**Protocol Narrative: Biomedical Full Committee**

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the IRB does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

Attach this protocol to the “Basic Study Information” section of the ZOT IRB application. Other supplemental documentation (i.e. consent, recruitment, other) can be attached in “Local Site Documents”.

1. Study Overview

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| **1.1 Basic Information** | **Submission Details** |
| **1.1.1 IRB Number:** | Click or tap here to enter text. |
| **1.1.2 Short Title:** | Click or tap here to enter text. |

* 1. **Background & Purpose:** 
     1. Describe the purpose, specific aims or objectives and specify the hypotheses or research questions to be studied.
     2. Provide the scientific or scholarly rationale for the research and describe the relevant background information and the specific gaps in current knowledge that this study intends to address.
     3. Provide relevant preliminary information (animal and/or human).
     4. Describe the primary outcome variable(s), secondary outcome variables, and predictors and/or comparison groups as applicable for the stated study objectives/specific aims.
     5. List up to ten relevant references/articles to support the rationale for the research.

***This is included in a separate scientific protocol attached.***

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**1.3 Study Design:** Provide an explanation of the study design (e.g., randomized placebo-controlled, cross-over, cross-sectional, longitudinal, etc.) and, if applicable, describe stratification/ randomization/blinding scheme.

***This is included in a separate scientific protocol attached.***

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* 1. **Statistics:** 
     1. Describe the statistical methods for the stated specific aims and hypotheses. The analysis plans should match the stated study specific aims and hypotheses.
     2. Provide precise definitions of the study endpoints and criteria for evaluation; if the primary outcomes are derived from several measurements (i.e., composite variables) or if endpoints are based composite variables, then describe precisely how the composite variables are derived.
     3. Describe the statistical method(s) that will be used to analyze the primary outcome(s) or endpoints.
     4. If applicable describe secondary or post hoc analyses of primary outcome(s) or other exploratory analysis and if necessary, provide a breakdown of the methods used per outcome or endpoint.

***This is included in a separate scientific protocol attached.***

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2. Procedures

* 1. **Study Procedures:**
     1. Using lay language, provide a detailed chronological description of the procedures. If available, provide a study flow sheet or table of procedures or attach as a separate document.
     2. Specify the setting (public vs private) and location where research procedures will be conducted
        1. For research where participants or the performance site is located outside the United States, attach the [PI WORKSHEET - International Research](https://research.uci.edu/wp-content/uploads/HRP-450-PI-WORKSHEET-International-Research.docx).
     3. List all procedures involving the use and/or collection of photographs, or audio/video recording.
     4. List all data collection tools (e.g., measures, questionnaires, observational tool) below; include citations for standardized/validated measure(s). Attach any collection tools that are not standardized or not validated.
     5. If the research involves participant observation, indicate who and what will be observed, describe the information that will be recorded in the research records (indicate whether data will include personally identifiable information), and outline the procedures for collecting data (written notes, audio/video recording).
     6. Specify the total duration of a participant’s participation in the study and clearly outline the duration of participation for each study visit and sub-study, as applicable.

***This is included in a separate scientific protocol attached.***

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**2.2 Genetic Testing:** Indicate the type of genetic testing to be performed. Select all that apply.

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| Not applicable  Somatic or Non-Diagnostic Genetics  Gene Expression, Biochemical or Qualitative  Germ Line/Diagnostic Genetics of Mendelian Disorders  Germ Line Genetics of Complex Disease | Pedigree Analysis/Family Linkage  Pharmacogenetic  Somatic or Non-Diagnostic Genetics  Whole Genome Sequencing |

* 1. **Placebo/Sham Rationale:** 
     1. Review the [Placebo Algorithm](https://research.uci.edu/wp-content/uploads/placebo.pdf) and explain how the use of the placebo is ethical.
     2. Provide scientifically sound justification for use of placebo or sham procedure.
     3. Explain if the disease/condition has the potential to progress to a higher risk condition if not actively treated.
     4. Explain whether the natural fluctuation of the disease/condition is significant enough to necessitate the use of placebo or sham comparison.

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* 1. **Washout Rationale:**
     1. Provide scientifically sound justification for use of washout.
     2. Specify the duration of the washout period.
     3. Describe the increased participant monitoring that will occur during the washout period and detail any rescue plans for participants whose disease/condition worsens.

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**2.5 Multi-Site/Center Plan:** If UCI is the lead institution of a multi-site study or the UCI researcher is the lead investigator of a multi-center clinical investigation, describe the plan to manage the research project to ensure that the research is carried out in an ethical manner and to ensure adequate human research protections at all participating sites.

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| Click or tap here to enter text. |

**2.6 Non-UCI Performance Sites:** Specify if UCI researchers engaged in human subjects research activities (e.g., interact with subjects; have access to identifiable information) at an external (non-UCI) site and specify the locations.

No

Yes, the external site does not require IRB approval.

Yes, the external site requires separate approval from their IRB.

Yes, the external site requests that UCI serve as the sIRB. After initial IRB approval has been granted for the UCI site, attach the [PI WORKSHEET - Considerations for Serving as the Reviewing IRB](https://research.uci.edu/wp-content/uploads/HRP-833-PI-WORKSHEET-Considerations-for-Serving-as-the-Reviewing-IRB.docx) using the “Manage Participating Sites” feature.

