Study Currently in Longitudinal Status

- Request expedited review type on the Requested Review Type SmartForm
- On the Study Type SmartForm select only options that reflect what’s currently being done (if you are administering questionnaires, it’ll be social/behavioral study type, for instance)
- On the Protocol SmartForm attach the most recently approved protocol
- Answer the questions on the Recruitment SmartForm in a manner that indicates that the study is longitudinal and that recruitment has been completed.
- On the Informed Consent Determination SmartForm select ‘No’ and then select ‘Modification of Informed Consent’ on the Types of Waivers or Modifications SmartForm.
- On the Modification of Informed Consent SmartForm, in Q 1.0 explain that consent was obtained while the study was enrolling and that this is just the follow-up. Then in Q 2.1 answer ‘Yes’. In Q 2.2 state that consent was obtained and that this is a longitudinal study, and in the end, answer Q 2.3. On the HIPAA Authorization Determination SmartForm, select ‘Direct Authorization through consent form’. If the HIPAA Waiver Determination SmartForm blows in, select Not Applicable.
- Legacy Paper Determination, answer the questions on this
- Legacy Paper Conversion SmartForm respond to Q2.0, “Same protocol, no changes” and then in the text box explain the current status of the protocol (for example, enrollment complete all participants are in follow-up after week 36 and only questionnaires, follow-up evals continue etc.)
- Questions 3 – 8 are all uploads for the Continuing Review materials. Please ensure to upload in Q 6.0 the last signed informed consent.

Continuing Review Note:

- When the next continuing review is due, Approved Enrollment will blow in but the Current Enrollment will be blank (please see the screen shot below). This is fine, just make sure to explain in Q 1.0 that the study is closed to enrollment and in follow-up. Specify how many subjects were enrolled. This number should agree with what’s on the last paper CR that was submitted with the conversion.
### Subject Information: Enrollment Summary

<table>
<thead>
<tr>
<th>Approved Local Enrollment</th>
<th>Number of subjects approved to be enrolled locally:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># of Subjects</td>
</tr>
<tr>
<td>a. How many subjects do you need to complete the study?</td>
<td>200</td>
</tr>
<tr>
<td>b. How many additional subjects might be enrolled in this project but might discontinue participation in the study before completing all study interventions/interactions (either due to adverse event, withdrawal, etc.)?</td>
<td>0</td>
</tr>
<tr>
<td>c. If 1.1 (above) is 'Yes', how many additional subjects do you believe will undergo these screening procedures and will not count toward the numbers listed in questions a and b above (these subjects would be screen failures)?</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL (a+b+c) =</td>
<td>200</td>
</tr>
</tbody>
</table>

### Current Local Enrollment

<table>
<thead>
<tr>
<th>Number of subjects enrolled as of this Continuing Review period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Waiver of Informed Consent:</td>
</tr>
<tr>
<td>Waiver of Documentation of Informed Consent:</td>
</tr>
<tr>
<td>ICF:</td>
</tr>
</tbody>
</table>

If you have enrolled more subjects than you are approved for, submit a **Reportable Event - Deviation.**

If you need to increase how many subjects you want to enroll, submit a **Revision** after your CR is approved.

### 1.0

Describe your enrollment:

(For example, if you have enrolled more subjects than the IRB approved, please explain why. Or explain/describe which subjects were enrolled under a waiver, rather than ICF if both are used.)