Issue #12

VAIL HEALTH
INSTITUTIONAL REVIEW BOARD

Association for the Accreditation of Human Research Protection Programs, Inc. Full Accreditation

Electronic Informed Consent (eIC) Guidance

With eIC becoming more prominent in the research community and utilized by sponsors more frequently, we wanted to bring two guidance documents for reference to our research community here in the Valley.

Please keep in mind all the regulatory requirements of non-electronic informed consent document information are still required as defined in 45 CFR 46 and 21 CFR __ 50 and 56.

Photo Credit: Town of Vail

However, there are a few key features which are specific to the electronic consent process. One consideration is to utilize a platform which provides an audit trail of the consent process. Secondly, a platform which can assist in identifying authentic signature from the participants. Lastly, deciding on the safe and secure storage of this document for the required amount of time before destruction according to regulations.

The Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP) have a joint questions and answers guidance document for best practices when implementing eIC. This is a great reference when assessing the feasibility of utilizing eIC for your research protocol. A draft guidance for electronic systems and signature was also released, which proposes new best practices since the last one was released in 2007.

When considering the use of eIC please contact the IRB office for assistance in this process prior to submission.

Updated IRB Review Fees

As of March 15th, the IRB has updated our review fees.

Vail Health IRB charges a processing/administrative fee for the review of all industry sponsored human subject research. Charging industry sponsors for their share of the cost associated with the IRB review process allows the IRB to continue to provide the level of service necessary by our researchers.

These fees only apply to industry sponsored human subject research. There are no fees for industry sponsored exempt determinations.

To view the updated fees, please visit our webpage under Investigator Resources to reference our Investigator Manual on page 26.

Resources on IRB Webpage

We are striving to provide our researchers with easily accessible information and guidance. On our webpage you will find training videos, study templates, the investigator manual, Full Board meeting dates, and more.

Research Conflicts of Interest

Our research conflict of interest (COI) disclosure department requires the submission of an annual conflicts of interest disclosure xForm in IRBManager. This annual process will begin July 1st and the submission deadline will be August 14th.

Please email the research conflicts of interest office, ResearchConflictOfInterest@vailhealth.org with any questions or concerns regarding any research conflict of interest topic.

Upcoming Coordinator Meeting Dates

April 13th
May 11th
June 8th

Our coordinators meeting run about a half hour starting at 12pm. If you would like to be added to the meeting invites, please email the irboffice@vailhealth.org.

We update our research community on any upcoming changes and always provide an educational topic that addresses a current concern in the research community. These meetings are ones you don't want to miss!

Submission Turnaround Times
The latest updates

Total number of submissions for 2023: 110 submissions
(Includes all submission types)

135 Active Protocols

Full Board reviews: 16 days
Expedited reviews: 1 days
Exempt reviews: 1 days

*Calculated based on the time the IRB receives complete submission to approval. Includes times in data entry, department review, IRB pre-review, review, and post processing.

Upcoming IRB Meetings
Schedule

April 13, 2023
May 11, 2023
June 8, 2023
July 13, 2023
August 10, 2023

*Agendas for meetings are sent one week prior to the meeting date. Only studies ready for Full Board review are assigned to the meeting agenda.

Contact Us Anytime
We are here to help!

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