Example Submission

This slide deck serves as an example submission of a chart review study not receiving federal funding.

All data is collected from UCDH Epic EMR. No other data will be collected, and there are no other study procedures for this research.

Important Notice

If an individual or group outside of the study team is providing de-identified data from UCDH Epic EMR to the study team, this project does not constitute human subjects research. As such, it does not require IRB review.

If you would like the IRB to make this determination, submit the HRP-210 Request for Determination on IRBNet. No other forms or documents are required.

Examples of these items are included in this slide deck

1. HRP-503 UCD Health Medical Record Review Template
2. Initial Review Application

Additional requirements for a complete submission

3. Principal Investigator Signature on IRBNet
4. Other Required Signatures on IRBNet
   - Department Chair
   - Faculty Advisor if PI is a student, resident, or visiting scholar
5. Required CITI Training for PI (and Faculty Advisor)
   - Do NOT upload training completion certificates to IRBNet
   - It is the PI's responsibility to confirm that all other study staff have completed required CITI training prior conducting study procedures

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HRP-503 UCD Health Medical Record Review Protocol Template

Use of this Template

Yes	No	Use of this Template
☐	☒	**1. Is this research federally funded?** If yes, stop. Federally funded research requires additional IRB determinations. If this research is limited to secondary analysis, please complete the HRP-503 Record/Data/Specimen Secondary Analysis Review Template.
☒	☐	***2.*** **This research will use only data collected from the UCD Health EMR. No other data will be collected and there are no other study procedures for this research.** If no, stop. This template is for medical record review of UCDH EMR data only. The research may not include data collected through any other procedure. The research cannot involve data collected for non-clinical purposes (research interviews or surveys), data for another research study, or data released from another institution (e.g., via Data Use Agreement). If this research involves a data source other than the UCDH EMR, please complete the HRP-503 Record/Data/Specimen Secondary Analysis Review Template.

Read this section carefully to determine if you may use this template for your study.

For a link to the HRP-503 template we used for our example study, please click HERE.

HRP-503 UCD Health Medical Record Review Protocol Template

1) Protocol Title and 2) Objectives

1) Protocol Title

a) Title: Retrospective Study of Greyscale Disease in Children

b) Protocol Version Date: 14 February 2022

2) Objectives

a) Describe the purpose, specific aims, or objectives: The purpose of this study is to describe the progression and treatment of greyscale disease in children.

b) State the hypotheses to be tested: This is a descriptive study. As such, there are no hypotheses.

c) Describe how this research will add to existing knowledge or how the outcomes of this project will be used: While progression and treatment of greyscale disease is well-documented in adults, there is a paucity of research focusing on the disease in children. Outside of small case reports, this study would be the first to document greyscale disease progression and treatment in children.

Your protocol title should match the title of your project on IRBNet.

HRP-503 UCD Health Medical Record Review Protocol Template

3) HIPAA Protected Health Information (PHI) Obtained from UC Davis Health

3) HIPAA Protected Health Information (PHI) obtained from UC Davis Health

Protected health information (PHI) is defined by HIPAA as individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates. As a healthcare provider, UC Davis Health is a covered entity obligated to protect PHI. Access, disclosure or use of PHI for research purposes requires a signed HIPAA Authorization or IRB issued waiver of HIPAA Authorization. When PHI is extracted from the UCDH Epic EMR, it may not be re-disclosed/released outside the study team.

Under HIPAA, any data set which contains any one of the 18 HIPAA identifiers listed below is considered an identifiable data set. If a data set extracted from UCDH Epic EMR includes any of the 18 HIPAA identifiers, this means that it is PHI. To be considered a de-identified data set, at a minimum, all of the listed 18 HIPAA identifiers must be omitted from the dataset.

Data that is derivative of any of the 18 HIPAA identifiers (e.g., initials instead of name or partial phone number) is still considered identifiable. Check the box next to any identifier that will be documented in research records. If a derivative of an identifier will be documented, check the box next to the associated identifier. For example, if you are documenting the last four digits of subjects' social security numbers, please check social security numbers. If none of these will be documented in research records, select "None of the above."

Continues on next slide

Read this section carefully. It is common to forget that derivatives of the 18 HIPAA identifiers are also considered identifiers.

HRP-503 UCD Health Medical Record Review Protocol Template

3) HIPAA Protected Health Information (PHI) Obtained from UC Davis Health (cont.)

- ☒ Names
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social Security numbers
- ☒ Medical record numbers
- ☐ Health plan beneficiary
- ☐ Vehicle identifiers and serial numbers, including license plate numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Device identifiers and serial numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Internet Protocol (IP) addresses
- ☐ Biometric identifiers, including finger and voice prints
- ☒ Full-face photographs and any comparable images
- ☐ Geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
  - The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
  - The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.
- ☒ Elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
- ☐ Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.
- ☐ None of the above

This is a list of identifiers you will be documenting in your research records.

If you are NOT documenting any of the 18 HIPAA identifiers in your research records, check "None of the above."

Consistency Check | Initial Review Application, Data Confidentiality section

Jump to Data Confidentiality

HRP-503 UCD Health Medical Record Review Protocol Template

4) Description of Data Elements

4) Description of Data Elements

In the space below, describe any additional data elements that will be accessed and used for this research or upload your data collection form as a separate document to IRBNet.

- Demographic information
- Pathology reports
- Laboratory results
- Imaging
- Medications
- Surgical procedures

Continues on next slide

It is not acceptable to put "Entire Medical Record" in this section.

HRP-503 UCD Health Medical Record Review Protocol Template

4) Description of Data Elements (cont.)

NOTES ABOUT USE OF RECORDS AND DATA CONFIDENTIALITY

UC Davis Health Electronic Health Record (EMR/EPIC) also contains the clinical data for Marshall Medical Center (MMC). MMC patient data cannot be accessed for research purposes. Researchers must take the necessary steps to ensure that MMC data is not accessed, used, or disclosed for UC Davis Health research purposes.