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| Specify relying site(s): Click or tap here to enter text. |

**2.7 Non-UCI Collaborators:** Specify if researchers without a formal affiliation with UCI (i.e. not in UC path) are engaged in human subjects research activities and specify the collaborators.

No

Yes, the non-UCI researchers have obtained their own IRB or it is pending.

Yes, the non-UCI researchers request that UCI serve as their IRB. Attach the [PI WORKSHEET - Considerations for Serving as the Reviewing IRB](https://research.uci.edu/wp-content/uploads/HRP-833-PI-WORKSHEET-Considerations-for-Serving-as-the-Reviewing-IRB.docx) to the “External Study Team Members for UCI” prompt int the ZOT IRB application.

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| Specify relying collaborator(s): Click or tap here to enter text. |

3. Participants

**3.1 Participant Populations:** Select all that apply and address the required action, as applicable.

|  | **Type of Population** | **Required Action** | |
| --- | --- | --- | --- |
|  | Adults | N/A | |
|  | Adults not able to consent for themselves (e.g., cognitively impaired or medically incapacitated) | Attach the [PI WORKSHEET - Adults with Impaired Decision-Making Capacity](https://research.uci.edu/wp-content/uploads/HRP-417-PI-WORKSHEET-Cognitively-Impaired-Adults.docx). | |
|  | Pregnant individuals/fetuses | Attach the [PI WORKSHEET - Pregnant Women](https://research.uci.edu/wp-content/uploads/HRP-412-PI-WORKSHEET-Pregnant-Women.docx). | |
|  | Non-viable neonates | Attach the [PI WORKSHEET - Non-Viable Neonates](https://research.uci.edu/wp-content/uploads/HRP-413-PI-WORKSHEET-Non-Viable-Neonates.docx). | |
|  | Neonates of uncertain viability | Attach the [PI WORKSHEET - Neonates of Uncertain Viability](https://research.uci.edu/wp-content/uploads/HRP-414-PI-WORKSHEET-Neonates-of-Uncertain-Viability.docx). | |
|  | Prisoners | Attach the [PI WORKSHEET - Prisoners](https://research.uci.edu/wp-content/uploads/HRP-415-PI-WORKSHEET-Prisoners.docx). | |
|  | Children (minors) | Attach the [PI WORKSHEET - Children](https://research.uci.edu/wp-content/uploads/HRP-416-PI-WORKSHEET-Children.docx). | |
|  | American Indian or Alaska native tribes | | 1. Specify the tribal name. 2. Specify whether there is an applicable Tribal Law that provides additional protections for research subjects. |
|  | UCI inpatients or outpatients | N/A | |
|  | UCI students/staff/faculty | N/A | |

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| Click or tap here to enter text. |

**3.2 Inclusion Criteria:** Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential participants. Provide a breakdown per participant cohort, as applicable (e.g., adults vs parents vs children).﻿ Define any technical terms in lay language.

When utilizing [UCI Health Enterprise Information & Analytics](https://it.health.uci.edu/Enterprise-Data/requestdata.asp) services (e.g., pre-screening, information pull), the following additional information is required:

* ﻿Specify timeframes for each eligibility factor, as applicable.
* For diagnoses, procedures, and laboratory tests, provide [standard codes](https://athena.ohdsi.org/) whenever possible, such as ICD-9/10, CPT, LONIC, and SNOMED CT.

*Example Entry:*

* *Birth sex: female*
* *Age: >= 18 years old as of 2020-01-01*
* *The result of the most recent SARS-CoV-2 test (of any type), performed between 2020-01-01 and 2020-12-31, was positive*
* *With any sub-classification of type 2 diabetes (E11\*) diagnosed at any date prior to 2020-01-01*
* *Did NOT have an ED visit between 2020-01-01 and 2020-12-31*

***This is included in a separate scientific protocol attached.***

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| Click or tap here to enter text. |

**3.3 Exclusion Criteria:** Describe the specific criteria that will be used to decide which of the participants who meet the inclusion criteria listed above will be excluded from the research. Define any technical terms in lay language. There is no need to list the opposite of the inclusion criteria.

***This is included in a separate scientific protocol attached.***

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| Click or tap here to enter text. |

**3.4 Exclusion Rationale:** If eligibility is based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English speakers only), provide the scientific rationale for excluding each population.

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| Click or tap here to enter text. |

**3.5 Number of Participants:** For each participant group, use the table below to provide the estimate of the desired number of individuals who will complete the research. Insert separate rows for each category/group.

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| --- | --- | --- | --- | --- |
| **Category/group** | **Age Range** | **Number of individuals prescreened without consent** | **Max number of individuals to be consented, include including withdrawals and screen failures** | **Expected/targeted number of individuals needed to complete the study** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

**3.6 Pre-screen Number:** Explain how the pre-screen number was determined (e.g., cohort discovery, anticipated rate of enrollment). This number should reflect an estimate based on the anticipated rate of screen failure and/or rate of enrollment.

