**Protocol Narrative: Exempt Research Self-Determination**

This information is necessary for the Education and Quality Improvement Program (EQUIP) to conduct a quality assurance review of the self-determination.

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, EQUIP 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.

 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. Provide a summary of the background for this study and explain how it will contribute to existing knowledge.
		2. Describe the purpose, specific aims or objectives and specify the hypotheses or research questions to be studied.

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| Click or tap here to enter text. |

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.
		2. Specify the setting (public vs private) and location where research procedures will be conducted
		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). Maintain in the research record 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.

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* 1. **Deception or Withholding of Information:** If the study will involve any type of deception or incomplete disclosure to participants, respond below to provide the requested information.
		1. Provide scientific rationale for the use of deception or incomplete disclosure in the research.
		2. Describe the information that will be withheld from, or misinformation that will be provided to participants. For exempt research, the consent document must disclose the use of deception/incomplete disclosure.
		3. Explain whether the subjects would consider the information being withheld from them important when deciding about whether to participate in the research.
		4. Explain why the research could not practicably be carried out without the alteration of consent.
		5. Explain when and how the participants will be told of the deception/incomplete disclosure. Maintain in the research record the debriefing script, as applicable.
		6. Specify if participants will be given an opportunity to withhold use of their data given that they will not be fully informed about the purpose of the study until after data collection. For guidance, see [APA Ethical Standard 8.07](https://www.apa.org/ethics/code#807).

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**2.5 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.

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

**2.6 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.

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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.

[ ]  Adults

[ ]  Pregnant individuals/fetuses

[ ]  UCI inpatients or outpatients

[ ]  UCI students/staff/faculty

**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.

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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.

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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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* 1. **Expected/Target Number:** Explain how the target sample size was determined (e.g., power analysis; precision estimation).

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**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) | Maintain in the research record 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.
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|[ ]  Non-UCI Student records or student health medical records | * + 1. Specify the types of education records.
		2. Maintain in the research record: [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.
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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.
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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** |
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|[ ]  Colleagues provide participants with information about the research and how to contact investigators[[1]](#footnote-2)  |  |
|[ ]  Colleagues seek or obtain the participants’ permission for investigators to contact them1 |  |
|[ ]  Email/Postal Mail/Phone | 1. Specify how contact information will be obtained
2. Maintain in the research record 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. Maintain in the research record the recruitment material.
 |
|[ ]  Individual/Group/Class Presentation | * + 1. Specify whether the location is public (open access) or private (controlled access).
		2. Maintain in the research record the recruitment script.
 |
|[ ]  IRB approved participant screening protocol | Specify IRB number(s). |
|[ ]  Newspaper/Radio/Television | * + 1. Specify where recruitment will be posted.
		2. Maintain in the research record 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. Maintain in the research record recruitment material.
 |
|[ ]  Study team will approach students, employees, patients, economically, educationally, or cognitively disadvantaged  | Maintain in the research record **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** |
| --- | --- | --- |
|[ ]  Verbal/implied consent and/or parental permission | Maintain in the research record the [Study Information Sheet](https://research.uci.edu/wp-content/uploads/study-information-sheet.docx).  |
|[ ]  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. |
|[ ]  No consent  |  |

**7.2 Consent Process Description:**

* + 1. Provide a breakdown of the groups (as applicable) and consent procedures for each.
		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 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.

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| Click or tap here to enter text. |

 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** |
| --- | --- | --- |
|[ ]  Non-UCI Student records or student health medical records | * + 1. Specify the types of education records.
		2. Maintain in the research record 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.
 |
|[ ]  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).

[ ]  ***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

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| [ ]  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 | [ ]  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. |

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

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| Click or tap here to enter text. |

**10.4 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** |
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|[ ]  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.

[ ]  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****.**
* **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****.**

**11.1 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. |

**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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 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.

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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. |

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