Requirements for Addition of Research Personnel to an Ongoing Study

Generally, addition of research personnel is 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	Additional Information and Instructions – Please be sure that all packets are collated.
Form 001 - Protocol Submission Form	1	A complete and accurate form is required. Inconsistent or inaccurate responses may cause a delay in processing time. The purpose of the amendment/revisions must be summarized in the "Report" section of the form or attached as a separated sheet.
Form 002	1	Page 2 of Form 002 should be completed with the individual's name that is being added to the research study as well as the signature of the Principal Investigator.
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.
FDA Form 1572	1	For drug studies, a 1572 may be submitted, but it is not required unless the PI is changing.
Education and Requirements for All Researchers	N/A	Any research staff added to the study 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.