

## Exempt Human Research

### Definitions:

**Research:** As defined by DHHS any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**Clinical Investigation:** Any experiment that involves a test article and one or more human subjects, and that is subject to the FDA regulations. FDA regulations consider the terms “clinical investigation” and “research” to be synonymous. The following are considered experiments subject to FDA regulations:

- Any use of a drug, other than the use of an approved drug in the course of medical practice.
- Any use of a medical device to evaluate safety or efficacy of that device.
- Any activity where data are being collection to submit to FDA or to be held for inspection by FDA.

**Test article:** Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.

**Human Subject:** A defined by DHHS: a human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains either data through intervention or interaction with the individual, or identifiable private information. As defined by FDA: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A subject is also an individual on whose specimen a medical device is used.

**Intervention:** Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects’ environment that are performed for research purposes.

**Interaction:** Includes communication or interpersonal contact between an Investigator or his/her research staff and the research participant or their private identifiable information.

**Private Information:** Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the

information) in order to be considered information to constitute research involving human participants.

**Research Activities Involving Human Subjects:** Activities that either (1) meet the DHHS definition of “research” and involve “human subjects” as defined by DHHS OR (2) meet the FDA definition of “research” and involve “human subjects” as defined by FDA.

### **Policy:**

All research activities involving human subjects under the jurisdiction of the UHCMC IRB will be reviewed to determine (i) whether the research meets one or more of the exemption categories described in the federal regulations and (ii) whether it complies with UHCMC’s ethical standards. Research conducted under exempt review is also subject to all applicable institutional and IRB policies and procedures.

### **A) Exempt Eligibility:**

The Federal regulations allow certain research activities involving human subjects to be exempt from IRB full or expedited review [*see* [45 CFR 46.101\(b\)\(1-6\)](#); [45 CFR 46.401\(b\)](#); and [21 CFR 56.104\(d\)](#)]. There are however restrictions for research involving children (*see* [45 CFR 46, Subpart D](#)); and research involving prisoners does not qualify for exempt research (*see* [45 CFR 46, Subpart C](#)). In addition, FDA-regulated research does not qualify for IRB exemption unless it falls under the FDA’s emergency use provision for the use of a test article [[21 CFR 56.104\(c\)](#)] or Taste and Food Quality Evaluations and Consumer Acceptance studies [[21 CFR 56.104\(d\)](#)].

The UHCMC [Request for Exemption Checklist](#) lists the permitted exemption categories and the IRB (or investigators) may not create new categories of exempt research.

Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt. They must contact the IRB concerning the status of the proposed research; or regarding changes in ongoing research prior to its initiation.

An investigator may request a particular category of exemption by selecting their choice on the UHCMC [Request for Exemption Checklist](#). However, the final determination of applicability will be made by the IRB, namely the IRB Chair, Vice-Chair, designated IRB member or Senior IRB staff member who is familiar with the regulations. Documentation of the determination will be accomplished by completing the UHCMC IRB Exemption Determination form. The IRB Chair, Vice-Chair, designated IRB Member or senior IRB staff may (1) approve the request; (2) request minor revisions to the submitted documents in order to approve the request; or (3) disapprove the request. If the request is approved, the IRB staff will forward an approval information to the Investigator. The information will include the approved IRB exemption category; the expiration date; and notice that a

new application is required if research is to continue after the expiration date or is amended in the future.

If the request is disapproved, the IRB staff will forward a denial letter to the Investigator. The letter will state the reason for the denial and provide guidance to indicate that the investigator may resubmit for full board or expedited review. .

### **B) Department Research Scientific Review:**

All IRB Exemption requests must be reviewed and approved by the Department Research Scientific Review Committee (or Chairperson as appropriate) prior to being submitted to the IRB office. Each application must include a completed the UHCMC [Request for Exemption Checklist](#) and a research plan (*see* [IRB Policy, Protocol Submission Requirements](#));.

### **C) Duration of approval:**

Continuing review is not required for research that has been determined to be exempt. However, all research determined to be exempt, will be awarded an expiration date of six years from the time the exemption was approved. If the investigator wishes to continue the research project after the six year period, the investigator must re-submit the project as a new “Request for Exemption” for IRB review and approval. The request should include an updated protocol and summary of the work and results obtained during the previous approval period.

### **D) Amendments:**

Proposed changes to an exempt study after initial IRB approval must be submitted to the IRB for review prior to implementation. Certain changes may disqualify the research from exempt status (i.e., recruiting prisoners). Changes to a currently approved Exempt project should be submitted as follows:

- submit a “Request for Exemption Checklist” with the current Exemption number (e.g., EM-08-01) and current expiration date
- a memorandum discussing the change that is being made
- a version of the protocol clearly showing the changes being made (a “tracked changes” version using Microsoft Word)
- a clean version of the protocol with the new changes incorporated.

The IRB will review the proposed changes to determine if the project still qualifies for Exempt status. If the project is Exempt, approval will be given for implementation of the changes. The current number and the current expiration date will not change. If the IRB determines that the project no longer qualifies for Exemption, the investigator will be notified accordingly with instructions about how to proceed with IRB review.

### **E) Use and Disclosure of PHI (applicability of the HIPAA Privacy Rule):**

If the proposed research involves utilization of Protected Health Information (PHI), HIPAA regulations still apply, even if the IRB has determined that the research qualifies for IRB Exemption. Investigators must indicate applicability of HIPAA Privacy Rule on the Request for Exemption Checklist. Investigators must also submit the appropriate supporting documentation for review.

### **F) Certification in Human Subjects Protections:**

Investigators requesting a determination of exemption are required to be certified in Human Subjects Protections through the [Case CREC \(Continuing Research Education Credit\) Program](#).

### **References and/or Regulatory Citations:**

[45 CFR 46.101\(b\)\(1-6\)](#)

[45 CFR 46.401\(b\)](#)

[21 CFR 56.104\(c\)](#)

[21 CFR 56.104\(d\)](#)

### **Related Policies:**

[IRB Policy, Protocol Submission Requirements](#)

[IRB Policy, Certification in Human Subjects' Protections](#)

[IRB Policy, Assent from Children in Research Studies](#)

[IRB Policy, Use and Disclosure of Protected Health information \(PHI\) for Research Purposes – HIPAA and the Privacy Rule](#)

### **Related Forms:**

[IRB Checklist: Request for Exemption](#)