EXEMPT RESEARCH AMENDMENTS	SOP 4.3.01

1. Purpose & Policy

The purpose of this SOP is to provide guidance regarding amendments to exempt research. Categories of exempt research are stipulated in the Common Rule, Subpart A of 45 CFR 46 and IRB Policy *Section 4.3*.

2. General Information

In accordance with federal regulations, certain research involving study participants is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects but is still considered research requiring IRB review for an exemption determination. Caltech requires the submission of a protocol application in the IRB Protocol Application System (PAS) for review by the IRB for all exempt and non-exempt studies.

A modification to an IRB-approved exempt or non-exempt protocol requires the submission of a protocol amendment and official approval from the IRB before changes are implemented. The process for submitting an amendment to exempt protocols differs from non-exempt protocols. Investigators wishing to make changes to exempt research can amend their protocol by following the steps found in Section 4.

3. Training Requirements

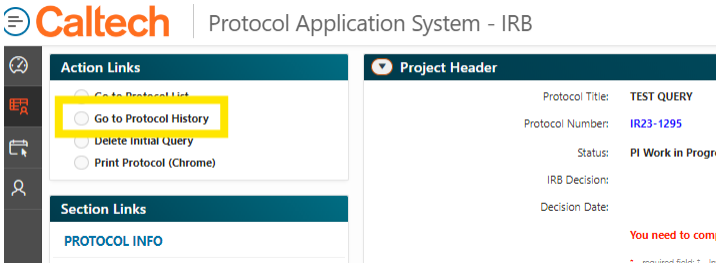
Other than the normally required and study specific training for all human subjects research, there are no additional specific training requirements associated with exempt research amendments; however, investigators should carefully read and follow this guidance.

4. Procedure

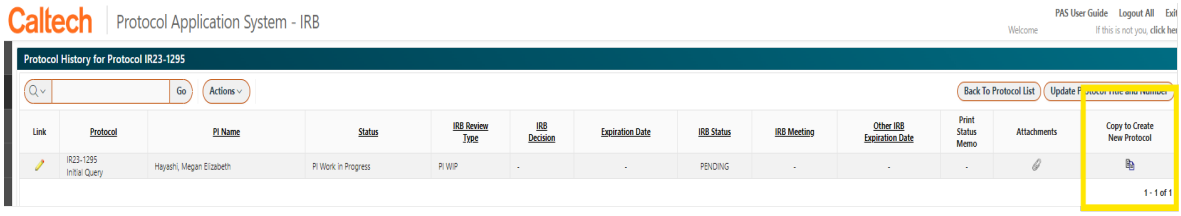
Apply the same steps below for exempt Initial Query studies and exempt Full Application studies.

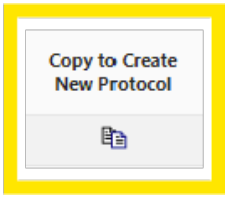
A. Principal Investigator Responsibilities

1. Open the Initial Query/Full Application protocol. Once in the protocol, under *Action Links,* select *Go to Protocol History.*



2. From the Protocol History page, click on the *Copy to Create New Protocol* icon on the far-right column. This will create a clone of the protocol with a new protocol number.





3. Edit the cloned protocol with the necessary changes and submit for IRB review.

B. IRB Responsibilities

1. The IRB Chair in consultation with other members of the IRB, as needed, will review the protocol and provide final determination.

2. If the changes do not alter the original exemption determination, the new protocol number will be updated to the old protocol number with a letter following, so that it tracks as an amendment to the original protocol (e.g., IR00-1234A). If the changes alter the original exemption determination, the study will be considered a new study and will keep the new protocol number.