

Example Submission

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

All subjects are adults.

Examples of these items are included in this slide deck

1 HRP-503 Surveys/Interviews and/or Focus Groups Review Protocol Template

2 HRP-502 Template – Exempt Research (2018 Common Rule Compliant)

3 Initial Review Application

4 Recruitment Email

5 Screening Script

6 Data Collection Tool: Participant Survey

7 Principal Investigator Signature on IRBNet

8 Other Required Signatures on IRBNet

Additional documents or requirements for a complete submission



Clickable Table of Contents

1) [Protocol Title](#)

2) [Objectives](#)

3) [Background](#)

4) [Enrollment Numbers](#)

5) [Inclusion and Exclusion Criteria](#)

6) [Procedures Involved](#)

7) [Study Timelines](#)

8) [Recordings](#)

9) [Data Management and Confidentiality](#)

10) [Risks to Subjects](#)

11) [Potential Benefits to Subjects](#)

12) [Sharing Results with Subjects](#)

13) [Data Banking](#)

14) [Review Requirement](#)

1) Protocol Title and 2) Objectives

1) Protocol Title

- a) Title: **Determination of Motivating Factors in the Decision to Enroll in Clown School**
- b) Protocol Version Date: **31 October 2021**

2) Objectives

- a) Describe the purpose, specific aims, or objectives:
The purpose of this study is to determine the environmental, cultural, and socioeconomic factors influencing young adults to enroll in clown school.
- b) State the hypotheses to be tested:
We hypothesize that in contrast to prior research on this topic that demonstrated socioeconomic factors are the primary motivator for clown school enrollment, the motivating factors for enrollment in clown school are now dominated by environmental and cultural factors.



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



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

3) Background

3) Background

a) Describe the relevant prior experience and gaps in current knowledge:

Since 2013, nearly 50% of accredited clown schools in the United States have closed due to a significant decrease in enrollment (Bozo, 2014). At the time, this reduction in enrollment was attributed to the marked decline in the number of clown-centric birthday parties, which often serve as a gateway into clowning for young adults who lack parental support (McDonald, 2015). Additionally, the cost of balloons during this time doubled (Penny-Wise, 2013). However, there has been a paucity of literature surrounding the motivating factors in clown school enrollment since the economic recovery from the Great Recession.

b) Describe any relevant preliminary data:

In the most recent study of the motivating factors for young adults' enrollment in clown school, the following factors were determined to be the most influential in the decision-making process: access to Federal Pell Grants for tuition and living expenses, work-study opportunities, and parental financial support (Barnum, 2014).

c) Describe how this research will add to existing knowledge or how the outcomes of this project will be used:

The American Clowning Association anticipates a shortage of 220,000 clowns by 2030. The outcomes of this project will be used to better understand this generation of clown school applicants.



Keep your background short and specific. Explain why you want to conduct this research.

4) Enrollment Numbers

4) Enrollment Numbers

- a) Total number of subjects to be enrolled in this study: 1,400
- b) If this is a reliance, list the number of subjects to be enrolled at each site, by site. (UC Davis: #, Relying Site 1: #, Relying Site 2: #) N/A
- c) Provide a rationale (e.g. statistical justification, power analysis) for the number of subjects to be enrolled.

There are approximately 135,000 students currently enrolled or have attended clown school since 2016. In prior qualitative research on this topic, informational redundancy was reached when one percent of recent and current students were surveyed. Given the population size of 135,000 for this study, we are aiming to receive 1,350 complete surveys. In order to account for respondents who may not finish the survey, we have set our enrollment maximum at 1,400.

5) Inclusion and Exclusion Criteria

5) Inclusion and Exclusion Criteria

a) Inclusion Criteria:

- Currently enrolled in an accredited clown school in the United States, or
- Attended an accredited clown school in the United States since 2016
- Major in Clowning Sciences

b) Exclusion Criteria:

- Not currently enrolled in an accredited clown school in the United States, or
- Did not attend an accredited clown school in the United States since 2016
- Major in Circus Finance
- Major in Pyrotechnics with an Emphasis in Fire Breathing

c) Age Range:

- Ages 18 to 25

d) If applicable, describe the screening procedures that you will use to collect data:

Subjects will confirm that they meet the inclusion criteria and do not meet the exclusion criteria prior to the start of the survey.



