### VII.B Project Description (B)

**VII.B.1. (REVISED from existing VII.B.1)**

Does this project involve any of the following (Check all that apply):

- **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project. *(UI Guide)*

- **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)

- **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track *(ClinicalTrials.gov & FDA)*.

- **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. *(ClinicalTrials.gov & FDA)*

- **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as “translational” or “basic science” aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.

- **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.

- **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition *(ClinicalTrials.gov & FDA)*

- **Other** – Describe: 

The question is a “select all that apply question.”

**VII.B.1 selections:**

- If Clinical (or Treatment) trial is selected, VII.B.1.a will open and require a response.
### VII.B.1.a is NEW and will appear if the above option is selected:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Phase I trials</td>
<td>Include initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients ([ClinicalTrials.gov &amp; FDA](<a href="http://ClinicalTrials.gov">http://ClinicalTrials.gov</a> &amp; FDA))</td>
</tr>
<tr>
<td>☐ Phase II trials</td>
<td>Include controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks ([ClinicalTrials.gov &amp; FDA](<a href="http://ClinicalTrials.gov">http://ClinicalTrials.gov</a> &amp; FDA))</td>
</tr>
<tr>
<td>☐ Phase III trials</td>
<td>Include expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling ([ClinicalTrials.gov &amp; FDA](<a href="http://ClinicalTrials.gov">http://ClinicalTrials.gov</a> &amp; FDA))</td>
</tr>
<tr>
<td>☐ Phase IV trials</td>
<td>Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use ([ClinicalTrials.gov &amp; FDA](<a href="http://ClinicalTrials.gov">http://ClinicalTrials.gov</a> &amp; FDA))</td>
</tr>
</tbody>
</table>

The question is a “select all that apply.”

### VII.B.1.b is NEW and would appear if:

- Any combination with Phase II, III, or IV is selected above
- OR Expanded Access is selected in VII.B.1
- OR Diagnostic Trial is selected in VII.B.1

**VII.B.1.b**

Provide the NCT (National Clinical Trial Identifier) number:  

The response will not be required, but optional.
# PRIVACY & CONFIDENTIALITY – Certificate of Confidentiality additions

## X. Privacy & Confidentiality

### X.7  Are you seeking a Certificate of Confidentiality from NIH for this study?

- [ ] Yes
- [ ] No

If No is selected, no further actions. If Yes is selected, X.8 will appear and **attachment categories**: NIH Certificate of Confidentiality (CoC) application, NIH COC correspondence and Certificate of Confidentiality (CoC) certificate.

### X.8  If yes, provide justification for why a Certificate of Confidentiality is being requested

### X.9  Describe in detail how the UI researchers will ensure the Certificate of Confidentiality protections will be implemented at participating sites. (Provide a response to the bulleted items listed below)

- obtain signed Assurances and IRB approvals from each participating institution
- review the consent forms used at each institution to be sure that the CoC protections and voluntary disclosures are appropriately described;
- ensure participating sites meet the obligations outlined with respect to the Certificate of Confidentiality Assurances.

If X.7 is Yes and VII.A.3 has "Coordinating Center" checked, question (X.9) will appear.