

UCSF Human Research Protection Program

Good Clinical Research Practice (GCRP) Top Four Tips on How to “Do It Right”

1. Above all else, respect and protect the safety, welfare, and rights of research participants.

- Follow your CHR approved protocol.
 - Obtain CHR approval before implementing changes to the protocol and/or informed consent form.
- Stay informed. Know your [responsibilities](#) under federal, state, HRPP and UCSF policies and guidelines.
- Ask questions. Contact the HRPP for information when in doubt about research regulations, policies or guidelines.

2. Principal Investigators (PIs) are directly responsible for all aspects of the research investigation.

- PIs must personally conduct or otherwise consistently oversee and supervise their research investigations
- PIs should be careful to not over-extend their ability to personally supervise their research projects, or over-delegate study responsibilities to non-clinician staff.
- [Delegation of study roles and responsibilities](#) should be documented in writing and revised as key study personnel change.
- Records should be kept for any and all [formal on-site study monitoring](#) that serves to document and verify: a) the progress of the study, b) the quality and integrity of the study data, c) that the rights and welfare of the participants were met.

3. Get organized, and stay organized.

Prior to initiating the recruitment/enrollment phase of study activities, have all of the key study components in place and ready to go. Some items to consider are:

- [Tracking systems](#) to manage deadlines and reporting requirements (e.g.; CHR renewal, adverse event reporting)
- Study-related forms (CRFs, current ICFs, etc.), files, binders
- [Screening/enrollment/withdrawal logs](#)
- [Study events tracking forms](#) to ensure that all protocol required events are performed as described
- A [Regulatory Notebook or Binder](#) in which all significant documents are maintained in a logical and chronologic order.

- If conducting an inpatient study:
 - Conduct in-service training for all personnel at the unit where the research will take place
 - Create template study orders and algorithms, as indicated
 - Conduct a mock enrollment or “dry run” to ensure that all study logistics are functional before launching a full study recruitment effort

4. Maintain proper documentation.

Remember: ***If it is not documented it did not happen.***

- All data and records should be complete, attributable, legible, dated, original, and accurate.
- Depending on the nature of the study, there may be case report forms (CRFs) provided by the sponsor to capture all protocol-required data for each subject. If there are no CRFs for the study, ensure that all data relating to the study are captured, using for example, data collection sheets/worksheets.
 - All CRFs and source documents should be completed in ink (preferably black ink).
 - All CRF and source documents should be initialed, signed and dated by the person making an entry, and/or the person reviewing/confirming the information.
 - Initial and date any errors or corrections by drawing a single line through the incorrect information (never completely scratch out, use “white out” or otherwise fully obliterate or obscure an existing data entry).
- An [Investigational Drug or Device Dispensing/Accountability Log](#) must be maintained, if the study includes an investigational drug or device.
- A signed and dated record entry, known as a *memo-to-file* or *note-to-file*, can be used to explain:
 - Missing or incomplete data
 - Any discrepancies in study-related information or data
 - Who, when and how study information was obtained