Consistency Check | Initial Review Application, Screening Scripts section: Select "Yes"

Jump to [Screening Scripts](#)

6) Procedures Involved

6) Procedures Involved

- Surveys – Upload all surveys you will use in this study to IRBNet.
- Interviews – Upload an interview script with the questions that will be asked during the interview to IRBNet.
- Focus groups – Upload a summary of the questions and issues that will be discussed during the focus sessions to IRBNet.
- Observation
 - a) Describe the behavior you will be observing and the setting of the observation:
 - b) Describe what you will be collecting or documenting for the research:
- Other
 - a) Describe any other data collection or research procedures you will be conducting:



Consistency Check | Initial Review Application, Protocol Information section: Select “Non-invasive procedures to collect information or specimens (interviews, questionnaires, observation, vitals, oral swabs, urine collection, etc.)”

Jump to [Protocol Information](#)

7) Study Timelines

7) Study Timelines

a) Duration of an individual subject's participation in the study:

An individual subject's participation is limited to the time required for the subject to read the consent script and complete the survey, approximately twenty minutes.

b) Estimated timeline to enroll all study subjects:

We anticipate all subjects will be enrolled from November 2021 to May 2022.

8) Recordings

8) Recordings

This research involves:

- Audio recordings
- Photographs
- Video recordings with audio
- Video recordings without audio
- None of the above

9) Data Management and Confidentiality

9) Data Management and Confidentiality

Before completing this section, see [Privacy and Confidentiality](#) and [HIPAA Guidance](#).

- a) List any identifiers that will be collected during the course of this study (e.g., name, medical record number, date of birth, video recordings, etc.):

No identifiers will be collected during the course of this study.

- b) If any identifiers will be stored, how long will they be kept?

N/A

- c) For data that is coded with a linking key, at what point will the linking key be destroyed?

N/A

- d) For any recordings, at what point will the recordings be destroyed?

N/A



Consistency Check | Initial Review Application, Data Confidentiality section: Select “All identifiers will be destroyed. There will be no way to link the data to an individual” and “NA – No identifiable data or specimens will be created or stored for this research.”

Jump to [Data Confidentiality](#)

9) Data Management and Confidentiality (cont.)

NOTES ABOUT USE OF RECORDS

UC Davis Medical Records: 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 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.

If identifiable protected health information is extracted from the UCDH EMR, it may not be re-disclosed/released outside the study team.

UC Davis Student Education Records: If this study involves use of UC Davis students' educational records (including records in the PI's own possession such as course exams/assignments), you must consult with the Registrar's office to see if all requirements of the Family Educational Rights and Privacy Act (FERPA) are satisfied.

Continues on next slide



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

10) Risk to Subjects

10) Risks to Subjects

This research may pose the risk of loss of confidentiality. The risk will be minimized through the processes described above. This study will abide by all applicable law, regulations, and standard operating governing the protection of human subjects, student information and protected health information.

Other – Describe:

11) Potential Benefits to Subjects

11) Potential Benefits to Subjects

Research subjects are not likely to receive any benefit from the proposed research, but others may benefit from the knowledge obtained.

Other – Describe:

12) Sharing Results with Subjects

12) Sharing Results with Subjects

Results will not be shared with subjects.

Results will be shared with subjects.

- a) If results will be shared, describe the results (study results or individual subject results) to be shared with subjects or others (e.g., the subject's primary care physicians):

13) Data Banking

13) Data Banking

a) Will the data ever be used by you or other researchers to answer a different research aim that is not included in this study?

Yes – Complete the remainder of Section 13.

No – Do not complete Section 13. Go to Section 14.

b) What will be banked for future use?

De-identified data/specimens. Banked data/specimens cannot be linked to an individual.

Identifiable data/specimens – Banked data/specimens will include identifying information.

Coded data/specimens – Banked data/specimens will be stripped of identifiers and assigned a code. A key will be maintained that links the identifiers to the data/specimens.