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| Click or tap here to enter text. |

* 1. **Expected/Target Number:**
     1. Explain how the target sample size was determined (e.g., power analysis; precision estimation).
     2. Power analysis should (at least) match the primary outcome/endpoint.
     3. Provide justification of the effect size for the primary outcome based on preliminary information, current knowledge/literature and/or cost consideration.
     4. If applicable, provide justification for any significant difference between the max and expected numbers listed above.
     5. If applicable, provide sample size justification for secondary outcomes.

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| Click or tap here to enter text. |

**3.8 Multi-site Number:** If applicable, specify total number of subjects across all sites (UCI & other sites).

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| Click or tap here to enter text. |

4. Screening Participants Without Consent

***This section is not applicable.***

**4.1 Source of Eligibility Information:** Select all that apply and address the required action, as applicable.

|  | **Source of Eligibility Information** | **Required Action** |
| --- | --- | --- |
|  | Oral or written communication with the prospective participant or Legally Authorized Representative (LAR) (i.e. self-report of medical information; medical records will not be screened) | Attach a screening script that adheres to [Recruitment Requirements](https://research.uci.edu/human-research-protections/research-subjects/) and includes the following:   * + - 1. **Description of the information that will be obtained and the reasons for performing the screening tests.**       2. Statement that if the individual is not eligible their identifiable information will not be used for research purposes and will be destroyed at the earliest opportunity consistent with conduct of the research. |
|  | Direct access to UCI Health medical records | A partial waiver of HIPAA authorization is required. |
|  | Center for Artificial Intelligence in Diagnostic Medicine (CAIDM) IRB #20184417 | A partial waiver of HIPAA authorization is required. |
|  | Experimental Tissue Resource (ETR) IRB #20128716 | A partial waiver of HIPAA authorization is required. |
|  | Health Enterprise Information & Analytics IRB #20128757 | A partial waiver of HIPAA authorization is required. |
|  | IRB approved research | * + - 1. For UCI IRB approved research, specify protocol number(s).       2. For other research, attach the IRB approved consent form that documents the sharing of information. |
|  | Student records or student health medical records | * + - 1. Specify the types of education records.       2. Attach a [Letter](https://research.uci.edu/wp-content/uploads/HRP-504-TEMPLATE-LETTER-School-Permission-to-Conduct-Research.docx) of [FERPA](https://studentprivacy.ed.gov/ferpa) clearance from the local school/district site or from the [UCI Registrar FERPA Analyst](https://www.reg.uci.edu/privacy/) for UCI student records. |
|  | Other | * + - 1. Describe/explain.       2. Specify the types of records/biospecimens.       3. Explain how the study team will obtain the records.       4. Specify whether the information/biospecimen was originally collected for research purposes. If research purposes, attach the IRB approved consent form that documents the sharing of information. |

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| Click or tap here to enter text. |

**4.2 Screening Variables:** Provide a complete list of ALL data points/variables/information that will be collected/recorded. Information collected/recorded from medical/student records must be limited to the contact information unless justified otherwise. Eligible participants should be recruited for the study.

***This is included in a separate document attached.***

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| Click or tap here to enter text. |

5. Recruiting Participants

***This section is not applicable.***

**5.1 Recruitment Methods:** Select all that apply and address the required action, as applicable.

|  | **Recruitment Method** | **Required Action** |
| --- | --- | --- |
|  | Center for Clinical Research (CCR) Find a Trial web page | Eligible clinical trials must be registered on [ClinicalTrials.gov](https://clinicaltrials.gov/). |
|  | CFCCC’s Chart Screening Protocol  IRB# 2009-6837 | N/A |
|  | Clinicaltrials.gov | ClinicalTrials.gov statement must be in included in consent documents, as applicable. |
|  | Colleagues provide participants with information about the research and how to contact investigators[[1]](#footnote-2) | A partial waiver of HIPAA authorization is required when a treating physician screens patient medical records outside of clinical care (i.e. solely for research purposes). |
|  | Colleagues seek or obtain the participants’ permission for investigators to contact them1 | A partial waiver of HIPAA authorization is required when a treating physician obtains verbal permission from a patient to disclose their name and contact information to the study team. |
|  | Colleagues, who are treating physicians, will send UCI IRB approved recruitment letter to their patients1 | Attach the recruitment letter to be signed by the treating physician. |
|  | Email/Postal Mail/Phone | Specify how contact information will be obtained and attach the recruitment letter or phone script. |
|  | Flyers/Brochures | * + 1. Specify where recruitment will be posted.     2. Specify whether the location is public (open access) or private (controlled access).     3. Attach the recruitment material. |
|  | Individual/Group/Class Presentation | * + 1. Specify whether the location is public (open access) or private (controlled access).     2. Attach the recruitment script. |
|  | IRB approved participant screening protocol | Specify IRB number(s). |
|  | Newspaper/Radio/Television | * + 1. Specify where recruitment will be posted.     2. Attach the Recruitment material. |
|  | Online/Social Media | * + 1. Specify where recruitment will be posted.     2. Specify whether the location is public (open access) or private (controlled access).     3. Attach: Recruitment material. |
|  | Participants are identified from another IRB approved study and they have given permission for future contact | Specify IRB number(s). |
|  | Study team will approach students, employees, patients, economically, educationally, or cognitively disadvantaged | **Attach recruitment and consent documents that reflect an individual’s decision to participate in research will not affect:**  **their relationship with UCI,**  **how their doctor cares for them as a patient or their care at UC Health in general and/or**  **how their instructor grades their performance in the course.** |
|  | Study team will contact potential participants who have given prior permission to be contacted for research studies | Specify how permission was granted and documented. |
|  | UCI Participant Pool | Specify pool(s). |
|  | Other | Describe below. |

