Human Research Protections (HRP) strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the ZOT IRB application process, email [OR-Web-Support@uci.edu](mailto:OR-Web-Support@uci.edu) for assistance.

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| INSTRUCTIONS |

This information is necessary for the HRP to verify the study follows [UCI HRP Policy](https://research.uci.edu/wp-content/uploads/all-hrp-policies.pdf) and [Statues](https://research.uci.edu/human-research-protections/irb-application-process/ethical-guidelines-regulations-and-statutes/).

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 HRP 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

**Short Title:** Specify the short study title.

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| Click or tap here to enter text. |

**Relying IRB Rationale:** Review [Eligibility Criteria: UCI is the Relying IRB](https://research.uci.edu/human-research-protections/single-irb-process/uci-is-the-relying-irb/) and indicate the rationale for UCI to serve as the Reviewing IRB.

Research is supported, or otherwise subject to regulation by any Federal department or agency that is a signatory of the 2018 Common Rule.

Research is an FDA-regulated clinical investigation.

Multi-site research conducted in the U.S. where the following is true: 1) the external IRB accredited/certified (e.g. AAHRPP, CARE-Q), or the organization is actively seeking accreditation/certification, and 2) the SMART IRB agreement is used.

**Exceptions:** Provide assurance that the research does not involve any of the following exceptions to cooperative research:

* more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe),
* research involving a highly specialized FDA-regulated medical product for which unique, localized expertise is required (\*Rare\*),
* research on drugs that is exempt from the requirements for an IND application under [§ 312.2(b)](https://www.ecfr.gov/current/title-21/part-312/section-312.2#p-312.2(b)),
* research on medical devices that meets the abbreviated requirements under [§ 812.2(b)](https://www.ecfr.gov/current/title-21/part-812/section-812.2#p-812.2(b)) or that meets the requirements for exempted investigations under [§ 812.2(c)](https://www.ecfr.gov/current/title-21/part-812/section-812.2#p-812.2(c)),
* research that is an investigator initiated/authored [clinical investigation](https://www.ecfr.gov/current/title-21/part-56#p-56.102(c)) not conducted under a UC Consortium,
* [expanded access](https://www.fda.gov/news-events/public-health-focus/expanded-access), [compassionate use](https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices#compassionate), or [right to try](https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB1668).

The research does not involve any of the exceptions listed above.

**IRB Agreement:** Indicate which IRB agreement applies.

Advarra IRB

National Cancer Institute Central Institutional Review Board (NCI CIRB)

SMART IRB (CHOC, MHS, NEALs, StrokeNet, UC). The External IRB must be a [Participating Institution](https://smartirb.org/participating-institutions/) that has signed v3.0 of the SMART IRB Agreement.

Western Copernicus Group IRB (WCG)

**SMART IRB:** Indicate the communication platform that will be used.

[**SMART IRB Online Reliance System**](https://smartirb.org/reliance/). Provide the [ORS](https://reliance.smartirb.org/) tracking number (optional).

[**IRB Reliance Exchange (IREx)**](https://www.irbexchange.org/p/)

SMART IRB Letter of Acknowledgement (LOA). Attach: External IRB’s version of the LOA.

2. PARTICIPANTS

**Participant Populations:** Select all that apply.

Adults

Adults not able to consent for themselves (e.g., cognitively impaired or medically incapacitated)

Pregnant individuals/fetuses

Neonates

Prisoners

Children (minors)

American Indian or Alaska native tribes

UCI inpatients or outpatients

UCI students/staff/faculty

**UCI Interaction/intervene:** Specify whether the UCI study team will interact or intervene with participants.

Yes

No, UCI will not be recruiting own subset of subjects. Instead, UCI will be accessing identifiable data/records/biospecimens for analysis only.

No, *describe/explain*.

