Regional Health

FAQ's for IRB / Regulations

Q What is an Institutional Review Board (IRB)?

A Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human participants. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research participants.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as participants in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human participants of research.

The IRB should be aware of who will conduct the consent interview. The IRB should also be informed of such matters as the timing of obtaining informed consent and of any waiting period (between informing the participant and obtaining the consent) that will be observed.

The consent process begins when a potential research participant is initially contacted. Although an investigator may not recruit participants to participate in a research study before the IRB reviews and approves the study, an investigator may query potential participants to determine if an adequate number of potentially eligible participants is available.

Q What does a potential participant need to know before deciding to be part of a clinical study?

A Before making their decision, the FDA recommends asking the following questions:

- What is the study trying to find out?
- What kinds of test and exams will I have to take while I'm in the study? How much time do these take? What is involved in each test?
- How often does the study require me to go to the doctor or clinic?
- Will I be hospitalized? If so, how often and for how long?
- What are the costs to me? Will my health insurance pay for it?
- What follow-up will there be?

Q What does a potential participant need to know before deciding to be part of a clinical study?

A

- What will happen at the end of the study?
- What are my other treatment choices? How do they compare with the treatment being studied?
- What side effects can I expect from the treatment being tested? How do they compare with side effects of standard treatment?
- How long will the study last?

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Q What protocol deviations or violations are required to be reported?

A Protocol deviations or violations that either increase the risk to participants or affect the integrity of the study data must be reported to the IRB. IRBs deem any deviation/violation from the protocol that increases the risk to participants or affects the integrity of the study data to be significant. An isolated issue may not be significant by itself but significance may increase with numerous deviations of the same nature. Significant deviations may be events such as: enrollment of participants who did not meet inclusion/exclusion criteria, use of the wrong informed consent document, or failure to perform appropriate procedures at a study visit. Submissions should be made on the IRB's Protocol Deviation Report Form and Investigators should submit information to the IRB within 10 working days after becoming aware of a significant protocol deviation.

Are there certain reporting requirements for research events?

Yes. Per federal regulations, certain events, such as adverse events, unanticipated problems, etc. need to be reported in a timely fashion and in a manner that is acceptable to the institution and/or IRB reviewing the study. The sponsor of the study may also have certain criteria for reporting, such as immediate (within 24 hours) notification when a serious adverse event has occurred. Principal Investigators will receive support from RHCR on understanding and following reporting requirements.

Q Are there any groups of participants that need special consideration when planning study recruitment strategies?

A Yes, these are "vulnerable populations", or special classes of participants that require special consideration for inclusion in a study.

A. Vulnerable populations under Federal regulation include:
- Fetuses and human in-vitro fertilization
- Women-potentially pregnant, pregnant, lactating
- Children, minors (under 18 years of age)
- Prisoners

B. Vulnerable populations within common sense guidelines include:
- Cognitively impaired persons
- Traumatized patients
- Comatose patients
- Terminally ill persons
- Elderly/aged persons
- Minorities
- Students, employees (with the possibility of feeling coerced)