

## Frequently Asked Questions – ECHN Institutional Review Committee

### Questions Related to the Need for IRC Review

#### Q: What is the definition of research?

- A. Federal research regulations and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) define research as a systematic investigation, including research development, testing and evaluation, designed (primary goal, purpose, or intent) to develop or contribute to generalizable knowledge.**

After a project has been designated “research”, the next step is to determine whether the project involves “human subjects”. “Human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- 1) data through (a) intervention or (b) interaction with the individual, or
- 2) identifiable private information or identifiable biospecimens.

All projects meeting the definition of “research” must be brought to the IRC’s attention.

In order for a project to require IRC review and approval, it must be both “research” and involve “human subjects”.

Refer to the ECHN Clinical Research Checklist for further guidance.

- If the project meets the definition of “research” and “human subjects” under item 1a above, (eg., use of drugs or devices), complete the **ECHN IRC Protocol Application for the Involvement of Human Participants in Research form#1** and submit to the IRC.
- If the project meets the definition of “research” and “human subjects” under item 2 above, complete the **ECHN IRC Protocol Application for Review of Data, Documents, Medical Charts, Records, Pathological or Diagnostic Specimens Form#2** and submit to the IRC.
- If the project meets the definition of “research” and “human subjects” under items 1b or 2 above, complete the **ECHN IRC Protocol Application for Surveys, Interviews, Questionnaires and/or Focus Group Studies Form#3** and submit to the IRC.
- If the project meets the definition of “research” but does not involve “human subjects” as defined above, complete the **ECHN Request for Exemption from Continuing IRC Review Form**.

#### Q. Who may act as the Principal Investigator for research studies?

- A.** At ECHN, only members of the active medical staff/senior healthcare professionals qualify to serve as the Principal Investigator.

Only one person may be designated as the Principal Investigator.

Students, residents or other trainees may be designated as co-investigators but not Principal Investigators.

#### Q: Does a case study / case series require IRC review?

- A:** In consistent practice with many other institutions, ECHN does not consider write up of a single case, or two or three cases, as constituting research. The retrospective summary of such a few number of cases is not considered to meet the systematic investigation element of the definition of research. A review of three cases would not require IRC review. A review of four or more cases may meet the definition of research, depending upon the nature of the project, and prospective IRC review may be required.

During presentation/publication of a case report/reports, do not use the word “research”; instead, designate it as an “educational” activity.

In all cases, complete the ECHN Certification of De-Identification for Educational Activity Form prior to initiating the case review and submit it to the manager of the Health Information Management (HIM) Department.

**Q: How do I know if my Quality Improvement/Assurance Project requires IRC review?**

**A: Quality Improvement (QI) and Quality Assurance (QA) projects involve systematic, data guided initiatives or processes designed to improve local systems of care (non-generalizable): clinical care, patient safety, healthcare operations, services and programs or for developing new programs or services (eg., teaching evaluations, patient/employee surveys). QI/QA is intended to use experience to identify effective methods, implement the methods broadly, and evaluate the immediate impact or effect of the implemented changes. As such, QI/QA is an intrinsic part of good clinical practice where lessons learned are used to enhance future healthcare delivery for patients, healthcare operations and services or programs at the institution in which the QI/QA activity is implemented.**

Refer to the ECHN Clinical Quality Improvement/Assurance Checklist for further guidance.

During presentation/publication of a QI/QA project, do not use the word “research”; instead, designate it as a QI/QA activity.

**Q: What type of IRC review is required for a research project using data/specimens?**

A: The type of review depends on how the data/specimens are obtained/received by the investigator and whether the data/specimens are **existing** or **prospectively** collected.

Research that is conducted on **existing** human data/specimens that are identifiable or linked to a human subject must be submitted for IRC review.

- The IRC may determine that research involving existing data/specimens qualifies for expedited review if a link is maintained between the data/specimen and the individual from whom it came.
- The IRC may determine that research involving existing data/specimens qualifies for exempt status if the investigator records the information in such a manner that there is no link between the subject and the data/specimens.
- If the original holder of the data/specimens provides the data/specimens without any link between the subject and the data/specimens (i.e., the data/specimens are anonymous), this does not constitute human subject research and IRC review is not required.

Note, the use of **existing** data/specimens means that **all** data/specimens needed for the study must already be available at the time of IRC submission and review.

For projects involving the use of **existing** or **prospectively** collected data/specimens, complete the **ECHN IRC Protocol Application for Review of Data, Documents, Records, Medical Charts, Pathological Specimens or Diagnostic Specimens Form#2**.

**Q: Does a pilot study have to be reviewed by the IRC?**

A: Yes. Any study involving human subjects, regardless of the number of subjects to be involved, must be reviewed and approved by the IRC prior to initiation.

**Q: If I am just looking at specimen samples (i.e., urine, blood, skin, etc.) that are being collected for a clinical purpose and that are otherwise going to be thrown away, do I have to get IRC review.**

A: Yes, all procedures that are looking at human samples (that are identifiable directly, or through codes) in the fashion of a systematic investigation outside of clinical care have to be reviewed by the IRC. These studies will most likely qualify for expedited review **OR** be granted IRC exempt status depending on the amount of confidential information accessed by the PI.

**Q: If I am doing research on cadavers or on samples obtained from cadavers, do I have to get IRC review?**

A: It depends. IRC review is not needed if the materials do not contain any personal identifiers (PHI). However, if personal identifying information is linked to the materials, then IRC review is required. The review is required because the IRC also acts as the privacy board and the HIPAA privacy regulation extends to deceased individuals.

**Q: If I want to make a change to my study after I've received approval, do I need IRC approval again?**

A: Yes. Any change to a previously approved study must be reviewed and approved by the IRC prior to implementation. This includes changes to any document related to the study (e.g. informed consent form, surveys, advertisements, recruitment letters, etc.) You will need to submit the ECHN Amendment Template form to request a modification / addendum to a previously approved study. The only exception to this is that a change can be implemented if it is needed to eliminate immediate harm to subjects or others. Such changes must be reported to the IRC within 5 business day.

IRC-FAQ

Rev. 12/1/14

Rev. 1/5/15

Rev. 4/22/19 (definition of research)