If PHI will be documented in research records, researchers should remove and destroy identifiers at the earliest possible opportunity consistent with the conduct of the research. In the Data Confidentiality section of the Initial Review Application, you will indicate how data is to be maintained for this research. The Initial Review Application's options for data maintenance are listed below. Unless there is a justifiable reason why data for this research must be maintained in an identifiable format, the expectation is that data will be maintained in one of the three other formats listed (i.e., coded with a linking key, coded without a linking key, or with all identifiers destroyed).

Definitions

- **Identifiable**
  Data or specimens will be labeled with identifying information.
- **Coded with linking key**
- Data will be stripped of identifiers and assigned a code. The research team will maintain a key that links the identifiers to the data set.
- **Coded without linking key**
  Data will be stripped of identifiers and assigned a code. The research team will not have access to a key that links the identifiers to the data set and will not attempt to re-identify the data.
- **All identifiers will be destroyed**
  There will be no way to link the data to an individual.

If the data will be coded, the codes cannot be derived from any identifiers related to the individual nor to the linking list. For example, a subject's initials cannot be used as part of the code, because the initials are derived from the subjects' name, and therefore still considered identifiable under the HIPAA PHI definition. In addition, the method to derive the unique codes cannot be disclosed.

If protected health information or personal information from the medical records will be stored on an encrypted device, investigators must follow applicable university policies (UC Davis Hospital Policy 1313, UCDHS P&P 2300-2499, and UC Business and Finance Bulletin on Information Security (IS-3)). Please contact the Biomedical Informatics Department for assistance with data security.

Do not alter or delete this section of the protocol template.

Initial Review Application

Clickable Table of Contents

Initial Review Application

General Instructions

General Instructions *

Welcome to the UC Davis Initial Review Application (IRA). You should complete one IRA for this project and update the IRA as necessary if modifications are made to the project. Please review the **Initial Review Application Guide** for guidance. The IRA is a dynamic form; you may not see all questions that appear in the Guide.

The IRA does not need to be completed in one sitting. Your work automatically saves each time you advance a page. You can save and exit the IRA at any time. After exiting the application, the Initial Review Application will be listed under the heading "Documents in this Package" on the "Designer" page of your project. Click the pencil icon to re-open the IRA and resume work or make edits. Use the "Jump To" button at the top right of the screen to revisit or make changes to completed pages.

Once complete, the IRA will provide a list of documents that should be submitted for this project. Use this list to build a complete submission.

Warning: Do not click the red X to the right of the document on the "Designer" page. This will permanently delete your work. Once deleted, it cannot be recovered.

Initial Review Application

PI Attestation

PI Attestation *

The Principal Investigator (PI) named in this application assumes all responsibility for the conduct of this research and for compliance with the requirements of the IRB. Before submitting this package to the IRB, the PI must electronically sign this application using the IRBNet "Sign this Package" feature.

In signing this package, the PI attests to the following:

1. I will personally conduct or oversee this research.
2. I will adhere to the reporting requirements as stated in the UCD Human Research Program Investigator Manual (**HRP-103, Appendix A**).
3. I will ensure that all personnel assigned to this study are qualified to perform the protocol procedures assigned to them.
4. I will ensure personnel complete all required **training** related to human subjects protections and the research protocol prior to engaging in research activities.
5. I will ensure personnel disclose any financial interests, as required by UCD Human Research Program Standard Operating Procedure: Financial Conflicts of Interest (**HRP-055**).
6. If this study requires a consent process, the consent process will comply with any applicable portions of UCD Human Research Program Standard Operating Procedures: Informed Consent Process for Research (**HRP-090**).
7. If this study requires documentation of consent, documentation of consent will comply with any applicable portions of UCD Human Research Program Standard Operating Procedure: Written Documentation of Consent (**HRP-091**).
8. If relying on an external IRB, the PI will comply with the requirements outlined in the UC Davis Human Research Program Standard Operating Procedure: IRB Reliance when UC Davis relies on an External IRB (**HRP-058**) as well as all IRB and protocol requirements of the reviewing IRB.

Missing Principal Investigator signature is one of the most common submission errors.

The Co-Principal Investigator signature may not substitute for the Principal Investigator's signature on a New Project submission.

For step-by-step instructions for providing electronic signature on IRBNet, please see our website.

Initial Review Application

Administrative Approval

Administrative Approval *

All new research conducted at UC Davis requires administrative approval prior to submission to the IRB. In addition, when there is a change in PI, administrative approval must be renewed. If this research is being conducted at UC Davis, and this is the initial review of this project or a change in PI, the following electronic signatures must be completed using the IRBNet "Sign this Package" feature:

- For all Departments, except the School of Nursing, the Chair's signature is required.
- For the School of Nursing, the Dean's signature is required.
- For principal investigators who are clinical nurses not associated with the School of Nursing, the Director for the Center for Nursing Science and Chief Nursing and Patient Care Services Officer signatures are required.
- For principal investigators who are students, medical residents, or visiting scholars, a Faculty Advisor's signature is also required.

In signing this package, the signatory attests to the following:

1. The PI is qualified by education, training and experience to personally conduct and/or supervise the research described in the protocol.
2. The PI has completed all applicable institutional credentialing processes to conduct this research.
3. The PI has sufficient resources to carry out this research as proposed.
4. The protocol is scientifically valid and employs research procedures which are consistent with sound research design, in accordance with UC Davis Human Research Program Worksheet: Scientific or Scholarly Review (**HRP-320**).
5. The PI will conduct this protocol in accordance with requirements in the UC Davis Human Research Program Investigator Manual (**HRP-103**) listed in the section "What are my obligations after IRB approval?"

Read this section carefully to determine the signature(s) you need in addition to the Principal Investigator's signature.

You will need to provide any additional signatories with access to your project on IRBNet. For step-by-step directions for how to provide access, please see our website.

Initial Review Application

Principal Investigator Information

Principal Investigator Information

Please enter the following information for the PI, PI First Name PI Last Name.

PI Title (Enter the professional title, e.g. Associate Professor, Nurse Manager, PhD Student, Medical Resident, Visiting Scholar, etc.) *

Professor

PI Degrees (List completed degrees or write "None") *

PhD

PI Department *

Med - Dermatology

PI Department - Other

If you selected "Other," please specify the PI's department.

PI Phone *

(000) 000-000

PI Email *

researcher@ucdavis.edu

PI Consent *

Will the Principal Investigator be involved in the consent process?

