Exemption from IND and IDE requirements - request must be made in writing and attached to the submission. Refer to the Investigational Test Article Policy and the Significant Risk/Nonsignificant Risk Device Determinations Policy for more information.
Informed Consent Form(s)/Child Assent Form(s)	18	Please refer to the *MLH Informed Consent Form Preparation Guide* on the ORP website and the Glossary of Lay Terms for Use in Preparation of Consent Forms on the Stanford website at: http://humansubjects.stanford.edu/general/glossary.html
Template Consent Form(s)	4	For NIH/DHHS research, the DHHS sample consent document when one exists.
Form 006 – HIPAA	18	When applicable for research studies which use protested health information. NOTE: The MLH

REQUIRMENTS FOR NEW PROTOCOL SUBMISSIONS/APPLICATIONS

Authorization Form(s)		IRB does not accept the use of any other HIPAA Authorization form.
Conflicts of Interest Disclosure Form for Researchers and Staff	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.
Grant/Funding Application(s) and MHLB IRB Grant Application Form (Form #005)	2	New grant/funding applications which involve human subjects research must be reviewed by the IRB when they are NIH/PHS funded or when required by a funding agency. Submit Form #005 and the relevant sections of the grant/funding application pertaining to the protocol which is submitted.
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 ORP website. It is the responsibility of the Principal Investigator to ensure that research staff complete all required training.
Funded/Sponsored Research	1	At the time of submission when a contract/funding agreement is finalized, provide a copy of contract funding agreement covering provisions for medical care or other care or services for research-related injury.

REQUIRMENTS FOR NEW PROTOCOL SUBMISSIONS/APPLICATIONS

Expedited Review

Generally, studies which are eligible for expedited review include, but are not limited to research involving data, specimens or records which is/was collected for non-research purposes or collection of data through noninvasive means. **If your request is not eligible for expedited review, you will be notified and may be requested to provide additional copies of materials below.**

Table 2

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

Form	Number of Copies	Additional Information and Instructions. No handwritten materials will be accepted.
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.
MLH 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 Protections. A new protocol will not be reviewed without all appropriate signatures. **Note: At the time of submission when a contract/funding agreement is finalized, provide a copy of contract funding agreement covering provisions for medical care or other care or services for research-related injury.**
Protocol	1	Please refer to the *MLH Protocol Preparation Guide* for assistance.
Miscellaneous Materials	1	For example, this may include recruiting or advertising materials.
Informed Consent Form(s)/Child Assent Form(s)	1	Please refer to the *MLH Informed Consent Form Preparation Guide* on the ORP website and the Glossary of Lay Terms for Use in Preparation of Consent Forms on the Stanford website at: http://humansubjects.stanford.edu/general/glossary.html
Template Consent Form(s)	1	For NIH/DHHS research, the DHHS sample consent document when one exists.
Form 006 - HIPAA Authorization Form	1	When applicable for research studies which use protested health information. NOTE: The MLH IRB does not accept the use of any other HIPAA Authorization form.
Conflicts of Interest Disclosure Form for Researchers and Staff	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.
Grant/Funding Application(s) and MHLB IRB Grant Application Form (Form #005)	1	New grant/funding applications which involve human subjects research must be reviewed by the IRB when they are NIH/PHS funded or when required by a funding agency. Submit Form #005 and the relevant sections of the grant/funding application pertaining to the protocol which is submitted.
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 ORP website. It is the responsibility of the Principal Investigator to ensure that research staff complete all required training.
Funded/Sponsored Research	1	At the time of submission when a contract/funding agreement is finalized, provide a copy of contract funding agreement covering provisions for medical care or other care or services for research-related injury.