**TEMPLATE: Research Involving Secondary Use of Data, Documents, Records or Specimens**

**Purpose:** Secondary research refers to the research use of information or biospecimens that were collected for another purpose such as clinical care, education records, or a different research project. If your proposed project involves any activities other than the secondary use of data, documents, records or specimens do not use this form.

**Protocol Title:**

**Principal Investigator Name:**

**Version Date:**

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| Section 1: Basic Information |

**1.1** Describe the aims, hypothesis, purpose and study procedures:

**1.2** Select the provider of the information and/or biospecimens (select all that apply):

|  |  |
| --- | --- |
| [ ]  Public source | Name of source:        |
| [ ]  Repository | Name of repository:        |
| [ ]  Commercial source | Name of commercial source:        |
| [ ]  Collaborator  | Name of collaborator:        |
| [ ]  Other | Describe:       |

**1.3** Describe the secondary data, documents, records or specimens that you will have access to (*including* *internet links*, *names of datasets, student records, specimens, databanks, URLs, etc.*):

**1.4** Identify how the data, documents, records or specimens were originally gathered:

**1.5** Provide the date range (*MM/DD/YYYY*) of the data, documents, records or specimens to be analyzed or collected: From:        to

**1.6** Enter the number of charts/records/specimens to be reviewed or analyzed (as determined by a sample size analysis or sponsor requirement):

**1.7** Do all the data, documents, records or specimens already exist at the time this study is being submitted for initial IRB review? ☐ Yes ☐ No

*If no*, explain:

**1.8** Identify if this research will include information on any of the following populations (check all that apply):

|  |  |  |
| --- | --- | --- |
| [ ]  Children | [ ]  Prisoners | [ ]  Induced Pluripotent Stem Cells |
| [ ]  Pregnant Women | [ ]  Students |  |
| [ ]  Neonates | [ ]  Human Embryonic Stem Cells |  |

**1.9** Will you have access to personally identifiable information (such as names, addresses, medical record numbers, unique identifiers, etc.)?

[ ]  Yes [ ]  No

*If yes*, indicate the earliest opportunity you will use to destroy all personal identifiers obtained and recorded:

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| --- |
| [ ]  Upon data entry and validation |
| [ ]  At completion of data analysis |
| [ ]  At completion of specimen processing |
| [ ]  If there are no plans to destroy the identifiers please provide justification:       |

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| Section 2: CODED DATA/WORKING WITH COLLABORATORS |

**2.1** Will you be working with a collaborator on this project? [ ]  Yes [ ]  No

*If yes*, describe the role of your collaborator. Is their role limited to providing specimens or will the collaborator be involved in study design, management, analysis, manuscript preparation? Explain:

**2.2** Select what agreements are in place with the provider of the information and/or biospecimens, and upload to the electronic application, if applicable: (select all that apply)

|  |
| --- |
| [ ]  Data Use Agreement (DUA) |
| [ ]  Material Transfer Agreement (MTA) |
| [ ]  Attestation from providers that the recipient will not have access to identifiers or key |
| [ ]  Other contract/agreement  |
| [ ]  Not Applicable |

**2.3** Will you be receiving information/biospecimens that are coded? (Coded data has identifying information (*such as name or social security number) that would enable the research team to ascertain the identity of the individual to whom the private information or specimens pertain which is replaced with a “code”, i.e., number, letter, symbol, or combination thereof*). [ ]  Yes [ ]  No

*If yes*, does an identity key exist for this data? [ ]  Yes [ ]  No

*If yes,* will researchers be granted access to the identity key? [ ]  Yes [ ]  No

**2.4** Will the collaborator collect the information/biospecimens specifically for your research through an interaction or intervention with living individuals?

[ ]  Yes [ ]  No

*If yes*, explain:

|  |
| --- |
| Section 3: PROTECTION OF DATA, DOCUMENTS, RECORDS OR SPECIMENS |

**3.1** Indicate how the data, documents, records or specimens that you obtain and/or the study information you record will be adequately protected from improper use and disclosure.

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| --- |
| [ ]  All electronic data and recorded information will be on an authorized system computer requiring a password for access. |
| [ ]  Private personal computers, laptops and portable devices will not be used or stored or access the data  |
| [ ]  Attestation from providers that the recipient will not have access to identifiers or key |
| [ ]  All electronic data recorded information will be encrypted  |
| [ ]  All paper records will be stored in a locked room/file-cabinet with access limited to the study team. |
| [ ]  All specimens will be stored in a secured/locked lab or freezer with access limited to the study team. |
| [ ]  I will obtain a Certificate of Confidentiality; explain:       |
| [ ]  Other; describe:       |

**3.2** Research involving data, documents, records or specimen pose the risk of loss of confidentiality. Are there any other risks besides breach of confidentiality?

[ ]  Yes [ ]  No

*If yes*, describe:

|  |
| --- |
| Section 4: DATA OR SPECIMEN BANKING FOR FUTURE USE |

*Data or specimen banking for future use is not to be confused with holding data or specimens for analysis at a later time for this project.*

4.1If congruent with any applicable consent, authorization or agreement, will identifiable data or identifiable specimens be banked for future use in another research project?

[ ]  Yes [ ]  No

*If yes*, describe where the data or specimens will be stored, how any personal identifiers will be maintained and the procedures to release data, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. (A separate repository protocol may be required):