I. Instructions

Follow the steps below to fill out the "Amendments to Previously Approved Research" form. You must submit the documents listed below in the order listed to OSP.

Note: Incomplete submissions (e.g. those missing documents, those documents missing information, those that are missing documentation of investigator training) will not be reviewed.

II. Review Process

Please read each of the following two (2) choices to determine which review process is appropriate for your research protocol and how to submit your amendment.

A. Review of Minor Changes by Expedited Procedure or Exempt Review

Some amendments to the research protocol and/or informed consent/assent documents may be reviewed as minor changes to previously approved research. Generally, minor changes are those that do not alter the risk-benefit relationship involved in the research. Examples of minor changes are; minor changes in procedures such as blood drawing, changes in/or additions to recruiting materials, and changes in interview schedules or questionnaires.

1. For Amendments to the Research Protocol and/or Protocol Application Form:
   a. If an exact page-for-page exchange is possible, submit the revised page(s) with the notation “AMENDMENT # (start with 1) – date” in the footer of EACH page.
   b. If the page-for-page exchange is not possible, submit the entire revised research protocol with the notation “VERSION # (start with 2) – date” on the first page of the research protocol and in the footer of each page.
   c. Highlight additions, strikethrough deletions or shadow amended or changed sections on all copies.
   d. Submit the original and one copy of the following collated documents:
      • The Amendment Form
      • Any document(s) from the sponsor or multi-center trial coordinator concerning the amendment
      • The Amended page(s) or Revised Research Protocol / Research Protocol Application

2. For Amendments to the Informed Consent/Assent Document:
   a. The entire revised informed consent/assent document(s) with the notation “VERSION # (start with 2) – date” in the footer of the page(s).
   b. Highlight additions, strikethrough deletions or shadow amended or changed sections on all copies of the revised informed consent/assent document(s).
   c. Submit the original and one copy of the following collated documents:
      • The Amendment Form
      • The revised informed consent/assent document(s)
      • Any document(s) for the sponsor concerning the amendment to the informed consent/assent document(s)
      • An unmarked copy of the revised informed consent/assent document(s) (2 copies and the original).
3. **For Amendments to Both the Research Protocol and/or Protocol Application Form AND The Informed Consent Document(s):**

   a. If an exact page-for-page exchange is possible, submit the revised page(s) with the notation “AMENDMENT # (start with 1) – date” in the footer of EACH page.

   b. If the page-for-page exchange is not possible, submit the entire revised research protocol and/or application AND informed consent/assent document(s) and/or the HIPAA Research Authorization with the notation “VERSION # (start with 2) – date” on the first page of the research protocol and in the footer of the page(s).

   c. Highlight additions, strikethrough deletions or shadow amended or changed sections on all copies of the revised research protocol and/or application AND informed consent/assent document(s).

   d. Submit the original and **one copy** of the following **collated documents:**

      • The Amendment Form
      • Any document(s) from the sponsor concerning the amendment
      • The Amended page(s) or Revised Research Protocol / Research Protocol Application
      • The revised informed consent/assent document(s)
      • Any document(s) for the sponsor concerning the amendment to the informed consent/assent document(s)
      • An unmarked copy of the revised informed consent/assent document(s) (2 copies and the original)

B. **Review of Amendment and other changes requiring Convened Review:**

   All other proposed amendments to the research protocol and/or informed consent/assent document(s) that are not eligible for review under expedited procedures.

1. **For Amendments to the Research Protocol:**

   a. If an exact page-for-page exchange is possible, submit the revised page(s) with the notation “AMENDMENT # (start with 1) – date” in the footer of each page.

   b. If the page-for-page exchange is not possible, submit the entire revised research protocol with the notation “VERSION # (start with 2) – date” on the first page of the research protocol and in the footer of each page.

   c. Highlight additions, strikethrough deletions or shadow amended or changed sections on all copies.

   d. Submit the original and eight (8) copies of the following **collated documents:**

      • The Amendment Form
      • The Amended page(s) or Revised Research Protocol / Research Protocol Application
      • Any document(s) from the sponsor concerning the amendment

2. **For Amendments to the Informed Consent/Assent Document:**

   a. The entire revised informed consent/assent document(s) with the notation “VERSION # (start with 2) – date” in the footer of the page(s).
b. Highlight additions, strikethrough deletions or shadow amended or changed sections on all copies of the revised informed consent/assent document(s).

c. Submit the original and eight (8) copies of the following collated documents:
   - The Amendment Form
   - The revised informed consent/assent document(s)
   - Any document(s) for the sponsor or multi-center trial coordinator concerning the amendment to the informed consent/assent document(s)
   - Any unmarked copies of the revised informed consent/assent document(s) (2 copies and the original)

3. For Amendments to Both the Research Protocol and/or Protocol Application Form AND The Informed Consent Document(s):
   a. If an exact page-for-page exchange is possible, submit the revised page(s) with the notation “AMENDMENT # (start with 1) – date” in the footer of each page.
   b. If the page-for-page exchange is not possible, submit the entire revised research protocol and/or application AND informed consent/assent document(s) with the notation “VERSION # (start with 2) – date” on the first page of the research protocol and in the footer of the page(s).
   c. Highlight additions, strikethrough deletions or shadow amended or changed sections on all copies of the revised research protocol and/or application AND informed consent/assent document(s).
   d. Submit the original and eight (8) copies of the following collated documents:
      - The Amendment Form
      - Any document(s) from the sponsor concerning the amendment
      - The Amended page(s) or Revised Research Protocol / Research Protocol Application
      - The revised informed consent/assent document(s)
      - Any document(s) for the sponsor concerning the amendment to the informed consent/assent document(s)
      - An unmarked copy of the revised informed consent/assent document(s) (2 copies and the original)