- ○ Yes
- ◉ No

UCD Investigator *

Is the PI listed on this application a UC Davis or UC ANR Investigator (Faculty, staff, student, visiting scholar, volunteer, etc.)?

- ◉ Yes
- ○ No (Non-UC Davis Investigator - reliance agreement required)

The Principal Investigator's name will be automatically filled in based on the Project Overview. To change the PI in the Initial Review Application, update the PI information in the Project Overview.

Initial Review Application

Co-Principal Investigator

Co-Principal Investigator *

A Co-PI can sign IRB submissions after the initial approval and may assume responsibility for the research should the PI be unavailable. The Co-PI should be from the same institution as the PI. A Co-PI is not required.

Is there a Co-Principal Investigator (Co-PI)?

- (●) Yes
- ( ) No

Initial Review Application

Co-Principal Investigator Information

Co-Principal Investigator Information

Co-PI First Name *

Co-PI's First Name

Co-PI Last Name *

Co-PI's Last Name

Co-PI Degrees (List completed degrees or write "None") *

PhD

Co-PI Title (Enter the professional title, e.g. Associate Professor, Nurse Manager, PhD Student, Medical Resident, Visiting Scholar, etc.) *

Associate Professor

Co-PI Department *

Med - Dermatology

Co-PI Department - Other

If you selected "Other," please specify the Co-PI's department.

Co-PI Phone *

(000) 000-0000

Co-PI Email *

researcher2@ucdavis.edu

Co-PI Consent *

Will the co-Principal Investigator be involved in the consent process?

- ○ Yes
- ◉ No

Initial Review Application

Primary Contact

Primary Contact *

Is the Principal Investigator the primary contact for this study?

- ○ Yes
- ◉ No

Initial Review Application

Primary Contact Information

Primary Contact Information

Please enter the following information for the primary contact.

Primary Contact First Name *

Primary Contact's First Name

Primary Contact Last Name *

Primary Contact's Last Name

Primary Contact Phone *

(000) 000-0000

Primary Contact Email *

researcher3@ucdavis.edu

Primary Contact Degrees (List completed degrees or write "None") *

BS

Title (Enter the professional title, e.g. Associate Professor, Nurse Manager, PhD Student, Medical Resident, Visiting Scholar, etc.) *

Medical Student

Primary Contact Consent *

Will the primary contact be involved in the consent process?

- ○ Yes
- ◉ No

Initial Review Application

Review Information

Review Information

An IRB reliance agreement allows an IRB to review research being conducted at another institution. See **Single IRB and Reliances** for more information.

The following situations may require an IRB reliance agreement:

- Multi-site research that is federally funded or supported.
- Individual research personnel who are not affiliated with an Institution. For example, a private clinician acting as research personnel.

Note: Research determined to be **exempt** does not qualify for a reliance agreement.

UC Davis IRB Relying *

Is UC Davis IRB **ceding review** of this research to another IRB under a reliance agreement?

- ○ Yes
- ◉ No

UC Davis IRB Reviewing *

Is UC Davis IRB **reviewing** this research for external site(s) or personnel under a reliance agreement? If you are a non-UC Davis researcher applying for UC Davis IRB review under a reliance agreement, select "Yes."

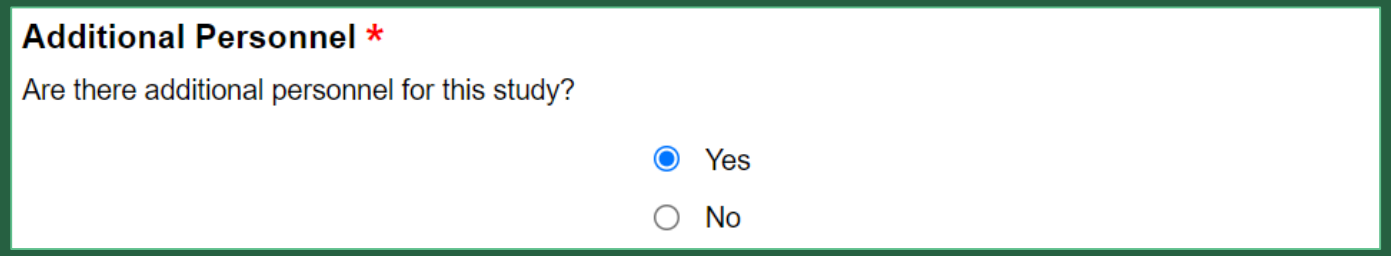
- ○ Yes
- ◉ No

Our example study is not a multi-site project. As such, it does not qualify for a reliance agreement.

Even if it were a multi-site project, our example study would not qualify for a reliance agreement because it is an exempt study. For more information about what it means for a study to be exempt, please see our website.

Initial Review Application

Additional Personnel



If you have a Faculty Advisor, make sure to add them as additional personnel if they are not acting as your Co-Principal Investigator.

Initial Review Application

Additional Personnel Information

Additional Personnel Information

Please provide the following for each additional personnel for this study.

Person 1

First Name *

Person 1's First Name

Last Name *

Person 1's Last Name

Degrees (List completed degrees or write "None") *

None

Title (Enter the professional title, e.g. Associate Professor, Nurse Manager, PhD Student, Medical Resident, Visiting Scholar, etc.) *

Undergraduate Student

Consent *

Will this person participate in the consent process?

- ○ Yes
- ◉ No

Sub-Investigator *

Is this individual a sub-investigator?

- ○ Yes
- ◉ No

Initial Review Application

Outside Financial Interest

Outside Financial Interest *

Information:
SFI: Significant financial interest (per UC Davis PPM 230-05 II.I) - anything of significant monetary value, including but not limited to salary or other payments for services; equity interests (e.g. stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights and royalties from such rights); or holding a position as an office, director, agent, or employee of a business entity. "Significant financial interest" includes such interests held by a Principal Investigator or other Investigators and by their spouses, domestic partners and/or dependent children.

Related: (per UC Davis PPM 230-05, Exhibit A III.B) When completing the Supplemental Form for a project sponsored by the federal government or other agency for which Form 800 is required, Principal Investigator and other Investigators shall consider all significant financial interests to determine if any are related to the (sponsored) project.