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| Click or tap here to enter text. |

**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*.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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. |

**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. |

3. SCREENING PARTICIPANTS WITHOUT CONSENT

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

**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: 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. | |
|  | UCI Student records or student health medical records | | 1. Specify the types of education records. 2. Attach: [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 [UCI Registrar FERPA Analyst](https://www.reg.uci.edu/privacy/) for UCI student records. | |
|  | | 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: IRB approved consent form that documents the sharing of information. |
|  | | 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.    1. If yes, attach: IRB approved consent form that documents the sharing of information. |

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| Click or tap here to enter text. |

**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.

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

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| Click or tap here to enter text. |

4. RECRUITING PARTICIPANTS

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

**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: Recruitment letter to be signed by the treating physician. |
|  | Email/Postal Mail/Phone | 1. Specify how contact information will be obtained. 2. Attach: 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: Recruitment material. |
|  | Individual/Group/Class Presentation | 1. Specify whether the location is public (open access) or private (controlled access). 2. Attach: Recruitment script. |
|  | IRB approved participant screening protocol | Specify IRB number(s). |
|  | Newspaper/Radio/Television | 1. Specify where recruitment will be posted. 2. Attach: 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. INFORMED CONSENT

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

|  | **UCI 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 Consent and/or assent form. 2. 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: Consent and/or assent form. |
|  | Verbal/implied consent and/or parental permission | Attach: [Study Information Sheet](https://research.uci.edu/wp-content/uploads/study-information-sheet.docx) |
|  | Verbal/implied assent (child or adult unable to consent) | Attach: 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 (Non-exempt research) | N/A |
|  | No consent or parental permission |  |
|  | No assent (child or adult unable to consent) | N/A |
|  | Not applicable, study does not involve a consent process at UCI. | N/A |

**Consent Process Description:** Provide a step-by-step description of the consent process, including:

1. Provide a breakdown of the groups and procedures for each consent/assent process (i.e., consent/assent process applies only to certain parts of the study).
2. Describe the type of setting(s) in which the consent 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 to participate 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.
6. If applicable, explain if permission will be obtained from individuals other than parents, and if so, how will the study team determine that the individual providing permission has the authority to do so.

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| Click or tap here to enter text. |

**Non-English Speaking Participants:**

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*.

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| Click or tap here to enter text. |

6. HIPAA AUTHORIZATION

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

**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

**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: [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: [Appendix - Waivers of Consent, Signed Consent, or HIPAA Authorization](https://research.uci.edu/wp-content/uploads/Appendix-Waivers-of-Consent-Signed-Consent-or-HIPAA-Authorization.docx) |
|  | No HIPAA authorization | Attach: [Appendix - Waivers of Consent, Signed Consent, or HIPAA Authorization](https://research.uci.edu/wp-content/uploads/Appendix-Waivers-of-Consent-Signed-Consent-or-HIPAA-Authorization.docx) |

7. STUDY INFORMATION AND BIOSPECIMENS SOURCES OTHER THAN THE

PARTICIPANT (SECONDARY DATA ANALYSIS)

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

**Information/Biospecimen Source:** Select all that apply and address the required action, as applicable.

|  | **Source of Eligibility Information** | | **Required Action** | |
| --- | --- | --- | --- | --- |
|  | UCI Student records or student health medical records | | 1. Specify the types of education records. 2. Attach: [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 [UCI Registrar FERPA Analyst](https://www.reg.uci.edu/privacy/). | |
|  | | Direct access to UCI Health medical records | | 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. |

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|  | 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)). |

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|  | 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.    1. If yes, attach: IRB approved consent form that documents the sharing of information. |

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| Click or tap here to enter text. |

**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).

* 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.

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

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| Click or tap here to enter text. |

8. PRIVACY AND CONFIDENTIALITY

**Identifiable 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) |

**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. |

**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. |

**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. |

**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. |

**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. |

**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. |

9. 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)**.**

**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. |

**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. |

**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. Describe the broadest possible future uses, including limitations or restrictions (if any) on future uses or users.
2. Specify who will establish and manage the biorepository/registry/database.
   1. If applicable, 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).
3. Specify what information/biospecimens will be included in the biorepository/registry/database.
4. If applicable, explain why participant identifiers are required to manage the biorepository.
5. Describe what information/biospecimens be shared with researchers including whether participants identifiers will be shared.
6. If biorepository/registry/database is managed by the UCI study team, address the following:
   1. **Describe the process for researchers to request information/biospecimens. Include v**erification that documentation of the recipients' IRB approval, as applicable for human subject research, will be kept on file.
   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. 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.
7. Specify how long information/biospecimens will be stored in the biorepository/registry/database.

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| Click or tap here to enter text. |

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