



California Health Sciences University

CHSU COMMON RULE COMPLIANCE POLICY

CHSU is committed to ensuring that all human subjects research is conducted in accordance with the ethical principles stated in the Belmont Report which provides the ethical foundation for the federal regulations for the protection of human research subjects (<https://www.ncbi.nlm.nih.gov/pubmed/20543620>).

The “Common Rule” is the term for U.S. Federal Policy for the protection of human subjects (45 CFR part 46) which outlines the criteria and mechanisms for IRB (Institutional Review Board) review of human subjects research. All studies approved after January 21, 2019 are required to comply with the Revised Common Rule. Details on the Common Rule and its requirements and revisions can be found at <https://www.hhs.gov>.

All University personnel involved in the conduct and oversight of human subject research must abide by the fundamental principles set forth in the Belmont Report and the requirements of the Common Rule.

Fundamental to compliance with the requirements of the Common Rule is that any research involving human subjects must obtain approval of an IRB prior to initiating any study. Copies of any IRB applications and subsequent IRB action must be submitted to the Provost (or designee). Following IRB approval, should there be any modifications of or deviations from the approved protocol, the approving IRB and Provost (or designee) must be notified. Copies of any required resubmission to the IRB must also be provided to the Provost (or designee).

As stated in the approved CHSU IRB Policy, the Rocky Vista University IRB (RVU IRB) is the preferred method through which CHSU research investigators should pursue IRB review and approval. Any IRB which reviews or approves CHSU research must be compliant with the Common Rule requirements.

Further, all IRB-approved research by CHSU investigators that subsequently is suspended or terminated or in any way is non-compliant with IRB approval must be reported by the investigator(s) to both University officials and the approving IRB. In order to resume such research activities, regardless of who initiated the suspension, a modification requesting re-initiation of the study must be submitted for approval to the Provost (or designee) and to the IRB for review.

Among the revised Common Rule requirements it is also mandated that any cooperative research involving multiple institutions must use a single IRB. CHSU investigators who may engage in such cooperative research are obligated to meet this requirement.



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- Policy Owner: Provost (or designee)
- Effective Date: 4/04/2019
- Approval by Provost Date: 4/10/2019
- Approval by President Date: 4/10/2019