**HRP-503b – TEMPLATE – CEDED REVIEW**

**Purpose:** This template should be used for expedited and full board research studies when Auburn University is a study site and will rely on an External IRB. Please note that Auburn University does not enter into agreements for exempt level research. The Principal Investigator is responsible for understanding their responsibilities in reporting to the AU IRB as indicated in HRP-103 – INVESTIGATOR MANUAL when relying on an external IRB.

**Protocol Title:**

**Principal Investigator Name:**

[ ]  PI is not a student.

[ ]  I have read the PI eligibility statement and confirm that the above named PI meets criteria to be a PI on an IRB protocol at AU.

**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:

**1.5** Does the sponsor require a single IRB for this project? [ ]  Yes [ ]  No

**SECTION 2: PROJECT INFORMATION**

**2.1** What is the anticipated start date of the project: Click or tap to enter a date.

**2.2** What is the anticipated duration of the project?

**2.3** Provide a brief description of the project including the purpose of the study:

**2.4** Describe the research activities of AU key study personnel (i.e., scope of work):

**2.5** Does the study target any special populations? Answer yes or no to each population:

|  |  |
| --- | --- |
| Minors (under the age of 18) | [ ]  Yes [ ]  No |
| Auburn University students | [ ]  Yes [ ]  No |
| Non-AU students | [ ]  Yes [ ]  No |
| Pregnant women, fetuses, or any products of conception | [ ]  Yes [ ]  No |
| Prisoners, justice-involved, or wards  | [ ]  Yes [ ]  No |
| Temporarily or permanently impaired | [ ]  Yes [ ]  No |
| Other (please specify): | [ ]  Yes [ ]  No |

**2.6** Does the study involve any of the following:

|  |  |
| --- | --- |
| Procedures subject to FDA regulations (drugs, devices, etc.) | [ ]  Yes [ ]  No |
| Use of school records of identifiable students or information from instructors about specific students | [ ]  Yes [ ]  No |
| Protected health or medical information when there is a direct or indirect link which could identify the participant | [ ]  Yes [ ]  No |
| Collection of sensitive aspects of the participant’s own behavior, such as illegal conduct, drug use, sexual behavior, or alcohol use | [ ]  Yes [ ]  No |

**2.7** Provisions to maintain the confidentiality of data, including collection, transmission to/from AU, and storage at AU:

**\*\*IF AVAILABLE, INVESTIGATORS SHOULD UPLOAD A COPY OF ALL STUDY MATERIALS, AS APPLICABLE, FOR AU UNDER ‘LOCAL SITE DOCUMENTS 🡪 OTHER ATTACHMENTS’. EXTERNAL IRB MATERIALS SHOULD ALSO BE INCLUDED.\*\***

**SECTION 3: RELIANCE INFORMATION**

**3.1** Reviewing IRB Protocol Number:

**3.2** Reviewing IRB (IRB that will be relied on):

**3.3** Plan for reliance (i.e., IAA, SMART IRB, WCG):

*If reliance is documented with an IAA (also considered a ‘reliance agreement’) or a SMART IRB Acknowledgement Letter, please upload a copy of the document under ‘Local Site Documents 🡪 Other Attachments’ in Endeavor. Only when a copy of the final version of the approved protocol and IAA or SMART IRB Acknowledgement Letter (which includes all requested information and signatures of both Institutions’ Signatory Officials) are received and reviewed by the IRB Reviewer will AU IRB approval of the reliance agreement be issued. No research activities may occur until IRB approval is issued by both the reviewing and relying IRBs. The IAA is at the end of this document. A SMART IRB Acknowledgement Letter should be obtained from the reviewing IRB, and uploaded under ‘Local Site Documents🡪 Other Attachments’ within Endeavor.*

*For WCG (Commercial IRB): Auburn University has a Master Agreement with WCG to cover projects referred by the AU IRB. AU will issue a letter to the PI referring projects to WCG to be included in the WCG protocol submission. A copy of the WCG approved protocol must be uploaded into Endeavor under ‘Local Site Documents🡪 Other Attachments’ before AU IRB approval of the protocol. No research activities may occur until IRB approval is issued by both WCG IRB and the AU IRB.*

*Select ‘Yes’ to acknowledge this process.*[ ]  Yes

**3.4** Lead Site:

 Lead PI:

 Funding Source:

 AU OSP Number:

**SECTION 4: INSTRUCTIONS FOR ENDEAVOR**

***The request must be uploaded to Endeavor.***

Researchers submitting a request for ceded review, 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 ceded review ***and*** indicate that researchers will not begin any human subject research until IRB review and approval of the IRB of record.
	2. **Basic Study Information page, *Question 8 ‘Please indicate the proposed review category’*:** Select the appropriate level of review.
	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. **Local Study Team Members page:** Identify key study personnel.
	6. Under **Local Site Documents 🡪 Other Attachments**, upload all pertinent information such as the approved external IRB materials, any approval notices, completed IAA form, SMART IRB Acknowledgement Letter, or any other documents that would assist the IRB office.
	7. On other pages not mentioned specifically, if you do not have all of the developed or required materials, you may leave those items blank.
	8. If reliance is through an IAA, final approval will not be issued until the completed IAA is uploaded through the modification process in Endeavor. If an IAA is not necessary, delete the page following these instructions.

**Institutional Review Board (IRB) Authorization Agreement (IAA)**

|  |
| --- |
| **Name of Institution or Organization Providing IRB Review (Institution A)** |
| Name: |  |
| Federalwide Assurance (FWA) #: |  |
| IRB Registration #(s): |  |
| **Name of Institution Relying on the Designated IRB (Institution B)** |
| Name: | Auburn University |
| Federalwide Assurance (FWA) #: | FWA00001104 |
| IRB Registration #(s): | IRB00001220 |

The Officials signing below agree that **Institution B** may rely on the designated IRB for review of **Institution A** and continuing oversight of its human subjects research described below: (check one):

[ ]  This agreement applies to all human subjects research covered by Institution B’s FWA.

[ ]  This agreement is limited to the following specific protocol(s):

 IRB Protocol Title:

 Principal Investigator:

 IRB Protocol Number:

 Sponsor or Funding Agency:

Award #:

[ ]  Other (describe):

The Signing Officials agree that **Institution A** will provide IRB review and appropriate oversight for the project referenced above. The IRB at **Institution A** will make available copies of relevant minutes, the approved protocol, and/or protocol modifications to **Institution B** upon request. **Institution A** will notify **Institution B** of any adverse events reportable to OHRP in a timely manner. **Institution B** remains responsible for ensuring compliance with the IRB’s determinations and with the terms of its own OHRP-approved FWA. This agreement will remain in effect until the activities are completed and/or the protocol is closed. This document must be kept on file by both parties and provided to OHRP upon request.

**Institution A**

Name of Signatory Official:

Institutional Title:

Phone #:

Email:

Signature of Signatory Official: Date:

**NOTE:** The IRB of Institution A may need to be designated on the OHRP-approved FWA for Institution B.

**Institution B:**

Name of Signatory Official: Dr. Steven E. Taylor

Institutional Title: Senior Vice President for Research & Economic Development

Phone #: (334) 844-4784

Email: taylost@auburn.edu

Signature of Signatory Official: Date:

**NOTE:** Only when a copy of the final version of the IAA which includes all requested information, and the signatures of both Institutions’ Signatory Officials is reviewed by the AU IRB Reviewer will IRB approval be issued. No research activities may occur until IRB approval is issued.