# REQUIREMENTS FOR CONTINUING REVIEW FOR AN ONGOING STUDY

Federal Regulations require the continuing review of a research protocol, previously approved by the IRB to be conducted at an interval of no more than 365 days. Refer to the information in the following tables when preparing a request for continuing review. Please note that depending on the status of the study, the review process may vary.

## ACTIVE STUDY WITH NO SUBJECTS ENROLLED AT MAIN LINE HOSPITALS
## or
## STUDY CLOSED TO ACCRUAL - WITH SUBJECTS IN "NON-TREATMENT" FOLLOW-UP

For full board review, refer to Table 2 on page 2.

Generally, studies in the above status are eligible for expedited review. If your continuing review 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.

### Table 1 - Expedited Review

| Form | Number of Copies | Additional Information and Instructions. No handwritten materials will be accepted. |
|---|---|---|
| Form 003 – Continuing Review/Final Report Form | 1 | A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time. |
| Copy of Complete Protocol | 1 | Provide a description of the study and any relevant information pertaining to the study that has been recorded. |
| Approval letters of previous IRB Correspondence During the Approval Period | 1 | Copies of approval letters for all submissions during the review period should be included with the request for continuing review. *A summary may be provided as an alternate to a copy of each letter.* |
| DSMB/DMC Report(s) | 1 | When study is subject to oversight by a monitoring entity, provide all DSMB/DMC reports which have not been reviewed during the reporting period should be included. |
| Approved Informed Consent Form(s)/Child Assent Form(s) | 1 | Include the current approved Informed Consent form with the IRB stamp affixed. |
| Modified Informed Consent Form(s)/Assent(s) with Highlighted Changes using Track Changes | 1 | This is only required if changes are being made to the consent form at the time of continuing review. ONLY minor changes may be submitted with Continuing Review. *ALL Changes must be submitted with changes highlighted using track changes.* |
| Clean Copy (unstamped) of Informed Consent Form(s)/Assent(s) | 1 | Provide one clean copy of the informed consent form so that following review and reapproval, it can be stamped by the Office of Research Affairs and provided for use in the study. |
| Modified HIPAA Authorization Form (Form 006) with Highlighted Changes using Track Changes | 1 | This is only required if changes are being made to the HIPAA Authorization Form at the time of continuing review. ONLY minor changes may be submitted with Continuing Review. *ALL Changes must be submitted with changes highlighted using track changes.* |
| 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 or changes to previously approved grant 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 ORA website. It is the responsibility of the Principal Investigator to ensure that research staff complete all required training. |

# REQUIREMENTS FOR CONTINUING REVIEW FOR AN ONGOING STUDY

## ACTIVE STUDY WITH SUBJECTS ENROLLED AT MAIN LINE HOSPITALS

or

## STUDY CLOSED TO ACCRUAL – WITH SUBJECTS ENROLLED AT MLH AND CONTINUING TO RECEIVE TREATMENT

Generally, studies in the above status are not eligible for expedited review. Information must be provided on the most current version of the forms available on the ORA website.

Table 2

| Form | Number of Copies | Additional Information and Instructions – *Please be sure that all packets are collated. No handwritten materials will be accepted.* |
|---|---|---|
| Form 003 – Continuing Review/Final Report Form | 18 | A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time. |
| Copy of Protocol Synopsis | 18 | Provide a description of the key aspects of the study. |
| Copy of Complete Protocol | 4 | Protocol should include any modifications previously approved by the IRB. |
| Approval letters of previous IRB Correspondence During the Approval Period | 18 | Copies of approval letters for all submissions during the review period should be included with the request for continuing review. *A summary may be provided as an alternate to a copy of each letter.* |
| DSMB/DMC Report(s) | 18 | When study is subject to oversight by a monitoring entity, provide all DSMB/DMC reports which have not been reviewed during the reporting period should be included. |
| Approved Informed Consent Form(s)/Child Assent Form(s) | 18 | Include the current approved Informed Consent form with the IRB stamp affixed. |
| Modified Informed Consent Form(s)/Assent(s) with Highlighted Changes using Track Changes | 18 | This is only required if changes are being made to the consent form at the time of continuing review. *ALL Changes must be submitted with changes highlighted using track changes.* |
| Clean Copy (unstamped) of Informed Consent Form(s)/Assent(s) | 1 | Provide one clean copy of the informed consent form so that following review and reapproval, it can be stamped by the Office of Research Affairs and provided for use in the study. |
| Modified HIPAA Authorization Form (Form 006) with Highlighted Changes using Track Changes | 18 | This is only required if changes are being made to the HIPAA Authorization Form at the time of continuing review. *ALL Changes must be submitted with changes highlighted using track changes.* |
| Clean Copy (unstamped) of HIPAA Authorization(s) | 1 | When changes are made to the HIPAA form, provide one clean copy of the informed consent form so it can be stamped by the Office of Research Affairs and provided for use in the study. |
| 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 or changes to previously approved grant 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 ORA website. It is the responsibility of the Principal Investigator to ensure that research staff complete all required training. |