Contact information will be banked for future research opportunities.

c) Where will the data be banked?

d) How long will the data be banked?

e) Who will have access to the banked data?

f) Describe the procedures to release data. Include the process to request a release, approvals required for release, who can obtain data, and the data to be provided:

Note: Identifiable protected health information extracted from the UCDH EMR under an IRB-issued waiver of HIPAA Authorization may not be re-disclosed/released outside the study team.



Notice that we did not complete the rest of this section per the directions.

14) Review Requirement

14) Review Requirement

Some research projects require specific IRB determinations.

- a) Are there any contractual obligations or other considerations that require IRB review of this research, or review at intervals other than those required by the Common Rule or FDA?
 - Yes
 - No
- b) If yes, please describe:



If your research involves a contract or agreement with another entity, check to make sure that there are not any special requirements for IRB review.

Exempt Research (2018 Common Rule Compliant)

University of California at Davis Letter of Information

Title of study: Determination of Motivating Factors in the Decision to Enroll in Clown School

Investigator: Albert Bandura, PhD

Introduction and Purpose

You are being invited to join a research study. If you agree to participate in this research, you will be asked to complete a survey about factors influencing your motivation to enroll in clown school. Your participation in this research should take about twenty minutes.

Participation in research is completely voluntary. You are free to decline to take part in the project. You can decline to answer any questions and you can stop taking part in the project at any time. Whether or not you choose to participate, or answer any question, or stop participating in the project, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

Questions

If you have any questions about this research, please feel free to contact the investigator at (000) 000-000 or researcher@ucdavis.edu.



For a link to the HRP-502 consent script template we used for our example study, please click [HERE](#).



Clickable Table of Contents

[General Instructions](#)

[PI Attestation](#)

[Administrative Approval](#)

[Principal Investigator Information](#)

[Co-Principal Investigator](#)

[Co-Principal Investigator Information](#)

[Primary Contact](#)

[Primary Contact Information](#)

[Review Information](#)

[Additional Personnel](#)

[Additional Personnel Information](#)

[Outside Financial Interest](#)

[Protocol Information](#)

[Funding Information](#)

[UC Davis Health Billing Compliance](#)

[Research Location Information](#)

[External Sites](#)

[External Site\(s\) Information](#)

[Multi-Site](#)

[UC Davis CTSC](#)

[Ancillary Reviews](#)

[Recruitment Information](#)

[HIPAA](#)

[Screening Scripts](#)

[Consent](#)

[Information Sheet or Oral Consent Request](#)

[Consent Language](#)

[Non-English Information](#)

[Compensation for Participants](#)

[Drugs and Biologics](#)

[Medical Device\(s\)](#)

[International Study](#)

[Monitoring for Safety and Compliance](#)

[Vulnerable Participants](#)

[Targeted Participants](#)

[Data Confidentiality](#)

[Form Complete](#)

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.

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](#).

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](#).

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 *

Sociology

PI Department - Other

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

PI Phone *

(000) 000-0000

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.

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

Co-Principal Investigator Information

Co-Principal Investigator Information

Co-PI First Name *

Co-PI Last Name *

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

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

Co-PI Department *

Co-PI Department - Other

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

Co-PI Phone *

Co-PI Email *

Co-PI Consent *

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

Yes

No

Primary Contact

Primary Contact *

Is the Principal Investigator the primary contact for this study?

Yes

No

Primary Contact Information

Primary Contact Information

Please enter the following information for the primary contact.

Primary Contact First Name *

Primary Contact Last Name *

Primary Contact Phone *

Primary Contact Email *

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

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

Primary Contact Consent *

Will the primary contact be involved in the consent process?

Yes

No

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](#).

Additional Personnel

Additional Personnel *

Are there additional personnel for this study?

Yes

No



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

Additional Personnel Information

Additional Personnel Information

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

✘ Person 1

First Name *

Last Name *

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

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

Consent *

Will this person participate in the consent process?

Yes

No

Sub-Investigator *

Is this individual a sub-investigator?

