Requirements for Amendments, Addendum and Revisions to Approved Research Studies

Federal regulations require the revisions to a previously approved research study are reviewed by the IRB prior to implementing changes. Refer to the following two tables when preparing an amendment, addendum or revision to an approved research study. Please note that depending on the type of changes being made, the review process may vary.

MINOR CHANGES TO PREVIOUSLY APPROVED RESEARCH

For major changes, refer to Table 2 on page 2.

Generally, these types of changes are eligible for expedited review. Minor changes may include but are not limited to editorial changes to consent forms or protocols, addition of study personnel, change in number of study participants and change or addition of patient advertisement or recruitment materials. 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 1

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

Form	Number of Copies	Additional Information and Instructions
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. Minor changes may be summarized in the report section. Extensive changes should be provided as a separate document.
Summary of Changes	1	A detailed summary of changes MUST be provided for all study specific revised documents (e.g. Investigator Brochure). A "track changes" version of Word documents is sufficient.
Revised Protocol	1	A full copy of the protocol is required when extensive changes are being made to the protocol. *ALL Changes must be submitted with changes highlighted using track changes.*
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 as part of the amendment. *ALL Changes must be submitted with changes highlighted using track changes.*
Clean Copy (unstamped) of Informed Consent Form(s)/Assent(s)	1	When changes are made to the consent form, provide one clean copy of the informed consent form so it can be stamped by the Office of Research Protections and provided for use in the study.
Modified HIPAA Authorization(s) (Form 006) with Highlighted Changes using Track Changes	1	This is only required if changes are being made to the HIPAA Authorization Form as part of the amendment. *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 Protections and provided for use in the study.
Other Supporting Documentation	1	Attach other supporting documentation for your requested changes not previously outlined in the above items.
Other	N/A	For addition of study personnel, refer to Requirements for IRB Submission - *Addition of Research Personnel to an Ongoing Study*

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MAJOR CHANGES TO PREVIOUSLY APPROVED RESEARCH

Generally, these types of changes are not eligible for expedited review. Major changes may include but are not limited to change in study objectives, addition or deletion of an approved intervention, and significant changes to the risk profile.

Table 2

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

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. The purpose of the amendment/revisions must be summarized in the "Report" section of the form or attached as a separated sheet. Minor changes may be summarized in the report section. Extensive changes should be provided as a separate document.
Summary of Changes	18	A detailed summary of changes MUST be provided for all study specific revised documents (e.g. Investigator Brochure) for extensive revisions. *ALL Changes to study specific documents must be submitted with changes highlighted using track changes.*
Protocol with all revisions incorporated	4	Full copies of the protocol are required when extensive changes are being made to the protocol along with a detailed description of all changes made to the protocol.
Revised protocol pages/summary of changes to protocol	18	Revised protocol pages may be submitted when a summary of changes is provided. The complete revised protocol must be provided when this is not available.
Modified Informed Consent Form with Highlighted Changes using Track Changes	18	This is only required if changes are being made to the consent form as part of the amendment. *ALL Changes must be submitted with changes highlighted using track changes.*
Clean Copy (unstamped) of Informed Consent Form(s)/Assent(s)	1	When changes are made to the consent form, provide one clean copy of the informed consent form so it can be stamped by the Office of Research Protections and provided for use in the study.
Modified HIPAA Authorization(s) (Form 006) with Highlighted Changes using Track Changes	18	This is only required if changes are being made to the HIPAA Authorization Form as part of the amendment. *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 Protections and provided for use in the study.
Other Supporting Documentation	18	Attach other supporting documentation for your requested changes not previously outlined in the above items.
Other	N/A	For addition of study personnel, refer to Requirements for IRB Submission - *Addition of Research Personnel to an Ongoing Study*.