**TEMPLATE: Not Human Subject Research Determination**

**Instructions:** To obtain a Not Human Subjects Research determination from the IRB, submit this form in Huron. The IRB uses Worksheet HRP-310: Human Research to determine whether an activity is human subjects research. This worksheet can be found in the Huron Library or [HRPP Website](https://vpr.tamu.edu/human-research-protection-program/toolkit/worksheets/), and may be used as a guide. ***All human subjects research must be reviewed by the IRB prior to initiation.***

**Protocol Title:**

**Principal Investigator Name:**

**Version Date:**

|  |
| --- |
| Section 1: DESCRIPTION OF STUDY ACTIVITIES |

**1.1** Describe the aims, hypothesis, purpose, study procedures, and TAMU’s scope of work:

**1.2** Identify if an external collaborator will assist with this project. Select all that apply:

|  |
| --- |
|[ ]  No external collaborator(s) will assist in data collection or data analysis for this project |
|[ ]  This is a multi-site or collaborative research project |
|[ ]  External collaborator(s) will only receive access to de-identified or coded data collected for this project |
|[ ]  External collaborator(s) will only provide access to de-identified or coded data for use in this project |
|[ ]  External collaborator(s) will seek approval from their own institution’s IRB for this project |
|[ ]  Other:       |

**1.3** Describe how the information produced by this project will be disseminated. Select all that apply:

|  |
| --- |
|[ ]  Publishing project findings in national journals |
|[ ]  Summarizing findings in progress reports for funders |
|[ ]  Publishing results in dissertation or thesis  |
|[ ]  Present findings at national conferences and meetings of professional associations |
|[ ]  Presenting program results to local community groups and other local stakeholders |
|[ ]  Creating and distributing program materials, such as flyers, guides, pamphlets |
|[ ]  Creating toolkits of training materials and curricula for other communities |
|[ ]  Sharing findings through social media or on an organization's website |
|[ ]  Other:       |

|  |
| --- |
| *Definitions* |
| * *Interventions* include both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
 |
| * *Interactions* include communication or interpersonal contact between investigator and subject (e.g., surveys, interviews, *even if anonymous*)
 |

**1.4** Does this project involve obtaining information about a living individuals through an **intervention** or **interaction**? [ ]  Yes [ ]  No

 *If yes*, complete Sections 2

 *If no*, complete Section 3

|  |
| --- |
| Section 2: PRIMARY DATA |

**2.1** Describe what data will be collected, how, and by whom:

**2.2** Will any surveys, questionnaires, or interviews guides be used? [ ]  Yes [ ]  No

 *If yes*, attach all study materials to the Huron application, in the *Local Site Documents* page.

**2.3** Will the researchers obtain any identifiers that will allow the identity of the study participants to be known or ascertained? [ ]  Yes [ ]  No

|  |
| --- |
| Section 3: SECONDARY USE  |

**3.1** Describe the data/samples researchers will have access to, including names of datasets, repositories, URLs, etc.:

**3.2** Identify how the data/samples were originally gathered:

**3.3** Select the source 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:       |

**3.4** Select what agreements are in place with the provider of the information and/or biospecimens, and upload to the Huron submission, 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, describe:        |
| [ ]  Not Applicable |

**3.5** Will you be receiving information/biospecimens that are coded? (*Coded means that identifying information has been linked to a number or a letter and there is a key that connects the code to the identifying information.*)

[ ]  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

**3.6** 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:

**3.7**  If you are working with a collaborator, will your collaborator collect the information/biospecimens specifically for your research through an interaction or intervention with living individuals?

[ ]  Yes [ ]  No [ ]  Not Applicable

*If yes*, explain: