**HRP-503d – TEMPLATE – DEVELOPMENTAL APPROVAL**

**Purpose:** To provide documentation for developmental approval under 45 CFR 46.118. Developmental approvals are applicable in certain types of grants, cooperative agreements, or contracts with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. A complete IRB application will need to be submitted and approved by the IRB prior to involving any human subjects in the study. No work with human subjects, including recruitment, may be conducted under this determination.

**Protocol Title:**

**Principal Investigator Name:**

**Department Head/Chair Name:**

**Version Date:**

**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 AU 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 AU for this project? [ ]  Yes [ ]  No

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

**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** Briefly describe the purpose of the research study (<500 words).

**2.2** Describe the role of the AU research team.

**2.3** Describe the research activities involving human subjects. Specify whether existing data or specimens will be used and, if yes, specify the source of the data or specimens.

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

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

**2.6** Provide the anticipated timeline for the human subjects components to be developed and implemented, as well as an anticipated timeline for when the completed IRB application will be submitted for IRB review:

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

*If yes*, please describe:

**2.8** [ ] I acknowledge that no work with human subjects, including recruitment, may be conducted under this 45 CR 46.118 determination.

**SECTION 3: INSTRUCTIONS FOR ENDEAVOR**

***The developmental approval request and grant proposal must be uploaded to Endeavor.***

Researchers submitting a request for a 45 CFR 46.118 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 Study Information page, *Question 3 ‘Brief Description’*:** Provide the reason why you are requesting a 45 CFR 46.118 determination ***and*** indicate that researchers will not begin any human subject research until IRB review and approval of a full protocol has been granted.
	2. **Basic Study Information page, *Question 8 ‘Please indicate the proposed review category’*:** Select Developmental Approval.
	3. **Basic Information page, under *Attach the protocol*:** Attach this completed form.
	4. **Study Funding Sources page**: Add the funding source and related information and upload the entire grant proposal or contract.
	5. Complete the **Local Study Team Members** page.
	6. Upload the grant under **Local Site Documents 🡪 Other Attachments**.
	7. 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.