PI WORKSHEET: Considerations for Relying on an External IRB Review

This worksheet is required for the following submission types when research involves a request to rely on an external IRB: Expedited research or Full Committee research.

The purpose of this worksheet is to provide considerations that the institution may evaluate when considering requests to outsource review to a commercial IRB or to require a pSite’s IRB to serve as sIRB. For more information, visit: [UCI is the Relying IRB](https://research.uci.edu/human-research-protections/single-irb-process/uci-is-the-relying-irb/).

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

* 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. Single IRB Review Criteria

**2.1 Eligibility Criteria:** The following are circumstances in which UCI may rely on an external IRB for review of a multisite study or collaboration. (Check if “Yes.” All must be checked.)

[ ]  The study is determined to involve Human Research.

[ ]  UCI is engaged in the research activities.

[ ]  The study is not determined to be Exempt.[[1]](#endnote-2)

[ ]  The external IRB and performance sites are in the United States.

[ ]  The external IRB maintains an OHRP-approved Federalwide Assurance (FWA).

[ ]  At least one of the following is true (check all that apply):

[ ]  the study is federally funded (PI anticipates NIH or federal funding)

[ ]  More than single IRB review is not required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

[ ]  Research for which any Federal department or agency determines and documents that the use of a single IRB is not appropriate for the particular context.

[ ]  the study is FDA-regulated cooperative research

[ ]  More than single IRB review is not required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

[ ]  Research does not involve a highly specialized FDA-regulated medical product for which unique, localized expertise is required (\*Rare\*).

[ ]  Research does not involve drugs that are 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 does not involve medical devices that meet 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 is not an investigator initiated/authored [clinical investigation](https://www.ecfr.gov/current/title-21/part-56#p-56.102(c)), unless conducted under a UC cancer consortium.

[ ]  Not [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).

[ ]  other cooperative research that meets the following criteria (all must be checked):

[ ]  Research does **not** involve any (of the above) HHS or FDA exceptions to cooperative research.

[ ]  UCI has a master service agreement with the external IRB or the SMART IRB agreement v3.0 is used, and

[ ]  [IRB staff to confirm] A UCI director has reviewed the external IRB’s human research protection program plan and policies to confirm, at minimum, that their program has a quality assurance program and is otherwise appropriate to serve as the Reviewing IRB.

**2.2 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.

[ ]  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).

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| Click or tap here to enter text. |

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

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

[ ]  Western Copernicus Group IRB (WCG)

1. Considerations to Rely on a Commercial IRB

[ ]  ***This section is not applicable.***

The institution will evaluate on a case-by-case basis ceding IRB review. The following characteristics of the study will be evaluated to determine whether to rely on a Commercial IRB (e.g., Advarra, WCG, etc.). (At least one of the following considerations should be true)

[ ]  The project is commercially sponsored research.

[ ]  The UCI is the lead site of a Multi-Site Study and the institution has elected to use a commercial IRB for the review of the study.

[ ]  Other relevant considerations.

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| Click or tap here to enter text. |

1. [IRB Staff to Confirm] General Considerations for Relying on an Other (Non-Commercial) IRB

[ ]  ***This section is not applicable.***

The following are additional considerations for evaluating the institution’s willingness to rely on an institution with a valid OHRP-approved Federalwide Assurance (FWA). (At least one of the following considerations should be true)

[ ]  Single IRB review is mandatory.

[ ]  The reviewing IRB has sufficient expertise and experience reviewing and overseeing research of similar nature to the proposed study.

[ ]  The reviewing IRB has sufficient expertise with certain features of the protocol or the participant population that may pose special concerns (e.g., recruitment of socially or economically disenfranchised populations, local cultural mores, or unique clinical circumstances).

[ ]  Whether relying on an external IRB review could create or mitigate unique institutional risks, such as conflicts of interest.

[ ]  Implications for the institution of the decision, including:

[ ]  analysis of lost research opportunities (i.e., unwillingness of a sponsor or funder to allow local);

[ ]  the additional administrative time and costs associated with establishing authorization agreements.

[ ]  Resources needed by the study team to learn and adhere to the policies and procedures of the reviewing IRB.

1. Participants

**5.1 Participant Populations:** **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

**5.2 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. |

**5.3 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** |
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| 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. |

**5.4 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. |

**5.5 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. |

1. Screening Participants Without Consent

[ ]  ***This section is not applicable.***

**6.1 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. |

**6.2 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. |

1. Recruiting Participants

[ ]  ***This section is not applicable.***

**7.1 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[[2]](#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. |

1. Informed Consent

**8.1 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 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 the consent and/or assent form. |
|[ ]  Verbal/implied consent and/or parental permission | Attach the [Study Information Sheet](https://research.uci.edu/wp-content/uploads/study-information-sheet.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 | N/A |
|[ ]  No assent (child or adult unable to consent) | N/A |
|[ ]  Emergency exception to informed consent  | N/A |

* 1. **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:**
		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. |

 9. HIPAA Authorization

[ ]  ***This section is not applicable.***

**9.1 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

**9.2 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) |

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

[ ]  ***This section is not applicable.***

**10.1 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) or Delia Tifrea (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. |

 11. Privacy and Confidentiality

**11.1 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) |

**11.2 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. |

**11.3 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

|  |  |
| --- | --- |
| [ ]  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. |

**11.5 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. |

* 1. **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. |

**11.7 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. |

 12. 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****.**
* **When transferring data to a for profit entity for clinical research, contact** **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****.**

**12.1 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. |

* 1. **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. |

* 1. **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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* 1. **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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1. For a HHS funded or supported, non-exempt collaborative research study involving human subjects, any site that is engaged must rely on the sIRB for review. If the research as a whole is non-exempt and an institution is engaged in the research (even if their portion of the research is exempt), then the institution must rely on the sIRB. *(Correspondence with OHRP, September 27, 2022)*. [↑](#endnote-ref-2)
2. Colleagues do not obtain consent for research or act as representatives of the investigators. [↑](#footnote-ref-2)