# What should I submit: An Amendment or a Report?

Ask yourself the following 2 questions:

1. Am I asking the IRB for approval of a change?
2. Am I giving the IRB new information?

If you are asking the IRB for approval of a change, submit an amendment. If you are giving the IRB new information, submit a report. If you have new information that will also require changes to your application, protocol, consent form(s), etc., submit a report AND an amendment.

When a situation requires that both an amendment and report be submitted, they should both be submitted on the same day. In ERICA, submit the report first and then the amendment; this will allow you to link the amendment to the corresponding report. If another amendment or renewal is currently outstanding, please contact the IRB to make arrangements. The IRB will review the report and amendment together at the same meeting.

Here are some example scenarios:

*Revisions were made to the recruitment flyer.*

- Submit an amendment, because changes were made that must be reviewed and approved by the IRB.

*The sponsor's monthly patient newsletter was just released.*

- Submit a report of information, because this is new information and no changes need to be made to the study.

*A DSMB report was released. The DSMB indicates that the study is progressing as planned and no changes need to be made at this time.*

- Submit a report of information, because this is new information and no changes need to be made to the study.

*A DSMB report was released. The DSMB indicates that new risks have been identified with the study procedure and the protocol summary and consent form will need to be revised to include the new risks.*

- Submit a report of a problem or event and an amendment.
    - The DSMB report is new information that may be an unanticipated problem involving risks to participants or others and must be submitted via a report.
    - The revised protocol summary and consent form have changes that must be reviewed and approved by the IRB via an amendment.

*Changes were made to the Sponsor/Company Protocol. No new risks were included in the protocol.*

- Submit an amendment, because changes were made that must be reviewed and approved by the IRB.

*Changes were made to the Sponsor/Company Protocol. New risks were added to the protocol. These risks are not present in the currently approved consent form.*

- Submit a report of a problem or event and an amendment.

    - The new risks must be reported as a potential unanticipated problem involving risks to participants or others via a report.
    - The IRB must review and approve the revised Sponsor/Company Protocol and consent forms via an amendment.

*Changes were made to the Investigator Brochure (IB) or a drug package insert.*

- Submit an amendment, because changes were made that must be reviewed and approved by the IRB.

*You have decided to start enrolling children ages 12-17 in addition to adults 18-years and older.*

- Submit an amendment, because changes are being made to the study that must be reviewed and approved by the IRB.

*You have identified some non-English speaking participants who are eligible and would like to enroll in your study. You have had the consent form translated into their language(s).*

- Submit an amendment, because changes are being made to the study that must be reviewed and approved by the IRB.

*A current participant is incarcerated and the study is not approved to enroll prisoners. Because of the incarceration, the participant will be withdrawn from the study.*

- Submit a report of information, because this is new information and no changes need to be made to the study.

*A current participant is incarcerated and the study is not approved to enroll prisoners. The study will be revised to included prisoners as a population so that this participant can still be enrolled in the study.*

- Submit a report of information and an amendment.
    - The incarceration must be reported to the IRB via a report of information.
    - The revised study application providing justification for the inclusion of prisoners must be reviewed and approved by the IRB via an amendment.

*You receive a quarterly progress report from the sponsor. No new risks are identified.*

- Submit a report of information, because this is new information and no changes need to be made to the study.