FRED HUTCH
Institutional Review Board

Policy/Procedure

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POLICY STATEMENT

It is the policy of Fred Hutchinson Cancer Research Center (Fred Hutch) that all personnel involved in the design, conduct, or reporting of research awarded to or sponsored through Fred Hutch receive

training in the protection of human subjects in research. It is also the policy of Fred Hutch that all Institutional Review Office (IRO) Staff and Institutional Review Board (IRB) Members receive training and ongoing education opportunities.

DEFINITIONS

See *IRB Glossary of Terms and Acronyms* (050) for full definitions of the following:

CITI

Clinical Trial

Clinical Trial Staff

Fred Hutch Personnel

GCP

Human Research Protection Training

Individual Investigator Agreement

Investigator

PRINCIPLES/OVERVIEW

The NIH requires education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Investigators must provide a description of education completed in the protection of human subjects for each individual identified as "key personnel" in the proposed research.

In addition, effective January 1, 2017, the NIH requires investigators and clinical trial staff to be trained in Good Clinical Practice when involved in the design, conduct, oversight, or management of NIH-funded clinical trials. The FDA also expects IRBs to evaluate the qualifications of investigators, which may include verification of GCP training, as appropriate.

Fred Hutch requirements (1) exceed those of the NIH and FDA, (2) apply to all studies where Fred Hutch is the IRB of record regardless of funding source, and (3) apply to all Fred Hutch investigators and their research staff regardless of whether Fred Hutch is the IRB of record or the research is approved under another IRB of record. The training requirements described here reflect Fred Hutch's commitment to the protection of research participants and the conduct of scientifically valid and reproducible research.

Training of IRO staff and IRB members in regulations, guidelines, ethics and policies applicable to human participant research is critical to Fred Hutch's ability to protect the rights and welfare of research participants consistently throughout the institution.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch, and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

1. Human Research Protection Training

A. Requirements for Fred Hutch Personnel

Training in the protection of human research subjects is required for all Fred Hutch Personnel involved in one or more of the following activities:

- Design: developing the research concept, scientific method, or objectives for a study that involves intervention or interactions with a human subject or the use of identifiable data or tissue derived from a human subject.
- Conduct: implementation and management of research involving human subjects. Staff conducting research includes principal investigators, research staff working on a research study, and others engaged in research activity supporting the research study (e.g., conducting interviews, surveys, data collection).
- Reporting: analyzing, summarizing, or preparing manuscripts involving data derived from a research study involving human subjects.

B. Requirements for Non-Fred Hutch Personnel

The Human Research Protection Training requirements outlined in Section 1.A. also apply to the following non-Fred Hutch Personnel:

- Affiliate investigators, from institutions that do not hold an OHRP assurance, who are relying on the Fred Hutch IRB through an *Individual Investigator Agreement* (052).
- Principal investigators whose primary appointment is through an organization other than Fred Hutch (e.g. UW, Seattle Children's, Benaroya Research Institute, Group Health) and who are submitting a protocol through the Fred Hutch IRB for review.
- Local Principal Investigator whose participating site is engaged in a Fred Hutch research project; and whose site is relying on Fred Hutch as the IRB of Record through an *IRB Authorization Agreement* (043) between Fred Hutch and their institution.

All other non-Fred Hutch Personnel working on human research projects overseen by the Fred Hutch IRB are responsible for meeting the Human Subjects Training requirements of their parent institution (e.g. UW employees). The Principal Investigator is responsible for attesting to the Fred Hutch IRB that his/her staff is appropriately trained.

2. Human Subjects Training Courses

A. Initial and Ongoing Human Subjects Training

Initial training is required within 60 days for personnel who are new to Fred Hutch or have not had training in human research protection before but are newly required to because of a change in position and/or responsibility. Accepted courses include:

- In-person lecture at Fred Hutch
- CITI online course (www.citiprogram.org):
  - *Biomedical Research – Basic Course*

- *Social Behavioral Research – Basic Course*

- PRIM&R (Public Responsibility in Medicine and Research) Investigator 101 Course
- University of Washington Clinical Certificate Program – Introduction to Clinical Trials
- Other equivalent training (e.g., human subjects lectures at another institution) may fulfill the initial training requirement. IRO staff review the training's content and decide if it will serve. Note, GCP training does not fulfill the human subjects training requirement.

