

UC Davis Policy and Procedure Manual

Chapter 240, Research Integrity

Section 56, Minimal Risk Activities

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Definition

Minimal risk is the probability and magnitude of harm that is normally encountered in the daily lives of healthy individuals, or in the routine medical, dental, or psychological examination of healthy individuals (45 CFR 46.102(g)). Certain minimal risk activities qualify for expedited review by the Human Subjects Review Committee (HSRC).

Purpose of Expedited Review

The purpose of expedited review is to assure proper review of activities, but to reduce the time and effort required to obtain review and approval.

General Condition

Results of studies must protect the identity of individual subjects.

Activities that Qualify for Expedited Review

Studies that involve the following procedures are considered to entail minimal risk and qualify for expedited review:

Venipuncture

Collecting of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from normal subjects 18 years of age or older and in good health and not pregnant.

Noninvasive data recording

Recording of data from adults through the use of physical sensors that are noninvasive and do not involve input of significant amounts of energy into the subject.

- Such procedures include weighing, electro-cardiogram, electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography.

Plaque collection

Collection of both supra- and subgingival plaque, provided the procedure is not more invasive than routine prophylactic scaling of the teeth using accepted prophylactic techniques.

Collection of teeth, hair, nail clippings

Collection, in a nondisfiguring manner, of hair, nail clippings, and deciduous teeth.

Collection of excreta, sweat, saliva, placenta, amniotic fluid

Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

Exercise

Moderate exercise by healthy volunteers. (Individuals 35 years of age or older require special medical clearance.)

Other Minimal Risk Activities

Other individual studies may also be found by the HSRC to entail only minimal risk.

Reciprocity with other institutions

In addition, studies reviewed and approved by another institution's review board (IRB) may be submitted under minimal risk procedures.

- These studies must be accompanied by the Protocol Form for Research Involving Human Subjects, Form 710A (see Section 710, Exhibit A), plus a copy of the approval by the outside institution.
- The HSRC may require full review of the protocol at its discretion.