1. PURPOSE
   1. This procedure establishes the process for creating reliance agreements between the UC Davis IRB and other IRBs, Institutions, or Investigators.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. DEFINITIONS
   1. Cooperative Research: See SOP: Definitions (HRP-001)
   2. Reliance Agreement: See SOP: Definitions (HRP-001)
   3. HIPAA: See SOP: Definitions (HRP-001)
4. POLICY
   1. Federally-funded studies initially approved on or after January 21, 2019 which meet the definition of cooperative research must rely upon approval by a single IRB except as described at 45 CFR 46.114(b)(2).
   2. Reliance agreements will not be entered into for studies which are exempt from the requirements for IRB review or deemed to be not human subjects research.
      1. Exceptions may be granted on a case by case basis when it is determined by the UC Davis IRB that entering into a reliance agreement will not be more administratively burdensome than conducting the review at each institution separately.
   3. IRB staff members cannot disapprove research.
   4. The UC Davis IRB will, upon request when serving as the IRB of record, review requests for HIPAA waivers and issue HIPAA waivers which meet criteria for approval under the HIPAA Privacy Rule.
   5. The Executive Associate Vice Chancellor for Research, the IRB Director, the IRB Associate Director, and IRB reliance staff members are delegated the authority to sign Cede Letters and SMART IRB agreements on behalf of the Institutional Official.
   6. The Executive Associate Vice Chancellor for Research, the IRB Director, and IRB Associate Director are delegated to sign IRB Authorization Agreements (IAAs) and Individual Investigator Agreements (IIAs) on behalf of the Institutional Official.
   7. When the UC Davis IRB relies on another IRB for the review of a study which involves an Exception From Informed Consent (EFIC) procedure as described in 21 CFR 50.24, the UC Davis IRB cannot issue a Cede Letter until the results of the Community Consultation required under the above regulation has been reviewed by a UC Davis IRB Chair and been determined to be appropriate within the local context.
5. RESPONSIBILITIES
   1. IRB staff members carry out the procedures described herein when a reliance agreement is being reviewed.
   2. IRB staff must follow SOPs HRP-058 and HRP-059, as applicable, when executing reliance agreements.
6. PROCEDURE
   1. IRB staff members will review all study documents for the following before an agreement to rely on another IRB is forwarded to the Institutional Official, or designee, for execution:
      1. Consistent contraceptive language and methods amongst all documents
         1. For the purpose of determining inconsistencies in regards to contraceptive methods and what constitutes “highly effective methods with an error rate <1%”, the UC Davis IRB uses the CDC Contraceptive Guidance for Health Care Providers and the “Modern Methods” section of the World Health Organization’s (WHO) Family Planning /Contraception webpage.
         2. If inconsistencies are discovered which do not represent a safety concern after consultation with an appropriate physician, such inconsistencies will be allowed.
      2. The California Bill of Rights must be included in the consent process for all studies which meet the definition of a “medical experiment” as provided in the California Protection of Human Subjects in Medical Experimentation Act.
      3. If the study will collect, obtain, or analyze biospecimens, the following paragraph must be included in the consent document per UCOP Guidance Memo 14-07: “Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.”
      4. If the study will obtain consent signature via an electronic method, the UCD IRB template language on rights of the subject for electronic consent must be included in the consent document in order to ensure compliance with California’s Uniform Electronic Transactions Act.
      5. If the study meets any of the criteria of Section II.A.1 of UC Davis Medical Center Policy 2317, the following text must be included in the consent document: “If you agree to participate in this research study, a signed copy of this consent document will be filed in your electronic medical record (EMR) to ensure people caring for you at UC Davis Health will have the information they need about this research study when they provide care for you.”
         1. If the study meets the above criteria and is either funded by the National Institutes of Health (NIH) or has received a Certificate of Confidentiality (CoC) from the NIH, the following language must also accompany the above statement: “Placing a copy of this consent form in the EMR is intended only to give information to caregivers providing treatment for you while you are on this study.”
      6. HIPAA authorization language should not be present within the consent document to be used at UC Davis. UC Davis utilizes a separate template HIPAA Authorization document for research studies, when such authorization is required.
   2. IRB staff members can rely on WORKSHEET: Reliance Agreement (HRP-334) when reviewing external reliance agreements for compliance with applicable regulations and policies before a reliance agreement is forwarded to the Institutional Official, or designee, for execution.
   3. Fees assessment
      1. IRB staff will facilitate referral of projects which require that fees be assessed against a grant or contract to the Office of Research Business and Finance Department for reconciliation.
      2. Fees will be assessed by the Office of Research Business and Finance Department as described on the UC Davis IRB’s fee schedule according to that Department’s policies and procedures.
   4. Review and approval of non-UCD sites
      1. When UC Davis acts as the IRB of record for an externally funded multi-site study, additional sites beyond UC Davis will not be reviewed and approved until either:
         1. A notice of award is received from the funding agency, if Federally funded.
         2. A contract is executed between UC Davis and the study sponsor which includes costs for IRB reliance fees.
7. MATERIALS
   1. WORKSHEET: Reliance Agreement (HRP-334)
   2. CHECKLIST: External IRB review of UC Davis Human Subject Research (HRP-442)
8. REFERENCES
   1. 21 CFR 50.24
   2. 45 CFR 46.101(b) (pre-2018 Common Rule)/45 CFR 46.104 (2018 Common Rule)
   3. 45 CFR 46.114
   4. [California Protection of Human Subjects in Medical Experimentation Act](http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=20.&title=&part=&chapter=1.3.&article)
   5. [California Uniform Electronic Transactions Act](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=CIV&division=3.&title=2.5.&part=2.&chapter=&article=)
   6. [CDC Contraceptive Guidance for Health Care Providers](https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/intro.html)
   7. [HIPAA Authorization for Research](https://research.ucdavis.edu/wp-content/uploads/UC-Davis-Health-HIPAA-Authorization-Form-9.2017.pdf)
   8. HRP-001
   9. HRP-058
   10. HRP-059
   11. [UC Davis IRB Fee Schedule](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/fees)
   12. [UC Davis Medical Center Policy 2317](https://intranet.ucdmc.ucdavis.edu/policies/hospital_policies_and_procedures/medical_records/2317.shtml)
   13. [UCOP Guidance Memo 14-07](https://researchmemos.ucop.edu/php-app/index.php/site/document?memo=UlBBQy0xNy0wNA==&doc=3709)
   14. [WHO Family Planning/Contraception Webpage](https://www.who.int/en/news-room/fact-sheets/detail/family-planning-contraception)