|  |  |
| --- | --- |
| Summary of the Research |  |
| Location Where Research Will Be Carried Out |  |
|

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| There Will Be Interaction with Subjects

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

 |

 |  |
| Explanation of How Selection of Subjects Will Be Equitable |  |
| Explanation of How Subjects Privacy Will Be Protected |  |
|

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Surveys Instruments Will Be Used

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

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 |  |
| Please complete the Research Information Sheet ([Consent Templates > Exempt Research Subject Information Sheet](http://icahn.mssm.edu/research/pphs/researcher/forms)) and attach the completed document.  |

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| Research Information Sheet |  |  |

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| PI must attest to the following. \* Selection of subjects is equitable. \* Research Information Sheet will be provided to subjects.  |

NOTE: No prisoners can be involved in exempt research. Typically, no interactions with minors can occur in exempt research.

NOTE: If you are accessing PHI, even if you are not recording identifiers, HIPAA regulations may apply. In some cases, a request for Waiver of HIPAA authorization or Alteration of HIPAA may be granted.

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| Exemption Categories

|  |  |
| --- | --- |
|  | (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |
|  | (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation. Does not apply to interviews, surveys or interactions with children as subjects. SUBMIT A COPY OF ANY SURVEY INSTRUMENTS YOU WILL USE. |
|  | (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |
|  | (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. GUIDANCE on this category: (i) Existing means previously collected and in existence at the time of submission of this form. (ii) Publicly available means completely unrestricted access for anyone, and no requirements or approval process needed to access the data (an example is census data). (iii) Identifiers linked to the participants means the data is coded and the researcher or collaborator has the ability use the code (subject ID#) to go back to identifiers. (iv) Application must include listing of all information (variables) to be obtained, how data/specimens will be labeled, and the source. |
|  | (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. |
|  | (6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. |

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| --- | --- | --- | --- | --- | --- |
| Health Related Information Will Be Viewed, Recorded, or Generated

|  |  |
| --- | --- |
|  | Yes |

 |

|  |  |
| --- | --- |
|  | No |

 |

 |
| Description of Health Information That Will Be Viewed, Recorded, or Generated | character count: 0 |
|

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Non-Health Related Information Will Be Viewed or Recorded

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

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| --- | --- | --- | --- | --- | --- |
| HIV / AIDS Related Information Will Be Viewed or Recorded

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

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| --- | --- | --- | --- | --- | --- |
| Data That Will Be Viewed, Recorded, or Generated Contains ANY of the Following Directly Identifiable Information

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

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 |  |
| Check all that apply: |  |  |
| Will Be Viewed

|  |  |
| --- | --- |
|  | Name |
|  | Social Security Number |
|  | Medical Record Number |
|  | Address by street location |
|  | Telephone number |
|  | Fax number |
|  | Web Uniform Resource Locators (URLs) |
|  | Internet Protocol (IP) Address |
|  | Health Plan Beneficiary Number |
|  | Account Number |
|  | Certificate |
|  | License Number |
|  | Vehicle Identification Number (Including License Plate Numbers) |
|  | Full-Face Photographic Images |
|  | Biometric Identifiers (Finger and Voice Prints) |
|  | Geographical Subdivisions Smaller Than a State |
|  | All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date) |
|  | Email Address |

 |  |  |
| Will Be Recorded

|  |  |
| --- | --- |
|  | Name |
|  | Social Security Number |
|  | Medical Record Number |
|  | Address by street location |
|  | Telephone number |
|  | Fax number |
|  | Web Uniform Resource Locators (URLs) |
|  | Internet Protocol (IP) Address |
|  | Health Plan Beneficiary Number |
|  | Account Number |
|  | Certificate |
|  | License Number |
|  | Vehicle Identification Number (Including License Plate Numbers) |
|  | Full-Face Photographic Images |
|  | Biometric Identifiers (Finger and Voice Prints) |
|  | Geographical Subdivisions Smaller Than a State |
|  | All Elements of Dates for Dates Directly Related to an Individual (i.e., Birth Date, Admission Date, Discharge Date) |
|  | Email Address |

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| Data Collection Sheet |  |  |

 |  |  |
| A Data Collection Sheet is required if you are either performing a retrospective review, or your study meets the category of exempt 4 research, or your study meets the category of expedited 5 research. Please upload it here. |

|  |
| --- |
|  |
| Data Collection Source(s)

|  |  |
| --- | --- |
|  | Participant |
|  | Medical Chart (Paper or Electronic) |
|  | Data Warehouse |
|  | External Site |
|  | Other Research Study |
|  | Pathology |
|  | Clinical Database |

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| Obtaining HIPAA Authorization

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

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 |
| Requesting Waiver or Alteration

|  |  |
| --- | --- |
|  | Waiver |
|  | Alteration |

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|

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| --- | --- | --- | --- | --- | --- |
| Research Could Be Practicably Conducted Without Access to and Use of Protected Health Information (PHI)

|  |  |
| --- | --- |
|  | Yes |

 |

|  |  |
| --- | --- |
|  | No |

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 |
| Explanation Why Research Could Not Be Practicably Conducted Without a Waiver or Alteration of Authorization |  |
|

|  |  |
| --- | --- |
| How PHI Will Be Protected from Improper Use or Disclosure |  |

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| --- | --- | --- | --- | --- | --- |
| PHI Will Be Destroyed at the Earliest Opportunity Consistent with the Research

|  |  |
| --- | --- |
|  | Yes |

 |

|  |  |
| --- | --- |
|  | No |

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| --- | --- | --- | --- | --- | --- |
| PHI Will Be Shared

|  |  |
| --- | --- |
|  | Yes |

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|  |  |
| --- | --- |
|  | No |

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 |  |
| PI must attest to the following.\* I assure that the protected health information (PHI) will not be disclosed to any other person or entity not listed on this form except where required by law or for the authorized oversight of this research project. If at any time I want to reuse this PHI for other purposes or disclose it to other individuals or entities I will seek approval from the IRB.  |

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| --- | --- |
| Location Where Data Will Be Stored |  |

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| --- | --- | --- | --- | --- | --- | --- | --- |
| How will the data be stored?

|  |  |
| --- | --- |
|  | With a Code That Can Be Linked to the Identity of the Participant |
|  | Anonymously |
|  | Other |

 |  |

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| --- | --- | --- | --- | --- | --- |
|  |  | **Research Personnel Responsible for:** | **Accessing Data** | **Receipt or Transmission of Data** |  |
| **X**  | 1 |  |

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| --- | --- |
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| --- | --- |
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| **X**  | 2 |  |

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| **X**  | 3 |  |

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| Duration Data Will Be Stored |  |
| Steps That Will Be Taken to Secure the Data During Storage, Use, and Transmission |  |
|  |  |
| Data Analysis Plan Including Any Statistical Procedures |  |
|  |