Examples include but are not limited to the following:

1. Financial interest in a business entity that develops, manufactures, or improves a product or offers services related to the research project.
2. Financial interest in a business entity that might manufacture or market a drug, device, procedure, or any other product used in the project that will predictably result from the research project.
3. Consulting income from a business entity where the consulting activity could reasonably appear to be related to the research project.
4. Financial interest in a business entity where the consulting activity could reasonably appear to be related to the research project.
5. Financial interest in a business entity that is related to the intellectual property in which the investigator is named as an inventor if the research project could reasonably appear to be affected by the interest.

Question:
Do any personnel responsible for the design, conduct or reporting of the protocol have any 'Significant Financial Interests' (as defined in PPM 230-05.II.G) RELATED to the work to be conducted under the proposed project that was received within the last twelve months or that you expect to receive in the next twelve months? Include financial interests of the spouse, registered domestic partner, or dependent children of such personnel. More information about conflicts of interest in human research can be found **here**.

- ○ Yes
- ◉ No

Initial Review Application

Protocol Information

Protocol Information

Author *

Who authored (wrote) the protocol?

UC Davis Researcher

Study Procedures *

Select all procedures that will be conducted for research purposes as directed by the study protocol. **Do not select procedures done for standard of care treatment or for reasons other than research.**

- [x] Analysis of information or specimens collected for reasons other than this project (medical records, student records, research records collected for another study, analysis of left-over specimens, etc.)
- [ ] Non-invasive procedures to collect information or specimens (interviews, questionnaires, observation, vitals, oral swabs, urine collection, etc.)
- [ ] Collection of blood by finger stick, heel stick, ear stick, or venipuncture
- [ ] Use of xrays or microwaves
- [ ] With the exception of collection of blood by finger stick, heel stick, ear stick, or venipuncture, collection of information or specimens when the collection requires penetration of tissue (tissue biopsy, implantation of a device, etc.)
- [ ] Use of medical drugs or devices in a manner already approved by the FDA
- [ ] Use of medical drugs or devices in a manner not approved by the FDA

This should be the only answer selected for a chart review study.

Initial Review Application

Funding Information

Funding Information *

Here is a list of sponsors from the Project Overview page: Department.

If there is no sponsor for this research, enter the word "Departmental" in the sponsor field on the Project Overview page.

Indicate the type of funding. Select all that apply.

- [ ] Industry Sponsored
- [ ] Federal Grant
- [ ] Other Grant
- [x] Department Funded or No Funding
- [ ] Other

Initial Review Application

UC Davis Health Billing Compliance

UC Davis Health Billing Compliance *

Information:
UCD Health P&P 2317
If all or part of this research is conducted at UC Davis Health and meets one or more of the following criteria, it must comply with UC Davis Health P&P 2317:

a. All studies that utilize a drug or device;
b. All studies which require items or services that result in any charge or billing component (including billing to a third-party insurance, study sponsor, or patient) in the Epic billing system; or
c. All studies that include, as part of their protocol, any clinical intervention, including the invasion of any research participant (control or subject) body cavity (e.g. blood draw) when such an intervention takes place within a UC Davis Medical Center (UCDMC) licensed facility.

Question:
Is this study required to comply with UC Davis Health Policy & Procedure 2317: Documentation of Research Patient Status in the Electronic Medical Record (EMR)?

- ○ Yes
- ◉ No

Initial Review Application

Research Location Information

Research Location Information

Research Setting *

Describe the locations where recruitment, consent and research procedures will take place.

Formats | Font Family | Font Sizes

UC Davis Health computers will be used to:

- Access EMR
- Record and maintain data
- Analyze data

Resources Available *

Describe any special credentials, licensing, or training needed to perform research procedures. For example: Only trained phlebotomists will conduct blood draws; Physiological assessments will be conducted by certified clinicians; etc. If no specific training is required, write "N/A."

Paragraph | Arial | 10pt

The Principal Investigator and research personnel have adequate training to conduct this research, including required CITI training.

Initial Review Application

External Sites

External Sites *

External sites are locations outside the PI's home institution where research activities are carried out and there is no local PI. For example, an independent clinic, community center, school or international site is the location where research activities are conducted and there is no local principal investigator overseeing the activities. Will this PI conduct or oversee research activities at sites outside their home institution?

- ○ Yes
- ◉ No

Initial Review Application

Multi-Site

Multi-Site *

Multi-site research involves multiple principal investigators collaborating to conduct the project. When the same protocol, or portions of the protocol, are conducted at more than one location and there is a local PI at more than one site, the research is considered a multi-site study. Are other US institutions conducting some or all of this research project under a different PI?

- ○ Yes
- ◉ No

Since our example study does not involve any other Principal Investigators besides our local Principal Investigator, it is not a multi-site study.