B. Refresher Human Subjects Training

Refresher training is required every 3 years after completing initial training. Accepted refresher human subjects courses include:

- Retaking any initial human subjects training course listed above
- In-person lecture at Fred Hutch (basic or refresher lecture)
- CITI online course (www.citiprogram.org):
  - *Biomedical Research – Refresher Course*
  - *Social Behavioral Research – Refresher Course*
- Attendance at conferences on human subjects protection or clinical trial management
- Fred Hutch lectures on research ethics for trainees. (http://www.fredhutch.org/en/education-training/research-ethics.html)
- Testing through a book on human subjects protection
- Case studies conducted by investigators
- At least 1 year's IRB membership and participation in 6 IRB meetings in the last 2 years
- Other equivalent training (e.g., human subjects lectures at another institution) may fulfill the refresher training requirement. IRO staff review the training's content and decide if it will serve. Note, GCP training does not fulfill the human subjects refresher training requirement.

3. Good Clinical Practice (GCP) Training

A. Requirements for Fred Hutch Personnel

- Training in Good Clinical Practice is required for all Fred Hutch Personnel involved in the design, conduct, oversight, or management of clinical trials.

Examples of Fred Hutch Personnel required to complete GCP training are:

- Principal Investigators, Co-Principal Investigators, Sub-Investigators.
- Research Nurses recording participant data.
- Research Coordinators responsible for evaluating lab results or completing case report forms.
- Statisticians involved in the interpretation of data during the conduct of the trial.
- Staff members involved in the conduct of the trial, including responding to operational issues such as protocol violations, conducting site training, or advising sites in data management.

- Research managers who may not be involved in the actual conduct of the trial but are instead responsible for protocol management.

Examples of Fred Hutch Personnel generally not required to complete GCP training:

- Data entry staff who do not analyze or exercise judgment regarding the data
- Research lab staff
- Programmers
- Administrative staff

B. Requirements for Non-Fred Hutch Personnel

The GCP training requirements outlined in Section 3.A. also apply to the following non-Fred Hutch Personnel:

- Affiliate investigators, from institutions that do not hold an OHRP assurance, who are relying on the Fred Hutch IRB review through an *Individual Investigator Agreement* (052).
- Principal investigators whose primary appointment is through an organization other than Fred Hutch (e.g., UW, Seattle Children's, Benaroya Research Institute, Group Health, etc.) and who are submitting a trial through the Fred Hutch IRB for review.
- Local Principal Investigator whose participating site is engaged in a Fred Hutch research project; and whose site is relying on Fred Hutch as the IRB of Record through an *IRB Authorization Agreement* (043) between Fred Hutch and their institution.

All other non-Fred Hutch Personnel working on human research projects overseen by the Fred Hutch IRB are responsible for meeting the GCP training requirements of their parent institution. The Principal Investigator is responsible for attesting to the Fred Hutch IRB that his/her staff is appropriately trained.

Note: Cancer prevention or intervention trials conducted through the Fred Hutch / UW Cancer Consortium may be subject to additional training requirements beyond those required by the Fred Hutch IRB.

4. GCP Training Courses

A. Initial and Ongoing GCP Training

Initial training is required within 60 days for personnel who are new to Fred Hutch or have not had training in Good Clinical Practice before but are newly required to because of a change in position and/or responsibility. Accepted courses include:

- CITI online courses (www.citiprogram.org):
  - *Good Clinical Practice for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)*
  - *Good Clinical Practice for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)*
- GCP training offered by Institutes within the NIH, including NIAID (http://gcplearningcenter.niaid.nih.gov) and NIDA (https://gcp.nihtraining.com)
- Any TransCelerate-approved GCP training course

- Other equivalent GCP training provided by an industry sponsor or other organization may be accepted. Upon request, Clinical Research Support (CRS) and/or IRO staff will review the training and determine whether the course is acceptable.

B. Refresher GCP Training

Refresher training is required every 3 years after completing initial training. Accepted refresher GCP courses include:

- Retaking any basic GCP training course listed above
- CITI online refresher courses:
  - *GCP FDA Refresher*
  - *GCP ICH Refresher*
- Other equivalent GCP training provided by an industry sponsor or other organization may be accepted. Upon request, Clinical Research Support (CRS) and/or IRO staff will review the training and determine whether the course is acceptable.

