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>
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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 documentation as pertinent to your use (drug vs. device)

   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.