VAIL HEALTH
INSTITUTIONAL REVIEW BOARD

FDA Investigator-Initiated Readiness for Study Touch-base (FIIRST) Program Overview

The FIIRST program is a collaborative effort to assist in the preparation and initiation of FDA investigator-initiated studies through protocol specific insights and regulatory guidance for the investigator. The objective of this program is to provide the investigator with support while navigating the process for their proposed research and after approval. This program reviews the applicable regulations and responsibilities that will be expected of the investigator. Reviewing these aspects helps to ensure the investigator is knowledgeable of the expectations for such research.

The review prior to IRB approval will be the first touch base and the second touch base of the program is designed to support the investigator after the study has begun. Each helping to foster compliance. The referenced touch bases will be a scheduled meeting between a HRPP representative and the investigator with the inclusion of a study coordinator if available. Each touch base will be scheduled for 60 minutes.

The initial touch base takes place prior to the IRB approval to assist in concerns of the study conduct including any study feasibility and logistical questions. Additionally, this meeting will review the applicable federal and institutional regulations that will be applied to the study, review investigator responsibilities, assist in the set-up of the regulatory binder, and address any other questions.

The second touch base will take place after the first three subjects have been enrolled. This meeting is designed to be a check-in with the investigator to review the implementation of the approved screening/enrollment/randomization logs, eligibility documentation, informed consent process, drug or device records, and any deviations to date. This touch base will be focused on assisting in compliance and answering any questions.

If you would like to request a FIIRST program touch base, please email hrpp.quality@vailhealth.org.