ACCREDITATION EVIDENCE

Title: What is an IRB? Training offered at In-Service

Evidence Type: Corroborating

Date:

WAN: 22-0406

Classification: Presentation

PII: No **Redacted:** No

Questions

* What is an IRB and why do we need one at Western?
* Who needs to submit proposals to the IRB?
* If approved, how long is your proposal good for?
* Is training required prior to submitting proposals to the IRB?

IRB: Institutional Review Board

Chair: Members: Stacie Newberg, Kristine Clark, Daniel Francom, Dee Forest, Jamie Anderson, Aaron Jensen

What Is an IRB?

* IRBs are required by federal law to review human research that is either federally funded or subject to FDA oversight. We had and took the option to apply these requirements to any and all research we do.
* There is a required minimum of 5 members but these 5 must include: 1 scientist, 1 nonscientist and one person who is not affiliated with the institutions.
* Members will serve for 3 years.

Training

* All individuals who will be participating in any process of gather data/conducting research of any kind must complete training. This training is good for 2 years.
* Free Training provided by NIH: http://phrp.nihtraining.com/users/login.php?l=3

IRB Review

* We’re not machines.
* We strive for consistency but different reviewers can and do have different opinions.
* We have regular meetings

Guiding Ethical Principles

* Nuremberg Code of 1947
  * Voluntary consent of subject must be obtained.
  * Prior animal experimentation is needed to assess risks.
  * Human experimentation must be performed by qualified individuals.
* Belmont Report 1979
  * Respect for persons
    * Obtain informed consent, protect privacy and confidentiality
  * Beneficence
    * Do no harm, provide benefit when possible, limit risks
  * Justice
    * Equitable selection of subjects
    * Equal distribution of risks and benefits

Regulatory Requirements for IRB Approval

* Risks to subjects are minimized.
* Risks are reasonable in relation to anticipated benefits – if any.
* Selection of subjects is equitable.
* Informed consent will be sought and appropriately documented.
* When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Regulatory Requirements for IRB Approval

* When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
* When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included to protect the rights and welfare of these subjects.

Review Processes

Following an initial review of the application describing the nature of the research, a proposal may be:

* Exempt from further review
* Appropriate for an Expedited review by the chair
* Subject to Full Review by the full IRB.
* Western's IRB website:
  * http://www.wwcc.wy.edu/quality_improvement/irb/

Some Common Expedited Review Categories

* Blood collection – within limits.
* Collection of other biological specimens.
* Collection of data through non invasive procedures such as MRI, EKG.
* Research on existing data, specimens, materials collected for NON research purposes.
* Surveys, questionnaires.

Determining an Action

* Approval – the criteria for approval are met.
* Approved contingent/pending revisions– IRB stipulates specific revisions requiring simple concurrence by the investigator, then the IRB approve the revised research protocol
* Deferral - substantive clarifications or modifications required that are directly relevant to the criteria for approval.
* Denied – major ethical or scientific issues – PI can respond to the IRB or start over.