

Overview of UCSF Committee on Human Research (CHR) Review Requirements

When does a study require CHR review?

- Study is performed by UCSF faculty, staff, or students (where the research is conducted does not matter)
- Study involves living humans (including biological specimens, medical records, or other private information; definition is not limited to interactions or interventions with humans)
- Project is research, an investigation designed to contribute to generalizable knowledge

Guidance on surveys, records review, or secondary data analyses

- **Survey research** – Usually requires expedited approval. If the risks are more than minimal, such as the research involving questions about illegal drug use and/or illegal behavior or included questions about very sensitive aspects of a person's behavior, a full committee application would be required.
- **Records review** – Usually requires expedited approval, even if the subjects are the doctor's own patients, unless the data are being recorded or received without unique subject identifiers (including patient numbers). In that case, exempt certification would likely apply.
- **Secondary data analyses** – According to current federal guidance, secondary analyses requires CHR review. If the data include subject identifiers, then expedited approval is needed. However, if no subject identifiers are attached to the data, then the study can be certified as exempt.
- **Data or specimens obtained from another institution** (with that institution's IRB approval) – This is also the study of existing data and would be treated in the same manner as secondary data analyses described above.

Levels of CHR review

- **Full Committee Review:** Required for all studies involving greater than minimal risk (i.e., the risk of daily life). Examples include randomized studies, phase I, II, III and IV trials, studies using investigational drugs and/or devices, and some behavioral interventions.
- **Subcommittee Review:** Also called **Expedited Review**, is allowed when studies involve no greater than minimal risk and fit into one of the following categories:
 - **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults and children. (Certain restrictions apply.)
 - **Prospective collection of biological specimens** for research purposes by noninvasive means (i.e., nail clippings, external secretions, placenta, or buccal scrapings).
 - **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves but including MRIs, echocardiography, ultrasound.
 - **Research involving materials** (data, documents, records, or specimens) **that have been collected, or will be collected solely for nonresearch purposes** (such as medical treatment or diagnosis).
 - **Collection of data from recordings** (voice, video, digital, or image recordings) made for research purposes.
 - **Low risk behavioral research**, including research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- **Exempt Certification:** May be allowed if the research fits into one of the following four categories. Exempt studies require an application and review (good for three years) from the CHR.
 1. The research involves the **collection or study of existing data, records, or specimens** already publicly available or not linked to subjects directly or via identifiers
 2. The research is on **regular and special education instructional strategies**, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
 3. The research involves the use of **educational tests (cognitive, diagnostic, aptitude, achievement) or observations of public behavior**, except where: there are subject identifiers; disclosure of the information could place a subject at physical or financial risk; or research data includes sensitive aspects of the subject's own behavior, such as illegal conduct, drug/alcohol use, or sexual behavior.
 4. The research involves the use of surveys or interviews, educational tests, or observations of public behavior when the **subjects are elected or appointed public officials** or candidates for such positions.