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| Click or tap here to enter text. |

**5.2 Relationship with Participant Population:** Address whether members of the study team have an existing relationship with the study population(s).

No, describe how invasion of privacy will be reduced or managed.

Yes, describe the nature of the relationship.

* + 1. Specify how the potential undue influence of this relationship will be minimized.
    2. If applicable, specify how therapeutic misconception will be minimized in the recruitment/consent process.
    3. Specify the precautions taken to avoid compromised objectivity.

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| Click or tap here to enter text. |

6. Financial Considerations for Participants

* 1. **Payment to participants:**
     1. Describe any payments made to participants for their time & efforts in research. For more information visit, [Payments to Participants](https://research.uci.edu/human-research-protections/research-subjects/#payments).
     2. List the total payments for research participation.
     3. If there are multiple study sessions, payment should be offered on a pro-rated basis. Describe how payment will be pro-rated.
     4. Specify when payment will be made.
     5. If participants receive greater than or equal to $600, the protocol and the consent document must disclose that participant names and social security numbers are reported to UCI Accounting for tax purposes.

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| Click or tap here to enter text. |

* 1. **Costs to participants:**
     1. Describe any research-related cost to participants or their insurers, include covering parking costs.
     2. Describe any requirements for reimbursement (e.g. receipt) of out-of-pocket expenses paid by participants.

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| Click or tap here to enter text. |

7. Informed Consent

**7.1 Consent Methods:** Select all that apply and address the required action, as applicable.

|  | **Consent Methods** | **Required Action** |
| --- | --- | --- |
|  | Electronic signed consent [participant or Legally Authorized Representative (LAR)], parental permission, or assent (child or adult unable to consent) | 1. Attach the following as applicable:   consent and/or assent form  informational materials, including any videos and web-based presentations, which the subject will receive and view during the electronic process  any optional questions or methods used to gauge subject comprehension of key study elements.   1. For FDA-regulated clinical investigations, specify how the process is [21 CFR 11](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application) compliant. |
|  | Paper-based signed consent (participant or LAR), parental permission, or assent (child or adult unable to consent) | Attach the consent and/or assent form. |
|  | Verbal/implied consent and/or parental permission | Attach the following documents:   * + 1. [Study Information Sheet](https://research.uci.edu/wp-content/uploads/study-information-sheet.docx) and     2. [PI WORKSHEET - Waiver of Written Documentation of Consent](https://research.uci.edu/wp-content/uploads/HRP-411-PI-WORKSHEET-Waiver-of-Written-Documentation-of-Consent.docx) |
|  | Verbal/implied assent (child or adult unable to consent) | Attach the assent script. |
|  | Consent materials will be translated for non-English speaking participants or their LAR once IRB approval is granted | If study team members are responsible for obtaining informed consent from non-English speaking subjects, provide their qualifications to serve in this capacity (i.e. language fluency) in the Study Team section in the ZOT IRB form. |
|  | Short Form Consent | N/A |
|  | No consent or parental permission | Attach the [PI WORKSHEET - Waiver or Alteration of Consent Process](https://research.uci.edu/wp-content/uploads/HRP-410-PI-WORKSHEET-Waiver-or-Alteration-of-Consent-Process.docx) |
|  | No assent (child or adult unable to consent) | N/A |
|  | Emergency exception to informed consent | N/A |

**7.2 Consent/Assent Process Description:**

* + 1. Provide a breakdown of the groups (as applicable) and consent/assent procedures for each.
    2. Describe the type of setting(s) in which the consent/assent process will be conducted – if the setting is not private, describe the measures to protect confidentiality.
    3. Describe the measures that will be taken to provide prospective research participants (their parent or LAR) with sufficient opportunity to consider participating in the study.
    4. Specify the length of time participants are given to decide whether they wish to participate in the study.
    5. Explain how the study team will assess whether participants understand the information conveyed during the consent process.

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| Click or tap here to enter text. |

* 1. **Non-English Speaking Participants:**

7.3.1 Indicate how the participants or their LAR will be consented in their language.

A member of the study team is fluent in the language that will be used for communication, and that study team member will be available during emergencies.

24-hour translation service with sufficient medical expertise to discuss the research in this study.

Other, describe/explain.

* + 1. If applicable, address the following regarding the use of short form:
       1. Specify the languages that will utilize short form.
       2. Explain why short form consent is necessary for the research study. If enrollment of certain language speaking participants is not expected due to the disease or condition being studied and the anticipated study enrollment, please include study specific justification.
       3. Explain who will be performing the oral translation of the English-approved consent form. Specify the credentials, experience, and expertise of the individual(s) performing the translation.

