ORD/RRO SOP: Human Subject Protection Training Requirements

1. Purpose

The Queen's Medical Center (QMC) Office of Research and Development (ORD) and Research Regulatory Office (RRO) requires that all individuals engaged in research with human subjects must complete instructional training. This requirement reflects QMCs commitment to the protection of rights and welfare of human subjects in research.

2. Applicability

2.1 This SOP applies to all individuals identified as investigator or other research personnel on initial IRB/RIRC application and those who are added at a later date regardless of affiliation with QMC, Some examples include: those who obtain informed consent, conduct study procedure or interventions, administer surveys, collect or enter data, or who use/have access to private or personal information about individuals.

2.2 Required Training

- Human Subjects Research Training is required regardless of research funding source.
- Research HIPAA Training is required when accessing/using/disclosing protected health information.

2.3 Training Dependent on Nature and Funding

- GCP, RCR, and IRB training are required according to nature of research and/or funding.

3. Implementation

3.1 It is the responsibility of the investigators and their study staff to maintain current certification in human subject research protection, Research HIPAA training, and any other required certification (as appropriate to funding) while engaged in human subjects research. Training documentation must be available for review by the sponsor, Office of Research and Development, appropriate IRB, Auditors, representative of FDA or OHRP, or any other regulatory entity. Final IRB/RIRC approval and/or an award will not be made unless the training is complete.

3.2 Human Subjects Research Training

3.2.1 Required certification is provided through the Collaborative IRB Training Initiative (CITI) program, a web-based training program developed by experts in the "IRB community". It consists of a basic course in the Protection of Human Research Subjects for biomedical and social/behavioral research:

- "**Biomedical Research Investigators and Key Personnel"** composed of 16 modules, each with reading material and a brief on-line quiz. The format is "open-book" with text available at any time during the quiz. Accessible at https://ord.queens.org/cititraining.html .

3.2.2 Recertification must take place every **3 years** from the date of previous certification.

3.3 Research HIPAA Training

3.3.1 Research HIPAA training is required for all who have/will have access to Protected Health Information. Training is hosted by The Queen's Medical Center using HIPAA Training Manual, accessible at https://ord.queens.org/education.html#hipaa .

3.4 Depending on the nature of research and funding, other courses may be required. Accessible at https://ord.queens.org/cititraining.html

3.4.1 **Good Clinical Practice (GCP)**

3.4.1.1 This is mandatory for Principal Investigators and study research personnel working on FDA regulated studies or NIH funding studies that fit the NIH definition of a clinical trial. GCP training verification must be completed before sponsored project awards are issued.

3.4.1.2 GCP training certificate is valid for 3 years.

3.4.2 **Responsible Conduct of Research (RCR**)

3.4.2.1 This is required for all students and postdoctoral scholars serving on studies funded by the National Science Foundation. Some NIH programs also require RCR. RCR training verification must be completed before sponsored project awards are issued.

3.4.2.2 RCR training certificate is valid for 3 years

3.4.3 IRB Reference Resource or Biomedical Research Investigators and Key Personnel

3.4.3.1 This is required for all IRB members serving on The Queen's Medical Center Research and Institutional Review Committee

3.4.3.2 Certificates are valid for 3 years

4 Verification

4.4 RRO in conjunction with ORD tracks the completion of human subject training. Each individual is responsible for providing certificates to RRO.

4.5 RRO verifies the completion of human subject training during IRB review. Individuals who have not complied with this SOP, or have expired training, may be removed from any active studies.

4.6 The following University of Hawaii (UH) Human Research Protection certification are accepted:

4.6.1 Non-Exempt Biomedical Researchers and Key Personnel (for Biomedical/Clinical research)

4.6.2 Non-Exempt Social & Behavioral Sciences Researchers and Key Personnel (only for Social and Behavioral Sciences research)

4.6.3 GCP Course (involving medical devices or for IND)

4.7 Other equivalent human subject training may be accepted with approval from the ORD Director or RRO Manager. Confirmation may be requested through RIRC@queens.org .