**Protocol Narrative: Not Human 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. The EQUIP uses HRP-310-WORKSHEET-Human Research Determination to verify human research determinations.

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. **Purpose:** Describe the purpose, specific aims or objectives of the activity and specify the hypotheses or questions to be studied.

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| Click or tap here to enter text. |

* 1. **Activity:** Using lay language, provide a detailed chronological description of the activity.

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2. Secondary Analysis of Existing De-Identified Information/Biospecimen

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

**2.1 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** | **Max Number of Individuals** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |
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**2.2 Max Number:** Explain how the max number was determined (e.g., cohort discovery).

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

|  | | **Source of Information/Biospecimen** | **Required Action** |
| --- | --- | --- | --- |
|  | Center for Artificial Intelligence in Diagnostic Medicine (CAIDM)  IRB #20184417 |  |
|  | Experimental Tissue Resource (ETR)  IRB #20128716 |  |
|  | Health Enterprise Information & Analytics IRB #20128757 |  |
|  | 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. |
|  | 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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* 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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3. 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)**.**
  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. Provide a complete list of all information/biospecimens to be shared and provide rationale.

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| Click or tap here to enter text. |

**3.2 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, 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. Provide a complete list of all information/biospecimens to be shared and provide rationale.
    5. Describe the broadest possible future uses, including limitations or restrictions (if any) on future uses or users.
    6. Describe the procedures to release data or specimens, including the process to request a release, clearance required for release (e.g., non-human subjects research determination), and who can obtain information or biospecimens.
    7. Specify how long information/biospecimens will be stored in the biorepository/registry/database.

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