Reportable New Information

BEFORE REPORTING TO THE EMORY IRB PLEASE REVIEW OUR REPORTING REQUIREMENTS.

1. **RNI short title:** (uniquely identify this new information report)
   
   Concurrence for a single use expanded access

2. **Date you became aware of the information:**
   
   Today's date.

3. Indicate if this event is internal (subject enrolled by Emory personnel or event is under Emory SI or IRB oversight) or external (if not). Check all that apply.
   
   Internal

4. **Identify the categories that represent the new information:** (check all that apply)
   
   There are no items to display

   **Important!** Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

5. **Briefly describe the new information:**
   
   We are seeking the IRB chair concurrence for the use of DRUG/DEVICE. See attached documents for more information.

6. **In the submitter's opinion:**
a. * Does this information indicate a new or increased risk, or a safety issue?
   - Yes □
   - No ■

b. * Does the study need revision?
   - Yes ■
   - No □

c. * Does the consent document need revision?
   - Yes □
   - No ■

If revisions are required, describe them above and submit a study modification for review.

7. Related studies and modifications:

<table>
<thead>
<tr>
<th>ID</th>
<th>Short Title</th>
<th>Investigator</th>
<th>State</th>
<th>IRB Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

8. Attach files containing supporting information:

- **Name**
  - Device-A description of the circumstances necessitating the use (0.03)
  - Device-Copy of authorization from IDE/IND holder (0.02)
  - Device-Copy of consent document for expanded access use (using our current template)(0.02)
  - Device-Copy of uninvolved physician's assessment of use. (0.02)
  - Device-IDE protocol with description of device and name of IDE holder (0.02)
  - Drugs-A copy of all information submitted to the FDA in connection with the Expanded Access use request (0.01)
  - Drugs-Documentation of FDA approval for the Expanded Access Use request, including waiver of IRB approval (0.01)
  - Drugs-Informed consent form to be used (use our template)(0.01)

Attach redacted documentation as pertinent to your use (drug vs. device). Please do not include any patient identifiers in your documents (patient initials are often hidden in document footers - double check).

If using a drug, remember to check box 10b when submitting form 3926 to the FDA. If this isn't done, a full new study submission is required in order to obtain IRB approval for the use.