Initial Review Application

UC Davis Clinical and Translational Science Center

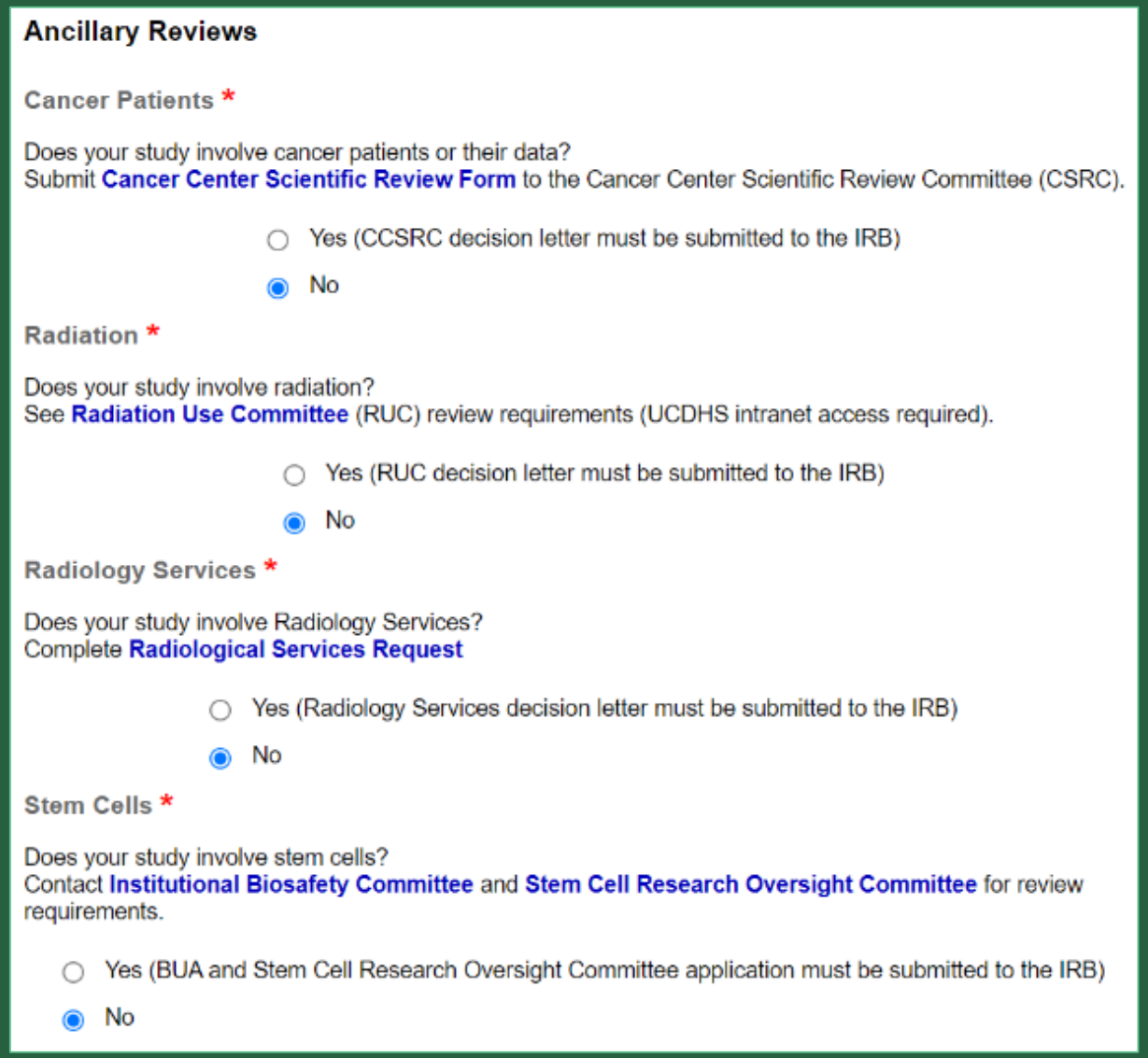
UC Davis Clinical and Translational Science Center *

Is this research supported by the **UC Davis Clinical and Translational Science Center (CTSC)**? This includes biostatistical support, REDCap databases, coordinators for hire (CCRC), regulatory support, study start-up and management, and the Clinical Research Center.

- ○ Yes
- ◉ No

Initial Review Application

Ancillary Reviews



Ancillary Reviews

Cancer Patients *

Does your study involve cancer patients or their data?
Submit **Cancer Center Scientific Review Form** to the Cancer Center Scientific Review Committee (CSRC).

- ○ Yes (CCSRC decision letter must be submitted to the IRB)
- ◉ No

Radiation *

Does your study involve radiation?
See **Radiation Use Committee** (RUC) review requirements (UCDHS intranet access required).

- ○ Yes (RUC decision letter must be submitted to the IRB)
- ◉ No

Radiology Services *

Does your study involve Radiology Services?
Complete **Radiological Services Request**

- ○ Yes (Radiology Services decision letter must be submitted to the IRB)
- ◉ No

Stem Cells *

Does your study involve stem cells?
Contact **Institutional Biosafety Committee** and **Stem Cell Research Oversight Committee** for review requirements.

- ○ Yes (BUA and Stem Cell Research Oversight Committee application must be submitted to the IRB)
- ◉ No

Continues on next slide

If your study involves cancer patient data, select "Yes" to this question.

For information about submitting to the CSRC, please see the Ancillary Reviews page of the IRB website.

Initial Review Application

Ancillary Reviews (cont.)

Inpatient Participants *

Does this study involve (1) patients who are admitted to UC Davis Medical Center for standard care or (2) UC Davis Medical Center admission for research-related activities?

- ○ Yes
- ◉ No

Hazardous Material *

Does your study involve infectious agents or biohazardous material subject to review by the Institutional Biosafety Committee?
Contact **Institutional Biosafety Committee** for review requirements.

- ○ Yes
- ◉ No

Recombinant DNA or Human Gene Transfer *

Does your study involve Recombinant DNA Molecules or Human Gene Transfer?
Contact **Institutional Biosafety Committee** for review requirements.

- ○ Yes (BUA must be submitted to the IRB)
- ◉ No

Identifiable Health Information *

Does your study involve access, collection, or use of protected health information?
Review **HIPAA guidance**

- ◉ Yes
- ○ No

Continues on next slide

The answer to this question is “Yes” for all chart review studies.

Initial Review Application

Ancillary Reviews (cont.)

Educational Records *

Does your study involve access of educational records or student health records for research?
Review **FERPA guidance**

- ○ Yes
- ◉ No

Community Engaged Research *

Does your study involve community consultation or community member involvement in study design, implementation, or sharing of results?
Contact **CTSC Community Engagement** Program for assistance.

- ○ Yes
- ◉ No

IT Evaluation *

Does your study involve electronic applications, systems, or devices that collect and/or transmit Protected Health Information (PHI) or Personally Identifiable Information (PII)?

IT Review Requirements
UC Davis Health - **IT Evaluation Process** (UCDHS intranet access required)
UC Davis Campus

- ○ Yes
- ◉ No

Continues on next slide

Initial Review Application

Ancillary Reviews (cont.)

Material Data Transfer *

Does your study involve transfer or receipt of tangible research material or raw datasets to or from another researcher, institution, or company?
Contact UC Davis **Innovation Access** for transfer requirements.

- ○ Yes
- ◉ No

Pathology *

Does your study involve the Clinical Lab or Pathology to process, retrieve, or analyze specimens?
Contact **Pathology Clinical Research Oversight Committee** for review requirements.