5. Documentation of Human Subjects and GCP Training

The investigators and Fred Hutch employees subject to this policy are required to submit documentation of human subjects and GCP training, if applicable, to the IRO. The investigator must attest to the satisfactory training of clinical trial staff, as applicable.

Documentation of human subjects and GCP training is maintained by the IRO within Hutch Learning (the Learning Management System). Names of those who have fulfilled their training requirements are listed on the IRO website along with the types of courses completed.

Individuals who fail to meet their training requirements may no longer be involved in human research under the Fred Hutch Human Subject Protection Program. The IRO will notify the Fred Hutch personnel, their supervisor, Principal Investigator, or Division Director as appropriate. The individual would need to respond to the notification, confirming they would not be involved in research; they can be reinstated when they complete their training.

If the Principal investigator of a study fails to meet the training requirements, the IRB may close the study. It can be reopened when the investigator completes the training.

6. Human Research Protection and GCP Training: IRO Procedures

The IRO staff is responsible for developing new training materials, improving and updating existing materials, presenting training sessions, identifying equivalent quality third-party training courses and notifying trainees of those opportunities, and maintaining training-related content on the IRO website. The *Ethical Conduct of Research with Humans Training Slides* (0281), and *Protection of Human Subjects in Research Training Handout* (0269), are provided to attendees prior to the in-person human subjects training.

The IRO documents individuals' human research protection training and/or GCP training as follows:

- Once the individual reports their training to the IRO and sends documentation of their training, the IRO staff enters the person's training information into the Learning Management System (Hutch Learning). In the case of in-person trainings presented at Fred Hutch, the IRO staff records each attendee's training information into Hutch Learning.

- The list of personnel with Human Subjects and/or GCP training is updated automatically and can be accessed here: http://is-ext.fhcrc.org/sites/extranet/irb/training/.
- A certificate of completion for the in-person training is available on Hutch Learning. A certificate or letter of completion is emailed by the IRO staff to non-Fred Hutch employees (external contacts) completing the in-person training.

IRO staff also provide certification letters of other confirmed completed training upon request to parties who require proof of individuals' current Fred Hutch-recognized training. Refer to the Training Certification Template Letters and the PI Training sample text for composing certificate letters.

A. Tracking Human Subjects and GCP Training

- New Fred Hutch Personnel:

  An email is automatically sent to new Fred Hutch Personnel to advise them to complete an IRO Training Form, which assists them in determining whether human subjects and GCP training is required for their position and to track training needs in Hutch Learning. The content of the IRO training survey is maintained by the IRO staff.

  When the survey email is sent, a reminder is automatically generated for 30 days follow-up. If the new employee has not completed the survey following 30 days after their first day, the employee is sent an automatic email reminder to complete the survey.

  In order to ensure training survey completion, a report will be run monthly to identify personnel that have not responded to the survey. These individuals will be contacted and prompted to complete the training survey.

  Upon completion of the training survey, a reminder is automatically created for 30 days follow-up. After 30 days, if the new employee has not completed training, the employee is sent an automatic email reminder to complete their training. If the individual does not fulfill human subjects or GCP training after 30 days (60 days after survey completion date), another email reminder is automatically sent and the IRO email inbox is copied on this email.

  A report will be run monthly to identify personnel that have not completed training. These individuals will be contacted and prompted to complete training. The individual's Division Director, PI, or supervisor may also be contacted as appropriate.

- Refresher training:

  Tracking individuals to complete the refresher human subjects or GCP training is similar to the tracking process for new individuals. An automated reminder email is sent to individuals 90 days prior to when training renewal is required and a reminder is automatically generated for follow-up 30 days later (60 days prior to expiration).

  If the individual has not completed the refresher human subjects or GCP training 60 days prior to expiration, a second automated reminder email is sent. A reminder is automatically generated for another 30 days (30 days prior to expiration).

  Thirty days prior to expiration, a third automated reminder email is sent. A reminder is automatically generated for another 30 days (expiration date). The IRO Assistant Director or designee contacts the individual at 30 days prior to expiration to remind them to renew their training.

