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

All subjects are adults.
**HRP-503 Surveys/Interviews and/or Focus Groups Review Protocol Template**

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

**Initial Review Application**

**Recruitment Email**

**Screening Script**

**Data Collection Tool: Participant Survey**

**Principal Investigator Signature on IRBNet**

**Other Required Signatures on IRBNet**
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.

For a link to the HRP-503 template we used for our example study, please click HERE.
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 2050. The outcomes of this project will be used to better understand this generation of clown school applicants.
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

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.
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
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

This research involves:
- Audio recordings
- Photographs
- Video recordings with audio
- Video recordings without audio
- None of the above
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
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

- 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

☑ 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

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.
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:
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.
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.
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

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.
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.

---

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)
**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-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 *
School of Education

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

Co-PI Phone *
(300) 000-0000

Co-PI Email *
researcher2@ucdavis.edu

Co-PI Consent *
Will the co-Principal Investigator be involved in the consent process?

- Yes
- No
Primary Contact

Is the Principal Investigator the primary contact for this study?

- Yes
- No
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”)** *

None

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

PhD Student

**Primary Contact Consent** *

Will the primary contact be involved in the consent process?

- **Yes**
- **No**
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.
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

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
- [x] No

Sub-Investigator *

Is this individual a sub-investigator?

- [ ] Yes
- [x] No
Outside Financial Interest

Information:

SFI: Significant financial interest (per UC Davis PPM 230-05 II.1) - 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 officer, 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

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 x-rays 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

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

Information:
UC Davis Health Policy & Procedure 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 Policy & Procedure 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
- [x] No
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 conduct this research.
Our example study is using clown school listservs to identify and recruit subjects.
Initial Review Application

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
- [x] 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 listserve.
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.

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

**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*
### Initial Review Application

**Ancillary Reviews (cont.)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Option 1</th>
<th>Option 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Participants</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hazardous Material</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Recombinant DNA or Human Gene Transfer</td>
<td>Yes (BUA must be submitted to the IRB)</td>
<td>No</td>
</tr>
<tr>
<td>Identifiable Health Information</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

*Continues on next slide*
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?
If your study does use advertising as a recruitment method, please make sure to upload any advertising materials to IRBNet.
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.
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
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.
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

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
- [x] No, non-English speakers will be excluded
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 Participation

**Compensation**

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

- [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:

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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
Compensation for Participants (cont.)

Form of Payment

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

N/A
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)

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 Pharmacopeia, 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](https://www.fda.gov/medical-devices/how-determine-your-product-is-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
- [x] No
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
- [x] No
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.
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

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
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 research.

Name of Cloud Service

If you are using a cloud service, provide the name of the cloud service.
Data Confidentiality (cont.)

Initial Review Application

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
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

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

Examples of these items are included in this slide deck.

Additional documents or requirements for a complete submission.

Reminder
Contact
hs-irbeducation@ucdavis.edu