- ○ Yes (Pathology Clinical Research Oversight Committee decision letter must be submitted to the IRB)
- ◉ No

Prospective Interventions *

Review the definition of a **clinical trial** for assistance with the next two questions.

Does this study prospectively assign human subjects to one or more interventions (e.g. drug, device, imaging, behavioral management, etc.)?

- ○ Yes
- ◉ No

Continues on next slide

Initial Review Application

Ancillary Reviews (cont.)

Effects on Health-Related Outcomes *

Does this study evaluate the effects of an intervention on health-related outcomes?

If subjects will be assigned to an intervention, will you be evaluating the effect of the intervention(s) on a health-related biomedical or behavioral outcome? If N/A, mark "No."

- ○ Yes
- ◉ No

NCT Number

If applicable, what is the NCT number (ClinicalTrials.gov number) for this study?

N/A

Initial Review Application

Recruitment Information

Recruitment Information

Recruitment Methods *

Please check any of the following methods that will be used to **identify and recruit** participants for this study:

- [ ] Advertising (fliers, social media, clinical trials websites, etc.)
- [x] Medical record review
- [ ] From a database of participants who have given prior permission to be contacted for research studies
- [ ] From personal contact (i.e. patients, former research participants, friends, etc.)
- [ ] Referrals
- [ ] Other

Recruitment Methods - Other

If you selected "Other," please specify.

N/A

Study Pages Contact

If your study is a clinical trial at UC Davis it will automatically be posted to UC Davis Study Pages to advertise for recruitment. Provide the email address of the study team's primary contact for subject recruitment.

N/A

Initial Review Application

HIPAA

HIPAA *

If you are using **protected health information** for this study, how will you comply with the HIPAA requirements? (Check all that apply)

- [ ] Signed HIPAA Research Authorization - Participants or their legally authorized representative will sign an authorization for participation in this research.
- [ ] Partial Waiver of HIPAA Authorization - Waiver for participant identification and recruitment. Signed HIPAA Authorization will be required for access, use, or disclosure of PHI for participation in research activities.
- [x] Full Waiver of HIPAA Authorization - Research will be conducted without signed HIPAA Authorization.
- [ ] Not applicable - I am not accessing, using or disclosing information subject to HIPAA or I am an external PI and my institution will issue HIPAA determinations for my site.

All chart review studies should request a Full Waiver of HIPAA Authorization.

Initial Review Application

Waiver of HIPAA Authorization

Waiver of HIPAA Authorization

You will need a Waiver of Research Authorization to use or share private health information for research or recruitment. Please answer the following questions so the IRB can make the determinations needed to issue this waiver.

HIPAA Compliance *

Does the use or disclosure of PHI involve no more than a minimal risk to the privacy of the individual based on at least the presence of the following? Please confirm below.

*For more information on P&P 2446 click **here**.*

1. I confirm that the minimum necessary information will be accessed under this waiver. If this is a partial waiver for recruitment, only information required for recruitment purposes will be accessed. If this is a full waiver for the study, only information required to complete the research will be accessed.
2. I confirm that only authorized persons will be granted access to the identifiers; identifiers stored on computers, electronic notebooks, mobile devices, and/or data-storage devices will be encrypted and password protected; identifiers maintained in paper format will be kept in a locked area accessible by only research staff who require access.
3. I confirm that all identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers or as otherwise required by law.
4. I confirm that protected health information from this research will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of PHI would be permitted.
5. For UC Davis Investigators accessing data through the UC Davis EMR, I confirm that I will use Quick Disclosure Activity in EMR or the Disclosure Tracking Database to track all medical records accessed as defined by P&P 2446.

- (●) Yes
- ( ) No

Continues on next slide

Initial Review Application

Waiver of HIPAA Authorization (cont.)

HIPAA Waiver Rationale *

What is your rationale for disclosing, accessing or using this information without prior authorization from the patient? (Check all that are true)

- [x] The research team will not have direct contact with the individuals prior to the disclosure, access, or use.
- [ ] Obtaining authorization could pose a risk to subjects' privacy, physical safety, or psychological well-being.
- [ ] Failure to obtain a complete or representative data set would prevent this study from drawing reliable conclusions.
- [ ] Other

HIPAA Waiver Rationale - Other

If you selected "Other", please explain why you will not obtain prior authorization.

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N/A

Initial Review Application

Screening Scripts

Screening Scripts *

Are you using any written or verbal screening scripts to screen participants prior to obtaining consent (such as telephone call scripts, web-based questionnaires, etc.)?

- ○ Yes
- ◉ No

Initial Review Application

Consent

Consent *

Which of the following are involved?

More information about requirements for the informed **consent process** and **consent documentation** is available on our website.

(Check all that apply)

- [ ] Signed Informed Consent: Research subjects will be informed about the research and will sign a consent document prior to enrolling in the research.
- [ ] Information Sheet or Oral Consent: Research subjects will be informed about the research and will agree to participate but will not sign a consent document. Appropriate for some exempt research or with an IRB issued Waiver of Documentation of Consent.
- [x] No consent process: Research subjects will not be informed about research and will not have an opportunity to agree to participate. Appropriate for some exempt research or under an IRB issued Waiver of Consent.

Initial Review Application

No Consent Process

No Consent Process

You indicated that you will not obtain informed consent from participants. To help the IRB determine if this is appropriate, please answer the following:

Rationale for No Consent Process *

What is your rationale for conducting this project without consent from participants? Select all that are true:

- [x] The research team will have no direct contact with potential research subjects.
- [ ] Obtaining consent could pose a risk to subjects' privacy, physical safety, or psychological wellbeing.
- [ ] Failure to obtain a complete or representative data set would prevent this study from drawing reliable conclusions.
- [ ] Other

Rationale for No Consent Process - Other

If you selected "Other", please explain why you will not obtain consent.

N/A

Initial Review Application

Consent Language

Consent Language *

Information:

When preparing your study for initial review, consider whether you may enroll individuals who cannot read the English consent document because their native language is not English. Generally, any research that holds the prospect of direct benefit should allow the enrollment of those unable to read English. There are two processes available to enroll subjects who are unable to read English because it is not their native language:

- Translated Documents
- Short Form Consent Process

If it is apparent that some or all the participants in the research will not be able to read the English consent document, then the consent document should be translated into the participants' native language. If you do not anticipate enrolling subjects who are unable to read the English version of the consent document, the short form consent process can be used. See **Consent Process: Overcoming Language Barriers** for more information.