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| Click or tap here to enter text. |

8. HIPAA Authorization

***This section is not applicable.***

**8.1 Information related to health or mental health care:** Select all that apply.

Derived from a medical or clinical record

Derived from observation of clinical care

Created or collected as part of health or mental health care

Used to make healthcare or mental healthcare decisions and/or provided to other healthcare professionals

Research information will be entered into the participants’ medical or clinical record

**8.2 HIPAA Authorization:** Select all that apply and address the required action, as applicable.

|  | **HIPAA Authorization Methods** | **Required Action** |
| --- | --- | --- |
|  | Signed HIPAA authorization (participant or Legally Authorized Representative) | Attach the [UCI HIPAA Research Authorization](https://research.uci.edu/wp-content/uploads/uci-hipaa-authorization.docx) |
|  | Partially waive HIPAA authorization for screening and recruitment purposes. | Attach the [PI WORKSHEET - HIPAA Waiver of Authorization](https://research.uci.edu/wp-content/uploads/HRP-441-PI-WORKSHEET-HIPAA-Waiver-of-Authorization.docx) |
|  | No HIPAA authorization | Attach the [PI WORKSHEET - HIPAA Waiver of Authorization](https://research.uci.edu/wp-content/uploads/HRP-441-PI-WORKSHEET-HIPAA-Waiver-of-Authorization.docx) |

9. Study Information and Biospecimens Sources Other Than the participant (Secondary Data Analysis)

**9.1 Information/Biospecimen Source:** This should reflect the portion of the research that gathers information or biospecimens from sources other than the participant. Select all that apply and address the required action, as applicable.

|  | | **Source of Information/Biospecimen** | **Required Action** |
| --- | --- | --- | --- |
|  | Access to medical records from another institution (not UCI) | Institutions' healthcare authorization for release of health information will be used or a waiver for release of health information will be granted from the institution. |
|  | Direct access to medical records from UCI Health | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required. |
|  | Center for Artificial Intelligence in Diagnostic Medicine (CAIDM)  IRB #20184417 | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required. |
|  | Experimental Tissue Resource (ETR)  IRB #20128716 | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required. |
|  | Health Enterprise Information & Analytics IRB #20128757 | Signed UC HIPAA authorization or a waiver of HIPAA authorization is required. |
|  | IRB approved research | * + 1. For UCI IRB approved research, specify protocol number(s).     2. For other research, attach the IRB approved consent form that documents the sharing of information. |
|  | Stored identifiable biospecimen(s) | * + 1. Specify clinic or operating room.     2. With the exception of biospecimens specifically listed as exempt in UCI Health Anatomical Pathology/Surgical Pathology - Procedure Number: S-23 or biospecimens obtained from Dermatopathology, retain evidence of Pathology clearance from Dr. Robert Edwards ([redwards@uci.edu](mailto:redwards@uci.edu)) or Delia Tifrea ([dtifrea@hs.uci.edu](mailto:dtifrea@hs.uci.edu)). |
|  | Student records or student health medical records | * + 1. Specify the types of education records.     2. Attach the [Letter](https://research.uci.edu/wp-content/uploads/HRP-504-TEMPLATE-LETTER-School-Permission-to-Conduct-Research.docx) of [FERPA](https://studentprivacy.ed.gov/ferpa) clearance from the local school/district site or from the [UCI Registrar FERPA Analyst](https://www.reg.uci.edu/privacy/) for UCI student records. |
|  | Other | * + 1. Specify source(s).     2. Specify the types of records/biospecimens.     3. Specify whether the information/biospecimen was originally collected for research purposes.     4. Explain how the study team will obtain the records. |

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| Click or tap here to enter text. |

* 1. **Information Variables:**
     1. Specify the date-range of the information used for the project (e.g. January 2002 to January 2020)
     2. Provide a complete list of ALL information points, variables, and/or information that will be collected/recorded (i.e. information abstraction form) from sources other than the participant (e.g., medical records).
     3. When utilizing [UCI Health Enterprise Information & Analytics](https://it.health.uci.edu/Enterprise-Data/requestdata.asp) services (e.g., pre-screening, information pull), the following additional information is required:
        1. Specify timeframes for each eligibility factor, as applicable.
        2. For diagnoses, procedures, and laboratory tests, provide [standard codes](https://athena.ohdsi.org/) whenever possible.

***This is included in a separate scientific protocol attached.***

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| Click or tap here to enter text. |

10. Privacy and Confidentiality

**10.1 Information: Indicate the** personally identifiable information **collected or retained for information analysis, recruitment, consenting and/or compensation. Select all that apply.**

Not applicable

|  |  |
| --- | --- |
| Names  All elements of dates that are directly related to an individual: birth date, admission date, discharge date, death date, and all ages over 89  All geographic subdivisions smaller than a state: street address, city, county, precinct, ZIP code, and geocodes  Telephone numbers  Email address  Social Security number  Health plan beneficiary numbers | Medical record number  Account numbers  Vehicle identifier and serial numbers: license plate  Web URLS  IP addresses  Biometric Identifiers: finger and voice prints  Full-face photographs and any comparable images  Any other unique identifier (does not include a code assigned by the investigator to identify the information) |

**10.2 Social Security Number: Explain why social security numbers are necessary, how they will be used, how they will be protected, and how long they will be retained.** Social security numbers should not be used if other unique codes (not derived from the social security numbers) can practicably be utilized to conduct the research.

