
UNIVERSITY OF WISCONSIN MEDICAL SCHOOL
OFFICE OF EXTRAMURAL SUPPORT
OFFICE OF CLINICAL TRIALS
POLICY AND PROCEDURE

Policy Title: Definition of a Clinical Trial and Related Issues

Effective Date: 05/08/03

Last Revision Date: 05/08/03

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I. POLICY PURPOSE AND BACKGROUND

The purpose of this policy is to (a) define the term “clinical trial”; (b) clarify differences between the terms “clinical trial” and “human subjects research”; (c) provide guidelines for determining when a project is included in either or both of the above categories, and (d) clarify Facilities and Administrative (F&A) cost, IRB fee, and OCT budget database issues related to the above.

II. DEFINITIONS

Clinical Trial: A subset of human subjects research. A clinical trial is operationally defined as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs treatments, devices, or new ways of using known drugs, treatments or devices). (NIH definition)

Facilities and Administrative (F&A) cost: F&A costs (or indirect costs) are real costs that provide reimbursement for actual institutional expenses that support extramural activities but cannot be directly charged to a grant or contract. The costs result from shared services such as libraries, physical plant operation and maintenance, utility costs, general, departmental and sponsored projects administrative expenses, and depreciation or use allowance for buildings and equipment. (definition from UW Office of Research and Sponsored Programs website).

Fee for Service: A fee-for-service agreement may exist between a funding source and a UW faculty member who is being reimbursed for services provided (for instance, registries as defined below).

Human Subjects Research: Research involving humans. Per 45 CFR 46.102(f), a *‘human subject’* is “a living individual about whom an investigator ... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

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Institutional Review Board (IRB): An institutional review board is an entity established to review and approve animal and/or human subjects research. IRBs review and approve all human subjects research in accordance with federal regulations (45 CFR 46). For the University of Wisconsin Medical School, the applicable IRB is the Health Sciences Institutional Review Board.

Interaction: An *interaction* includes communication or interpersonal contact between investigator and subject. (definition from the UW Health Sciences IRB Application For Exemption).

Intervention: An *intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (definition from the UW Health Sciences IRB Application For Exemption).

Office of Clinical Trials Budget Database: A web-based budgeting tool linked to current technical and professional fees charged by UW Hospital and Clinics and the UW Medical Foundation.

Private information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, 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 for obtaining the information to constitute research involving human subjects. (definition from the UW Health Sciences IRB Application For Exemption).

Registry: Registries are databases containing information on clinical practices, usually with an emphasis on the treatment of a particular disease. There is often no specific protocol or detailed inclusion/exclusion criteria except for a broad diagnosis, and monetary compensation for participation is usually nominal.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (definition from the Code of Federal Regulations, 45 CFR 46.102(d))

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University of Wisconsin IRB fee: The IRB fee is the fee charged to industrial sponsors of clinical trials at the University of Wisconsin. This fee became effective December 1, 2001. The fee structure is \$2500 for initial review of protocols, and \$750 annually for continuing review. These fees are structured to include F&A costs.

III. ENTITIES

UW Health Sciences IRB

UW Hospital and Clinics

UW Medical Foundation

UW Medical School Office of Extramural Support

UW Medical School Office of Clinical Trials

UW Office of Research and Sponsored Programs

IV. PROCEDURES

A. **Criteria for Entry of Human Subjects Research into the OCT budget database:**

- All studies involving UWHC or UWMF procedures and/or charges must be entered into the OCT budget database, regardless of funding source.
- All studies with industrial sponsors must be entered into the OCT budget database whether or not there are UWHC or UWMF charges/procedures. If there are no UWHC or UWMF procedures involved in the study, that information should be entered in the first “comment” field, at which point no further entries are necessary.
- Studies that do not involve UWHC or UWMF procedures **and** are not sponsored by industry are not required to be entered in the OCT budget database.

B. **Determining Whether a Human Subjects Research Study is a Clinical Trial.** OCT budget database staff will make an initial determination when the budget is entered in the budget database. OCT staff will apply the appropriate F&A rate and IRB fee to the study budget. Final responsibility of clinical trial

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designation will rest with the Medical School Office of Extramural Support, in consultation with the UW Office of Research and Sponsored Programs.

C. Applicable F&A Rates. F&A rates are listed on the UW Office of Research and Sponsored Programs webpage (<http://www.rsp.wisc.edu>). In almost all cases, F&A rates for industry-sponsored research will be one of the following:

- Clinical Trials – 20%
- Organized Research – 45.5%

D. Applicable IRB Fees

- For industry-sponsored clinical trials, the IRB fee (\$2500 for initial review, \$750 annually thereafter for continuing review) will be assessed. Exceptions to this policy and/or waivers must be approved by the Medical School Associate Dean for Research.
- For Human Subjects research projects that are not clinical trials, IRB fees will not be assessed.
- The UW Medical School Office of Clinical Trials will generate invoices to sponsors and investigator accounts as part of the clinical budgeting and billing process. Investigators are responsible for following up with sponsors to assure that the invoices are paid.

E. Registries

- In limited cases, registries may be determined not to constitute a research activity. Researchers who think their registries do not meet the definition of research as defined in II. above may contact either the Office of Extramural Support or the Office of Clinical Trials. Final determination of whether a registry does not constitute research rests with the Medical School Associate Dean for Research.
- In limited cases, IRB fee waivers may be granted for registries.

F. Questions

Questions about this policy should be directed to the Office of Extramural Support (Sandi Robins, 263-5978; Debbie Meltzer 263-4940) or the Office of Clinical Trials (Judy Van Kirk, 265-6508; Peggy Munson, 263-0383).