Question:
Is it possible you will enroll participants who are unable to speak or read English?

- (●) Yes, open to non-English speakers
- ( ) No, non-English speakers will be excluded

Initial Review Application

Language Barriers

Language Barriers

Overcoming Language Barriers *

How will you (1) conduct the consent discussion in a language understandable to the participant; and (2) conduct ongoing communication with the participant throughout the research and in case of emergency?

- [ ] At least one member of the research team is fluent in the language that will be used for communication and will be available during emergencies;
- [ ] The research team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study;
- [x] Other

Overcoming Language Barriers - Other

If you selected "Other", please specify.

We are requesting a waiver of informed consent for this research.

Translation of Consent Form *

Will you have the consent form (and other approved documents) translated into a language the participant(s) can understand?

- ( ) Yes
- (•) No

Initial Review Application

Compensation for Participants

Compensation for Participation

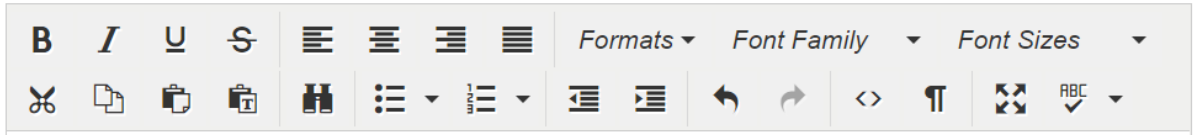
Compensation *

Will gifts, payments, compensation, reimbursement or extra credit be provided to the research participants?

- [ ] Participants will be compensated for their time.
- [ ] Participants will be reimbursed for their expenses.
- [x] Participants will not be compensated or reimbursed.

Total Compensation

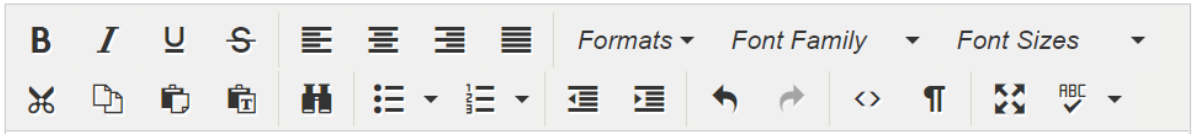
Indicate the maximum amount (excluding reimbursement for travel) research participants may receive? If different groups receive different amounts, please explain:



N/A

Pro-ration of Compensation

If compensation will be prorated, provide the amount of compensation per visit/procedure:



N/A

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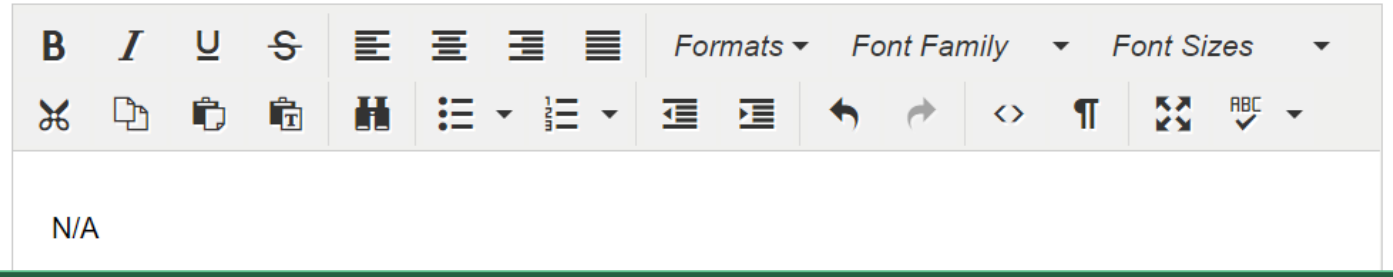
Initial Review Application

Compensation for Participants (cont.)

Form of Payment

When and how (form of payment) will participants be compensated?



Initial Review Application

Drugs and Biologics

Drugs and Biologics *

Information:

The risks of all drugs specified by the protocol must be described in the consent document. This includes investigational drugs and other drugs required for participation in this research. You must submit a package insert for all drugs required by the protocol with this application.

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.

Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

From FDA **glossary of terms**.

Question:
Are investigational drugs, biologics or dietary supplements being studied in this project?
Mark "Yes" only if the research involves a drug that is not FDA-approved or is being used outside of its approved labeling; this is an investigational drug.

- ○ Yes
- ◉ No

The answer to this question should be “No” for all chart review studies since no investigational drugs, biologics, or dietary supplements are being given as part of the study.

Initial Review Application

Medical Device(s)

Medical Device(s) *

Information:

The risks of all medical devices specified by the protocol must be described in the consent document. This includes risks of approved devices and investigational devices.

A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

From FDA **How to Determine if Your Product is a Medical Device**

Question:

Are any medical devices being studied in this project? Mark "Yes" only if this research involves a device that is not FDA-approved, is not approved for use as described in this research, or is operating under an IDE; this is an investigational device.

- ○ Yes
- ◉ No

The answer to this question should be “No” for all chart review studies since no medical devices are being used as part of the study.

Initial Review Application

International Study

International Study *

Will you conduct or oversee research outside of the US? Please note, collection of research data using online data collection tools targeting participants outside the US is international research.

- ○ Yes
- ◉ No

Initial Review Application

Monitoring for Safety and Compliance

Monitoring for Safety and Compliance

Research that is greater than minimal risk must be monitored for safety and compliance.

Method for Monitoring Safety *

How will this research be monitored for safety?

- [ ] Medical Monitor
- [ ] Data Safety Monitoring Board or Committee
- [x] Not Applicable/Minimal Risk
- [ ] Other

Monitoring Plan

Provide the page number(s) of the monitoring plan in the research protocol or describe your monitoring plan.

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N/A

Initial Review Application

Vulnerable Participants

Vulnerable Participants *

Will this study be open to enrollment of any of the following categories of participants? These participants may not be enrolled without specific IRB approval.