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| Click or tap here to enter text. |

**10.3 Personal Information: If University of California office records** (e.g., medical, employment, student applications, etc.) are disclosed to the research team, indicate whether the records include personal information. **Select all that apply.**

Not Applicable

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| --- | --- |
| Identifiable information as indicated above  Physical description  Education  Financial matters | Medical history  Employment history  Statements made by, or attributed to, the individual  Other, describe/explain. |

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| Click or tap here to enter text. |

* 1. **Identifiable/Personal Information Rationale:**
     1. Explain why the identifiable and/or personal information indicated in the prior sections are needed to conduct the research.
     2. Explain why the identifiable and/or personal information indicated in the prior sections are not more than the minimum necessary to conduct the research.

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| Click or tap here to enter text. |

**10.5 De-identification Methods:** Select all that apply and address the required action, as applicable.

|  | **De-identification Methods** | **Required Action** |
| --- | --- | --- |
|  | A code will be used. Participant identifiers will be kept separately from the information/biospecimens. The code key will be destroyed at the earliest opportunity, consistent with the conduct of this research. | N/A |
|  | A code will not be used. Participant identifiers will be kept separately from the information/biospecimens. | Provide the rationale below. |
|  | A code will not be used. Participant identifiers will be kept directly with the information/biospecimens. | * + - 1. Provide the rationale below.       2. Explain how identifiers are attached. |
|  | Participant identifiers will be removed from identifiable images/photographs/video/audio. | * + 1. Specify if recordings will be transcribed, how it will be done, and the timeframe for transcription.     2. Specify timeframe for the de-identification of the images/recordings and explain how they will be de-identified. |
|  | Participant identifiers will be kept directly with identifiable images/photographs/video/audio. | * + 1. Provide the rationale below.     2. Specify if recordings will be transcribed, how it will be done, and the timeframe for transcription. |

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| Click or tap here to enter text. |

**10.6 Publications/Presentation:** Specify whether participant identifiers will be disclosed in presentations or publications.

Yes, participant identifiers will be disclosed. Text regarding the disclosure must be included in the consent document and specific permission to disclose will be discussed with participants.

No, participant identifiers will not be disclosed.

**10.7 Identifier Retention:** Indicatehow long all subject/patient identifiers will be retained. This includes identifiers stored in paper format, stored electronically as well as video recordings, audio recordings, photographs, etc.

Destroyed after initial collection

Destroyed after compensation

Destroyed after information analysis

Destroyed after publication/presentation or end of protocol

Maintained indefinitely, provide rationale.

Other, describe/explain.

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| Click or tap here to enter text. |

**10.8 Information/Biospecimen Storage:** Select all that apply and address the required action, as applicable. For best practices for electronic research data security, review the UCI Information Security website: [Information and Resource Classifications](https://security.uci.edu/security-plan/plan-classification-protection.html#P2).

|  | **Information/Biospecimen Storage** | **Required Action** |
| --- | --- | --- |
|  | Biospecimens will be stored in a locked lab/refrigerator/freezer with limited access by authorized personnel. | Specify where biospecimens will be stored. |
|  | Information will be maintained on UCI [enterprise cloud storage](https://security.uci.edu/security-plan/Cloud.html) that adheres to the UCI [Protection Level](https://security.uci.edu/security-plan/plan-classification-protection.html) required for the research information. | Specify the UCI cloud platform. |
|  | Information will be maintained electronically. It will be password protected and maintained in an encrypted format. | Specify where the information will be stored electronically. |
|  | Information will be maintained in paper copy. Information will be stored in a locked area with limited access by authorized personnel. | Specify where the information will be stored. |
|  | Other | * + 1. Describe/explain.     2. Verify the storage method has received Security Risk Assessment (SRA) through [HS ServiceNow](https://ucihealth.service-now.com/itportal). |

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| Click or tap here to enter text. |

**10.9 Information/Biospecimen Transport:** If participant identifiers be transported or maintained on portable devices (e.g., laptop, smartphone, external hard drive, etc.), address the following:

* + 1. Specify the device/method of transportation.
    2. Explain why transporting or maintaining participant identifiers on portable devices is necessary.

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| Click or tap here to enter text. |

**10.10 Information/Biospecimen Retention:** Indicate how long research information/biospecimens will be retained.

In accordance with UCOP policy, information/biospecimens will be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

In addition, if the research involves the investigation of FDA regulated products, information/biospecimens will be retained for two years after an approved marketing application. If approval is not received, the information/biospecimens will be kept for 2 years after the investigation is discontinued and the FDA is notified per FDA sponsor requirements.

This research includes the potential for future secondary research using information/biospecimens which will be stored and maintained indefinitely.

Other, describe/explain.

