



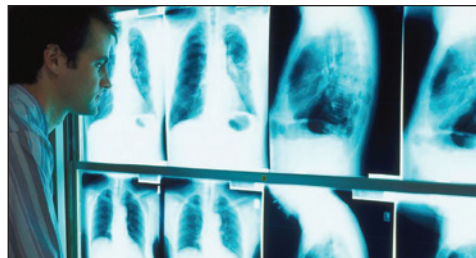
## Top Tips for speeding up your CHR approval



University of California  
San Francisco

## Getting started

1. Make sure science is sound. **Scientific or scholarly review**, preferably by a group of peers and certainly by a student's mentor, should occur *before* submitting a full committee application to the Committee on Human Research (CHR).
2. Determine **appropriate level of review**, or if review is required:
  - a. Full committee review
  - b. Expedited
  - c. Exempt Certification
  - d. Research does not meet definition of human research
3. Download and follow the **most current CHR Application Forms and Consent Templates** from the Human Research Protection Program (HRPP) website. Click on links in application for help.
4. Check the HRPP website to see which **Application Supplements** are needed for your particular study. There are several supplements, including: Inclusion of Children and Minors, Disclosure of Financial Interest, Human Biologic Specimen Collecting and/or Banking for Future Research, Surrogate Consent, Waiver of Informed Consent/ Authorization for Minimal Risk Research or Screening.



## Writing Musts

5. Consider **the audience** when writing application and consent documents:
  - a. **Avoid acronyms** if possible; if used, spell out before first use.
  - b. Write application with understanding that **not all members are scientists**, few if any are experts in your field, and unless someone is an expert, no one will be familiar with current standards of clinical care or standard procedures for discipline (IRB members are from several disciplines, and not comparable to an NIH peer review group.)
  - c. Consent documents should be written in **lay language** at no higher than 8<sup>th</sup> grade reading level or at an even lower reading level when appropriate. Avoid jargon, legalese, long complex sentences, and use of the passive voice.
6. Strive for **consistency** within and among the various parts of the submission:
  - a. Assure that all sections **within the CHR Application** are consistent with each other, i.e., the purpose, benefits and alternatives.
  - b. Assure that all sections **within the consent form** are consistent (see above).
  - c. Assure that the information in the **CHR Application matches that in the group or sponsor protocol** and the Investigator's Brochure.
  - d. Assure that the **application and consent form** are consistent.
  - e. Use the **same name for the subject groups** throughout the application and consent documents.
  - f. Use the **same name for the study drugs** throughout the submission.

## Including Details

7. Within both the application and the consent forms:
  - a. List and describe **procedures in chronological order**.
  - b. **Describe each study group** clearly and completely.
  - c. Distinguish between those procedures that are **standard of care and will be billed** from those procedures being performed for research purposes only.
  - d. Explain the alternatives available to subjects outside the study.
  - e. Describe **how risks will be minimized** and managed. For the application, provide a clear description of the **Data Safety Monitoring Plan**. A Data Safety Monitoring Board may also be required.
8. If you are using **investigational drugs** or **devices**:
  - a. Include a copy of the investigators' brochure with your application.
  - b. If there is no investigators' brochure, call the CHR office to discuss options.



## Recruiting and Consenting

9. Provide a detailed discussion of the **recruitment and consent process**. Include the who, what, when, where and how of each. Submit copies of all recruitment materials and consent documents, including scripts and the text of ads.
  - a. If minors are involved, be sure to address **assent for the minors** and include appropriately written assent forms. Include the supplement.
  - b. If you are requesting a **waiver of signed consent**, be sure to justify your request.
  - c. If you are requesting a **waiver of consent**, be sure to include the completed supplement and justify your request.
  - d. If you are including people with **cognitive impairments**, then you will have to address the issues of cognitive capacity.
  - e. If it is likely that you will have **subjects who do not read, speak or understand English**, then you will need to address this issue as well.



## Wrapping Up

10. **Write a cover letter** to
  - a. Explain and **highlight any particularly difficult or sensitive issues** to show that you have thought them through ahead of time, or ask for CHR input.
  - b. Inform the CHR if you have **special time constraints**, i.e., if study is being sent in “just in time” for NIH funding, or if you have a patient waiting.
  - c. Explain how many consent forms are being used if there are several—this is particularly important for research involving minors.
11. Do **a final review** of CHR Application and study documents. If you are preparing the application and are not the study PI, make sure the study PI has read the application and the consent documents.
12. If you have any questions about the process, call the CHR office at (415) 476-1814 and ask to speak to the Analyst of the Day or e-mail [chr@ucsf.edu](mailto:chr@ucsf.edu). Calls and e-mails will be returned within 24 hours.

**Bonus Tip:** Get **a separate CHR approval** for each study. Do not group related studies into a complicated application.

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