Full Review Explanation

HENRY FORD COLLEGE
FUTUREDRIVEN

Institutional Review Board

Research topics that do not meet the criteria for exempt or expedited status will be reviewed by the full IRB. The list of categories of research that may be reviewed by the IRB include:

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

2. Collection of data from voice, video, digital, or image recordings made for research purposes.

3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from federal regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

4. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

    a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

    b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

5. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; examples include

    a. weighing or testing sensory acuity;

    b. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

6. Continuing review of research previously approved by the convened IRB as follows:

    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

Prospective Principal Investigators (PIs) will submit one (1) original of the Full Review Application to the IRB Chair.

In the project form, the investigator must thoroughly discuss the purpose of the research, benefit to HFC, methodology for HFC students or employees, risk to subjects, obtaining consent, and disposition of the data. In addition, the investigator should present any information that will aid the IRB in understanding the nature of the research.

The PI must be available to discuss the project and/or consent forms at the discretion of the IRB. It is strongly recommended that new investigators have an advance copy of their project form reviewed by an IRB member or alternate before submitting final copies to the IRB Chair.