**TEMPLATE: 118 Determination Request**

**Purpose:** To provide documentation for the 118 determination request. The 118 determination is not approval by the IRB. A complete application will need to be submitted and approved by the IRB prior to involving any human subjects in this study. No work with human subjects, including recruitment, may be conducted under this determination.

**Protocol Title:**

**Principal Investigator Name:**

**Version Date:**

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| Section 1: FUNDING INFORMATION |

**1.1** Is your study funded (either directly or through a sub-award) by a Federal Agency (e.g., NIH, NSF, DOD, DOE, DOJ, etc.)?  Yes  No

**1.2** Is TAMU the primary awardee of this grant?  Yes  No

**1.3** Is this a collaborative project that involves multiple institutions?  Yes  No

*If yes*, identify all institutions involved in this project:     

**1.4** Will IRB approval be sought outside of TAMU for this project?  Yes  No

*If yes*, identify which institution will provide IRB oversight for this project:     

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| Section 2: Information request |

***46.118 Determinations*** can be granted to satisfy federal sponsor requirements (e.g., Just-In-Time) to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects. Under the federal regulations (§46.118) certain types of applications for grants are submitted with the knowledge that subjects may be involved, but definite plans would not normally be set forth in the application or proposal. These can fall under three categories:

* institutional type grants when selection of specific projects is the institution’s responsibility;
* research training grants in which the activities involving subjects remain to be selected; and,
* projects in which human subjects’ involvement will depend upon completion of instruments, prior animal studies, or purification of compounds.

**2.1** Explain why human subjects study information is not available at the time of this request:

**2.2** Identify the phase/specific aim of the project in which human subjects research is expected to be initiated:

**2.3** Provide the expected date that a full IRB application will be submitted to the IRB:

**2.4** Is there any additional information about this project that you would like to share with the HRPP/IRB?  Yes  No

*If yes*, please describe:     

**2.5** I acknowledge that no work with human subjects, including recruitment, may be conducted under this 118 determination.

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| Section 3: Instructions For Huron |

***The 118 determination request and grant proposal must be uploaded to Huron.***

Researchers submitting a request for a 118 determination from the IRB, please follow these instructions:

1. Click the **Create New Study** button
2. Complete the study form questions as appropriate or required, paying specific attention to the following questions:
   1. **Basic Information page, *Question 3*:** indicate that documentation of IRB review of the grant is needed AND researchers will not begin any human subject research until IRB review and approval has been granted.
   2. **Basic Information page, under *Attach the protocol*:** attach the 118 Determination Request (current form).
   3. **Funding Source page**: add the funding source and related information including the Maestro Funding Source, and upload the entire grant proposal or contract.
   4. On other pages not mentioned specifically, if you do not have all of the developed or required materials (e.g. consent documents, recruitment materials, etc.), you may leave those items blank. Note: You will later be required to complete these items once they have been developed.