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| Click or tap here to enter text. |

11. Information and Biospecimen Sharing

***This section is not applicable.***

All appropriate data use and/or materials transfer agreements will be finalized before sharing.

* **When transferring data to a non-profit, contact Wanda Seang, Ancillary Agreements Officer, at** [**wandas@uci.edu**](mailto:wandas@uci.edu)**.**
* **When transferring data to a for profit entity for clinical research, contact** [**or-ctcontracts@uci.edu**](mailto:or-ctcontracts@uci.edu)**.**
* **When transferring data to a for-profit, contact the** [**Industry Contract Officer**](https://innovation.uci.edu/about-uci-beall-applied-innovation/#team) **assigned to your department.**
* **When transferring tangible research material to an organization, contact** [**MaterialTransfer@uci.edu**](mailto:MaterialTransfer@uci.edu)**.**

**11.1 Return of Results:**

* + 1. Describe any clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly) and the plan for providing individual results to participants or others (e.g., primary care physician).
       1. Describe the validity and reliability of any results that will be offered to participants (e.g., tests are processed in a Clinical Laboratory Improvement Amendment (CLIA) approved lab). If a CLIA approved lab is not being used the test results cannot be used for medical treatment.
    2. If applicable, plan for offering participants any induvial results that are not clinically actionable.
    3. Describe the process for communicating results to participants and facilitating understanding of the results. In the description, include who will approach the participant regarding the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.
    4. Describe any plans to share results with family members (e.g. in the event a participant becomes incapacitated or deceased and the results could impact the participant or other blood relatives).
    5. If applicable, describe the plan to share overall study results with participants.

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| Click or tap here to enter text. |

**11.2 Multi-Site/Center Information Sharing:** Indicate whatinformation relevant to the protection of human participants will be recorded and shared between the participating sites. Select all that apply.

Not applicable

|  |  |  |
| --- | --- | --- |
| Information and Safety Monitoring  Interim Findings | Adverse Events  Unanticipated Problems to Participants or Others | Modifications/amendments to the protocol or consent document(s)  Other information that may impact risks to subjects or others, describe/explain. |

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| Click or tap here to enter text. |

**11.3 Sharing Within Scope:**

* + 1. Specify if information/biospecimens are shared with collaborators (i.e., researchers not covered under the UCI IRB), for purposes within the scope of the current project.
    2. Specify the collaborator and explain why they need access to the information/biospecimens
    3. Specify whether identifiable or de-identified (participants cannot be identified by other researcher) data will be shared.
    4. Provide a complete list of all identifiers to be shared and provide rationale.

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| Click or tap here to enter text. |

**11.4 State Mandated Reporting:** Each state has reporting laws that require some types of individuals to report some kinds of abuse (such as child or elder), and certain infectious diseases (such as HIV, TB) that are under public health surveillance.

* + 1. Specify if the UCI study team are likely to learn of abuse or infectious disease while conducting the research and whether they are obligated to report the information to state authorities (i.e. mandated reporters).
    2. Participants must be informed of the possibility of mandated reporting. If participant will not be informed these types of disclosures, please provide rationale.

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| Click or tap here to enter text. |

**11.5 Confidentiality Certificates:** Indicate whether a confidentiality certificate has been issued for the study research information.

|  | **Certificate Obtained** | **Required Action** |
| --- | --- | --- |
|  | Not applicable | N/A |
|  | Yes, research is *automatically* granted a certificate by the NIH, NIJ, or the CDC as a condition of the award or an equivalent protection as a condition of funding from another Federal agency. | **Requisite certificate language must be included in the** [**Consent Form**](https://research.uci.edu/human-research-protections/irb-forms/#irb-forms-1)**.** |
|  | Pending, a certificate has been/will be requested from NIH or FDA. Research involves a sensitive health-related topic that collects names or other identifiable, sensitive information pertaining to subjects. | **Requisite certificate language must be included in the** [**Consent Form**](https://research.uci.edu/human-research-protections/irb-forms/#irb-forms-1). Follow the [UCI Certificate of Confidentiality (CoC) Guidance](https://research.uci.edu/wp-content/uploads/equip-tip-Certificate-of-Confidentiality-Guidance.pdf) on how to apply for a CoC.  Attach the confidentiality certificate (when obtained). |

**11.6 Confidentiality Certificate Disclosure:** Indicate in what situations identifiable private information protected by a certificate will be disclosed. Select all that apply.

Not applicable

|  |  |
| --- | --- |
| No confidentiality disclosures are anticipated.  As required by Federal, State, or local laws, excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and subjects threats to harm themselves or others.  When necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and disclosed with the consent of such individual.  Disclosed with the consent of the individual to whom the information, document, or biospecimen pertains  Disclosed for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.  Other, describe/explain.   |  | | --- | | Click or tap here to enter text. | |

**11.7 NIH Data Sharing:** Indicate whether the study is subject to NIH data sharing requirements.

Not applicable

[NIH Policy for Data Management and Sharing](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html). Insert the following language into the consent: [Consent Language: NIH Data Management and Sharing (DSM)](https://research.uci.edu/wp-content/uploads/nih-dms-consent-language.docx)

[NIH Genomic Data Sharing Policy](https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html). Insert the following language into the consent: [Consent Language: NIH Genomic Data Sharing (GDS)](https://research.uci.edu/wp-content/uploads/informed-consent-template-language-for-gds.docx)

Other, describe/explain.

