**WHAT is a Consent Revision Log?**

The Consent Revision Log provides a concise summary of all proposed and approved revisions made to the consent/assent form.

Includes the following information

▪ Version/Date of revision

▪ Date submitted to IRB

▪ IRB approval date

▪ Expiration date

▪ Number of pages in revised consent form

▪ A brief description of the changes

▪ PI’s initials and date

**WHEN is a Consent Revision Log used?**

When multiple changes are made to the consent form over the course of the protocol, it can be time consuming to determine which changes were made on which date. The Consent Revision Log provides an easy reference for study staff to determine when changes were made to the consent/assent form and may also assist in ensuring the proper version of the consent form is used during the consent process or when proposing new revisions of the consent form.

**WHY would you need a Consent Revision Log?**

A Consent Revision Log provides a simple and concise way to document revisions made to the consent form, as well as the ability to track *proposed revisions* currently pending IRB review and approval. The Consent Revision Log may be particularly helpful when the research staff is large or the study will enroll subjects over a long period of time. The Consent Revision Log aims to provide a snapshot of consent/assent changes, past and present.

The Consent Revision Log may also be useful as quality assurance tool to ensure that all staff members can easily determine if a version of the consent form is out of date and which is the currently approved consent form. It may also serve as a useful tool to inform staff members that an amendment requesting changes to the consent/assent is pending IRB approval.

**HOW do you use it?**

Create a log that documents the version/date, date submitted to the IRB, date approved by the IRB, expiration date and a brief description of the changes. It may be helpful to reference page numbers or the corresponding date of the amendment form submitted. The PI should date and initial the log which serves as verification that the revised consent form should be used moving forward.

**WHERE do you put it?**

If a sponsor provides Consent Revision Log, file as instructed. Otherwise, the log may be filed in a location easily accessible and available for the research staff to reference and update as needed.

Applicable References for Consideration:

Information on the IRB’s informed consent is available on the VCU IRB Guidance page.