For all studies, if the research is limited to **only secondary analysis**, no special considerations are required, select "None of the above or N/A" for this question. Secondary analysis is the analysis of data/specimens collected for other purposes (e.g. medical records, student records, other research studies, etc.).

- [ ] Children
- [ ] Neonates (infants less than four weeks old)
- [ ] Prisoners
- [ ] Cognitively Impaired Adults
- [x] None of the above or N/A

Initial Review Application

Targeted Participants

Targeted Participants *

Will your study specifically target enrollment or collect information about the following characteristics? These groups may participate in research without special IRB approval, but there are additional considerations when these groups are targeted, or this information is recorded for research.

For all studies, if the research is limited to **only secondary analysis**, no special considerations are required, select "None of the above or N/A" for this question. Secondary analysis is the analysis of data/specimens collected for other purposes (e.g. medical records, student records, other research studies, etc.).

- [ ] Pregnant participants/Fetuses
- [ ] Students or Direct Reports of the PI
- [ ] Undocumented Individuals
- [ ] Members of underserved communities
- [ ] Members of populations underrepresented in scientific research
- [ ] Members of populations experiencing disparities in health and/or access to health care
- [x] None of the above or N/A

Initial Review Application

Data Confidentiality

Data Confidentiality

Identifiable Data *

Once data has been collected or received by this PI, how will it be maintained?
The data will be:

- [ ] Identifiable - Data or specimens will be labeled with identifying information.
- [x] Coded with linking key - Data will be stripped of identifiers and assigned a code. The research team will maintain a key that links the identifiers to the data set.
- [ ] Coded without linking key- Data will be stripped of identifiers and assigned a code. The research team will not have access to a key that links the identifiers to the data set and will not attempt to re-identify the data.
- [ ] All identifiers will be destroyed. There will be no way to link the data to an individual.

Data Protection *

Only authorized persons should be granted access to participants' identifiable information. Indicate how you will protect research subjects' identities and information. For research involving the access, use or disclosure of Protected Health Information, please contact the **Biomedical Informatics Department** for assistance with data security. Select all that are true:

- [ ] Identifiable data maintained in paper format and/or specimens labeled with identifiers will be kept in a locked area with limited access.
- [x] Identifiable electronic data will be maintained on a password protected, encrypted device.
- [ ] Identifiable electronic data will be maintained on a password protected, secured cloud service appropriate for the sensitivity of data collected.
- [ ] NA - No identifiable data or specimens will be created or stored for this this research.

Name of Cloud Service

If you are using a cloud service, provide the name of the cloud service.

N/A

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The expectation for chart review studies is that data will be coded or that no identifiers will be collected at all. If no identifiers are to be collected, please select the last checkbox.

Consistency Check | Protocol, 3) HIPAA Protected Health Information (PHI) Obtained from UC Davis Health

Jump to Section 3)

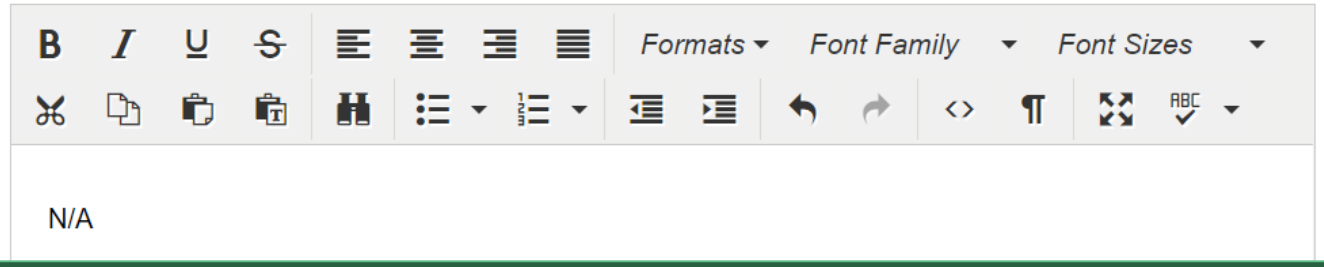
Acceptable cloud services include: UC Davis OneDrive, SharePoint, Teams, Azure, AWS, and REDCap

Initial Review Application

Data Confidentiality (cont.)

Data Transfer Protections

If you will be transferring data between locations, describe your plan to protect the data (for example, using lock boxes or locked cars when conducting field work or transferring data between sites):



Sensitive Data *

If the confidentiality of the research data were compromised, could it reasonably place subjects at risk of criminal or civil liability or otherwise be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

- ○ Yes
- ◉ No

Initial Review Application

Form Complete

Form Complete

Thank you for completing this application form.

The following is a list of required documents based on the answers provided in this application. Documents should be uploaded in the IRBNet Designer. Each document should be a separate file. Note that the file name of each document will be listed on your IRB determination letter. If you require a list of documents reviewed by the IRB, use unique file names.

If UC Davis is acting as the IRB of record for more than one research site, there are special submission instructions. Contact the UC Davis IRB Reliance Team at **hs-irbreliance@ucdavis.edu** for assistance.

When all files are complete, obtain the necessary signatures and submit to the IRB for review.

Additional documentation:

- Research protocol: HRP-503 or sponsor protocol
- Data collection tools: Questionnaires/Surveys/Interview Questions (if applicable)
- **Fee Form** (if applicable)

Resources

- **IRB Forms and Templates**
- **Ancillary Reviews**

The "Additional documentation" subsection tells you exactly what forms you need to upload to IRBNet.

This list of documents will be unique to your study based on your answers in the Initial Review Application.

Examples of these items are included in this slide deck

1. HRP-503 UCD Health Medical Record Review Template
2. Initial Review Application

Additional requirements for a complete submission

3. Principal Investigator Signature on IRBNet
4. Other Required Signatures on IRBNet
   - Department Chair
   - Faculty Advisor if PI is a student, resident, or visiting scholar
5. Required CITI Training for PI (and Faculty Advisor)
   - Do NOT upload training completion certificates to IRBNet
   - It is the PI's responsibility to confirm that all other study staff have completed required CITI training prior conducting study procedures

Questions?

Contact
hs-irbeducation@ucdavis.edu