Yes

No

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

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.**

- 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



Consistency Check | This should match Protocol, Section 6) Procedures Involved

Jump to [Protocol, Section 6](#)

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
- Department Funded or No Funding
- Other

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

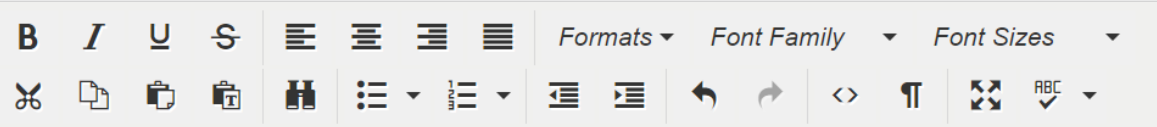
No

Research Location Information

Research Location Information

Research Setting *

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



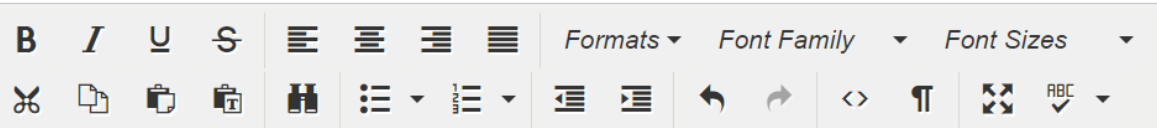
An email inviting potential subjects to participate in this study will be sent to clown school student listservs. Several clown schools have agreed to allow for the study team to send this recruitment email upon IRB approval.

This recruitment email will include a link to the screening script. Once potential subjects confirm that they have met the inclusion criteria and do not meet the exclusion criteria for this study, they will be presented the consent script. At the bottom of the consent script, potential subjects will be given the option to start the study survey or decline to participate.

Data analysis will be completed at UC Davis.

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."



No specific credentials, licensing, or training is need to perform research procedures.

The Principal Investigator and research personnel have adequate training to conduc this research.

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



Our example study is using clown school listservs to identify and recruit subjects.

External Site(s) Information

External Site(s) Information

List each external research site at which the PI will conduct or oversee the protocol:

✕ Site 1

Site Name *

Red Nose Clown School

Contact Name *

Red Nose Clown School Contact's First and Last Name

Contact Email *

Red Nose Clown School Contact's Email

External Site Engagement *

Are personnel from this external site conducting any of the following procedures for this research while working under the oversight of the PI listed on this application? Select all that apply.

- Obtaining research consent
- Collecting information from individuals
- Handling private, identifiable information
- None of the above

External Site Considerations *

Describe any site-specific regulations, policies or customs affecting the research at this external site. If the site is outside the US, describe how you will ensure the research conforms with the local laws or cultural norms.



Red Nose Clown School has agreed via email to allow the study team to send a recruitment email for this study to Red Nose Clown School's student listserv.

Continues on next slide

External Site(s) Information (cont.)

✖ Site 2

Site Name *

Clown College of California

Contact Name *

Clown College of California Contact's First and Last Name

Contact Email *

Clown College of California Contact's Email

External Site Engagement *

Are personnel from this external site conducting any of the following procedures for this research while working under the oversight of the PI listed on this application? Select all that apply.

- Obtaining research consent
- Collecting information from individuals
- Handling private, identifiable information
- None of the above

External Site Considerations *

Describe any site-specific regulations, policies or customs affecting the research at this external site. If the site is outside the US, describe how you will ensure the research conforms with the local laws or cultural norms.

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[Clipboard] [Paste] [Print] [Table] [List] [List] [Undo] [Redo] [Code] [Align] [ABC]

Clown College of California has agreed via email to allow the study team to send a recruitment email for this study to Clown College of California's student listserv.

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.

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

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

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

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

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

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?

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.)
- 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.

Recruitment email distributed to clown school listservs

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.



If your study does use advertising as a recruitment method, please make sure to upload any advertising materials to IRBNet.

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.
- 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.

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



On the “Form Complete” page at the end of the Initial Review Application, we will be instructed to upload our screening script.



Consistency Check | Protocol, Section 5d) Inclusion and Exclusion Criteria

Jump to [Protocol, Section 5d](#)

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.
- 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.