  If the individual fails to complete the refresher human subjects or GCP training at expiration, a final automated email reminder is sent. A report will be run montly to

identify personnel that have not completed refresher human subjects or GCP training. These individuals will be contacted and prompted to complete training. The individual's Division Director, PI, or supervisor may also be contacted as appropriate.

7. Other Training Materials Provided to Investigators

IRB Investigator Guidelines (056). These guidelines, available on the IRO website, are available as an orientation and reference for investigators. They summarize regulatory and institutional requirements, the IRB's role and review practices, the responsibilities of investigators, and other resources.

IRB Principal Investigator Responsibilities Memorandum (091). With every approval of a new study the principal investigator receives a copy of the *Principal Investigator Responsibilities Memorandum* (091). The memo reviews logistical details about IRB approval, modifications, adverse event reporting, deviations and violations, and closing studies, and provides contact information of IRO staff.

8. Training of IRO Staff

IRO staff are required to review IRO policies and supporting documents relevant to their responsibilities as per the *Change Control and Training Procedures* (0398). Training is assigned by job title per the *Document Matrix* (0413), and is required for new IRO staff, new documents, and when major revisions are made to documents.

Each new IRO staff member is required to take Human Research Protection Training.

IRO staff members are encouraged, though not required, to complete GCP training.

IRO staff are given the opportunity to receive training and continuing education. These opportunities may include:

- National and local conferences relating to human subjects
- Internal training opportunities through Hutch Learning
- Outside training opportunities through CITI, PRIM&R, Investigator 101, etc.
- FDA, OHRP, and other applicable federal agencies are monitored for updated guidance and regulations and are routed to staff

9. Training of IRB Members

All Fred Hutch IRB Members are appointed by the Fred Hutch Institutional Official. IRB Members will be reminded that no research subject to the Fred Hutch Human Research Protection Program can proceed without review and approval by the IRB even if it has been approved by some other Center department or official. All new Fred Hutch IRB Members (including alternate members) must complete Human Research Protection Training and an Orientation. The IRO Assistant Director (or designee) provides a comprehensive orientation for new members prior to their first IRB meeting which includes:

- An explanation of the meeting process;
- The IRB member reviewer responsibilities;
- The IRB members conflict of interest policy;
- Types of IRB review;
- The IRB member's role at the first meeting;
- An overview of the *Fred Hutch IRB Member Handbook;*

- Training Resources.

Each IRB member will receive a copy of the *Fred Hutch IRB Member Handbook.*

New IRB members are required to complete Human Research Protection Training.

IRB members are encouraged, though not required, to complete GCP training.

IRB chairs and members are given the opportunity to receive training and continuing education. These opportunities may include:

- National and local conferences relating to human subjects
- Outside training opportunities through CITI, PRIM&R, Investigator 101, etc.
- Educational materials distributed with IRB meeting materials
- The *IRB* journal is made available to all IRB members

SUPPORTING DOCUMENTS

Change Control and Training Procedures (0398)
Document Matrix (0413)
Ethical Conduct of Research with Humans Training Slides (0281)
Individual Investigator Agreement (052)
IRB Authorization Agreement – Fred Hutch as Institution A (043)
IRB Authorization Agreement – Fred Hutch as Institution B (043)
IRB Glossary of Terms and Acronyms (050)
IRB Investigator Guidelines (056)
Principal Investigator Responsibilities Memorandum (091)
Protection of Human Subjects in Research Training Handout (0269)

REFERENCES

NIH Guide Notice, June 5, 2000. http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

NIH Guide Notice, September 5, 2001. http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html

NIH Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects. http://grants2.nih.gov/grants/policy/hs_educ_faq.htm

NIH Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

Frequently Asked Questions: NIH Policy on Good Clinical Practice (GCP) Training for NIH Awardees Involved in NIH-funded Clinical Trials.
http://osp.od.nih.gov/sites/default/files/FAQs_on_NIH_GCP_Policy.pdf

OHRP Compliance Activities: Common Findings and Guidance 71(p)(d).
http://www.hhs.gov/ohrp/references/findings.pdf

FDA Guidance: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed.
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM328855.pdf