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| Click or tap here to enter text. |

**11.8 Future Contact with Participants:** If there is a plan to retain participant contact information to recruit them for future research, address the following:

* + 1. Describe the purpose of the future contact.
    2. Specify whether use of the contact information will be limited to the UCI study team.
       1. If applicable, describe who else could be provided with the contact information and criteria for approving requests.

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| Click or tap here to enter text. |

**11.9 Future/Secondary Research:** If information/biospecimens be shared, used again, or stored for undefined future research purposes beyond the aims/scope written in the current protocol (i.e. secondary research), address the following:

* + 1. Specify who will establish and manage the biorepository/registry/database.
    2. If biorepository/registry/database is managed by the UCI study team, address the following:
       1. Specify who on the UCI study team will manage the biorepository/registry/database (i.e., person responsible for receiving requests, stripping identifiers, distributing information/biospecimens).
       2. Provide the physical location where the information/biospecimens will be stored (i.e. building and room number, indicate if freezer is involved, etc.).
       3. Describe the security plan for the biorepository/registry/database.
          1. Specify if there are automated backup security systems to monitor storage equipment, including a backup power source in the event of a freezer failure or other emergency.
    3. Specify what information/biospecimens will be included in the biorepository/registry/database.
    4. Explain whether participant identifiers are required to manage the biorepository.
    5. Provide a complete list of all information/biospecimens to be shared and provide rationale.
    6. Describe the broadest possible future uses, including limitations or restrictions (if any) on future uses or users.
    7. Describe the procedures to release data or specimens, including the process to request a release, approvals required for release and who can obtain information or specimens.
    8. Specify how long information/biospecimens will be stored in the biorepository/registry/database.

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| Click or tap here to enter text. |

12. Risk/Benefit Assessment

**12.1 Risks:**

* + 1. Describe and assess any reasonably foreseeable risks of harm, discomforts, and hazards for each participant population. Risks can generally be categorized as physical, psychological, sociological, economic, and legal. A bullet point list is recommended.
    2. Include an assessment of their expected frequency (e.g., common – 65%, less common – 40%, unlikely – 5%, rare - <1%) and the seriousness (mild, moderate, severe).
    3. If this study will involve the collection of identifiable private information, include the risk of a potential breach of confidentiality.

***This is included in the UCI consent document attached.***

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| Click or tap here to enter text. |

**12.2 Risk Management:** Describe how the risks will be reduced or managed.

***This is included in a separate scientific protocol attached.***

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| Click or tap here to enter text. |

**12.3 Benefits:**

12.3.1If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below.

12.3.2Describe the potential benefits to society including the importance of the knowledge to be gained.

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| Click or tap here to enter text. |

**12.4 Alternatives to Participation:** Specify the alternatives to participation in the study available to prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable. Select all that apply.

No alternatives exist. The only alternative to study participation is not to participate in the study.

Routine standard of care available.

Other, describe/explain.

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| Click or tap here to enter text. |

13. Data And Safety Monitoring

***This section is not applicable.***

All clinical investigations involving greater than minimal risk to participants are, at a minimum, required to develop a data and safety monitoring plan to assure the safety and welfare of the research subjects. For more information, visit: [Data and Safety Monitoring for Clinical Research](https://research.uci.edu/human-research-protections/clinical-research/data-and-safety-monitoring-for-clinical-research/).

**13.1 Responsible Individuals:**

* + 1. Provide details of those individuals who will be responsible for the safety oversight of the protocol, including the relevant experience/expertise of everyone (for UCI PI-initiated studies conducted only at UCI, provide the names and titles as well).
    2. List who will be *locally* monitoring and collecting information on adverse events and/or unanticipated problems (e.g., UCI PI, Research Coordinator, etc.). Include the name, title and experience of the individual(s) and further describe each individual’s role in the oversight of participant participating in the protocol.

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| Click or tap here to enter text. |

* 1. **Frequency:**
     1. Specify how frequently accumulated protocol information will be reviewed and evaluated for participant safety, protocol conduct and progress, and, when appropriate, efficacy.
     2. Describe the events that would trigger an unscheduled review. Include stopping rules, rules for withdrawing participants, and un-blinding rules as appropriate.
     3. Describe the plan for annual reporting of the participants’ safety, and the protocol's conduct, progress, and efficacy, when appropriate.

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| Click or tap here to enter text. |

**13.3 Data Safety Monitoring Board (DSMB):** For clinical protocols involving a test article, it is common to have an *independent* DSMB. Specify whether the following requisite documentation is available and attach to ZOT IRB.

Not applicable, this study does not have an independent DSMB

Signed DSMB recommendation forms available

The finalized DSMB charter available

The finalized DSMB charter will be submitted before enrollment begins

1. Colleagues do not obtain consent for research or act as representatives of the investigators. [↑](#footnote-ref-2)