For our example study, subjects will be provided a consent script or information sheet. Subjects will agree to participate, but they will not sign a consent document.

If you plan to have subjects verbally agree to participate in your research or push a button to indicate that they are ready to proceed with participation, then this is also the option you would choose.

Information Sheet or Oral Consent Request

Information Sheet or Oral Consent Request

You indicated that there will be no signed consent document. To help the IRB determine if this is appropriate, please answer the following:

Written Consent *

Does this research involve any procedures for which written consent is usually required? For example, surgery, imaging, release of educational records, etc.

- Yes
- No

Consent Document *

Is the consent document the only document linking the participant to the research?

- Yes
- No

Distinct Cultural Group *

Are the research subjects members of a distinct cultural group or community in which signing forms is not the norm?

- Yes
- No



Our example study is not collecting any identifiable information about subjects. As such, we have answered “Yes” to this question.

If you are collecting any identifiable information, then you should answer “No” instead.

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

Non-English Justification

Non-English Justification *

If excluding non-English speaking subjects, provide a justification:

- This research is minimal risk with no direct benefit to research subjects
- This research specifically studies native English speakers
- This research requires validated or copyrighted materials only available in English
- Other

Non-English Justification - Other

If you selected "Other", please explain.

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.
- 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:

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N/A

Pro-ration of Compensation

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

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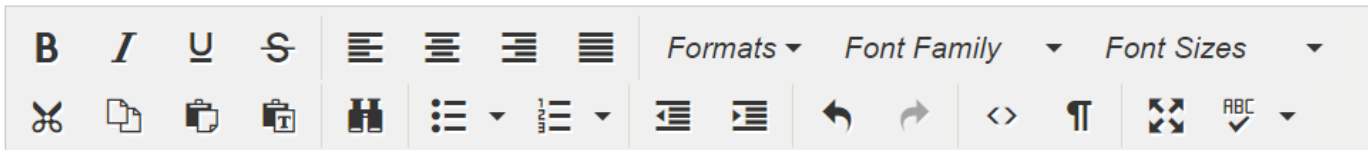
N/A

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Compensation for Participants (cont.)

Form of Payment

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



N/A

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

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

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

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
- 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.

A rich text editor toolbar with the following icons and labels from left to right: Bold (B), Italic (I), Underline (U), Strikethrough (S), Bulleted List, Numbered List, Indent, Outdent, a dropdown menu labeled 'Formats', a dropdown menu labeled 'Font Family', and a dropdown menu labeled 'Font Sizes'. The second row contains: Cut, Copy, Paste, Text Color, Background Color, Bulleted List, Numbered List, Undo, Redo, Link, Unlink, and a dropdown menu labeled 'ABC'.

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
- None of the above or N/A

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
- None of the above or N/A

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.
- 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.
- 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.



Consistency Check | Protocol, Section 9) Data Management and Confidentiality

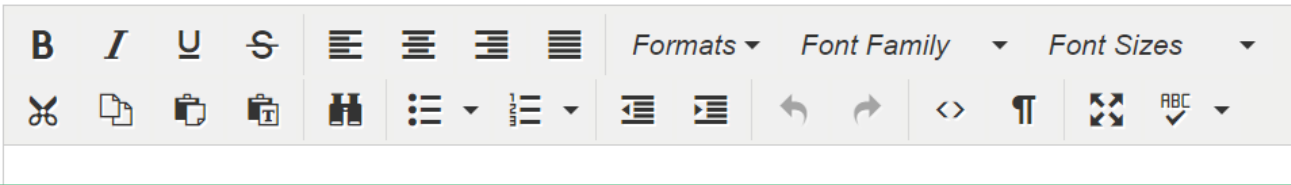
Jump to [Protocol, Section 9](#)

Continues on next slide

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):



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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

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)
- Screening Script
- Consent Script or Information Sheet (HRP-502 Consent Templates available for use)

Resources

- [IRB Forms and Templates](#)
- [Ancillary Reviews](#)

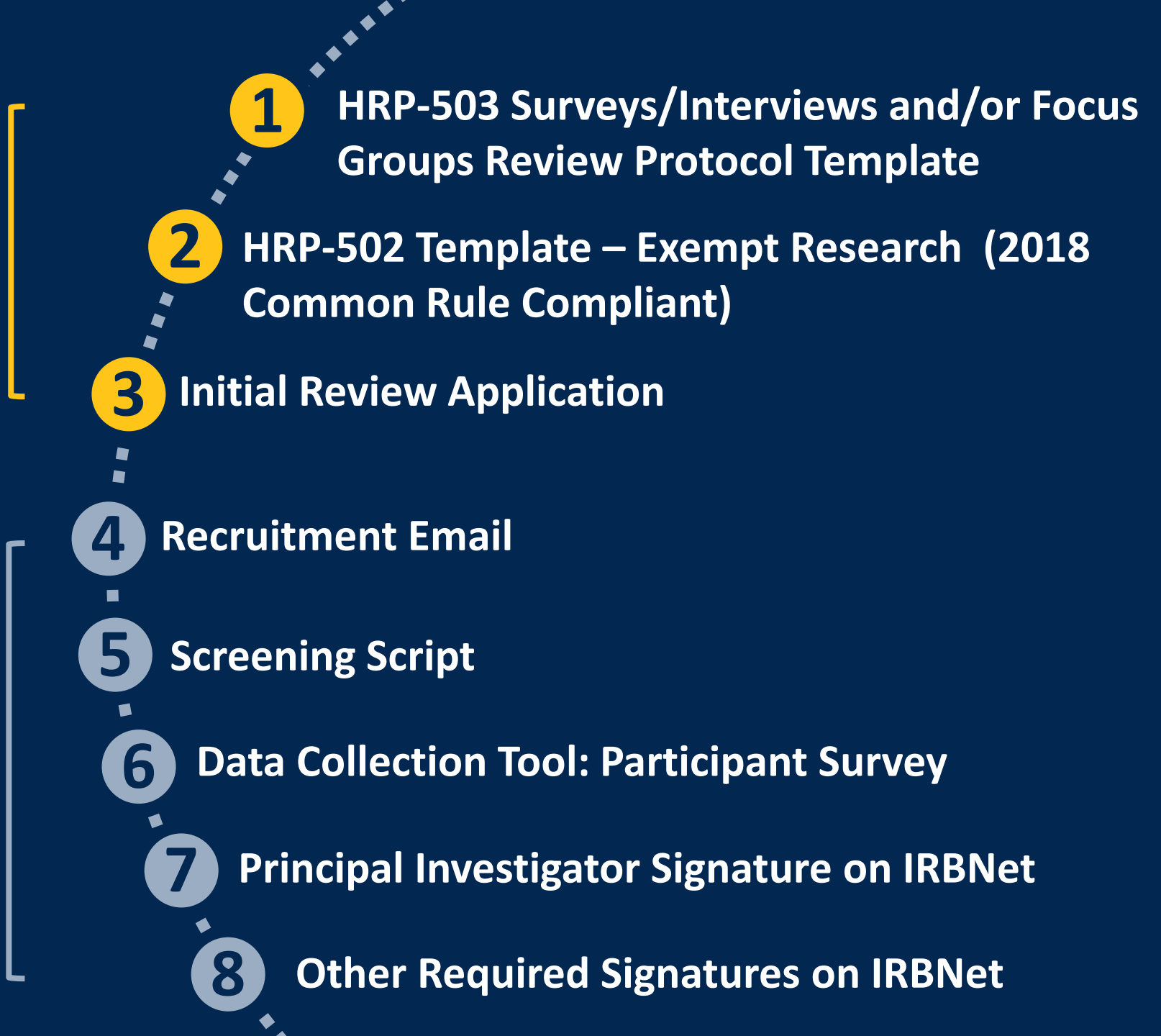


The “Additional documentation” subsection tells you exactly what forms you need to upload to IRBNet.

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

Reminder

Examples of these items are included in this slide deck



Additional documents or requirements for a complete submission

Questions?

Contact

hs-irbeducation@ucdavis.edu