IRB eProtocol

Labeling Attachments for eProtocol

*Label all files/attachments using the following format*

Consents/Assents/Scripts should be provided as a word document

- **New/Initial Submissions**
  (if there are multiple sets of documents for various groups indicate i.e. treatment, control or groups A, B, C etc as part of the document’s name)

- **Consent Information**
  Consent Documents are to be attached under the Protocol Information –Consent Information section
  - Consent 1 examples:
    - Consent 1 for Treatment Group (revision dated 1/1/2018)
    - Consent 1 for Group A etc… (revision dated 1/1/2018)
    - Behavioral Research Informed Consent for… (revision dated 1/1/2018)
  - Consent 2 examples:
    - Consent 2 for Control Group (revision dated 1/1/2018)
    - Consent 2 for Group B etc…. (revision dated 1/1/2018)
    - Behavioral Research Informed Consent for…. (revision dated 1/1/2018)

- **Assent Information**
  Assent Documents are to be attached under the Protocol Information –Assent Information section
  - Adolescent Assent 1 examples:
    - Adolescent Assent 1 for Treatment Group (revision dated 1/1/2018)
    - Adolescent Assent 1 for Group A etc…(revision dated 1/1/2018)
    - Adolescent Assent (revision dated 1/1/2018)
  - Adolescent Assent 2 examples:
    - Assent 2 for Control Group (revision dated 1/1/2018)
    - Assent 2 for Group B etc… (revision dated 1/1/2018)
- Oral Assent Script for Ages 7-12 (revision dated 1/1/2018)

**Other Supporting Documents-Attachments section**

All Other documents are to be attached under the Protocol Information-Attachments section.

*PDF format is acceptable for these documents.*

- CV/Resume for Principal Investigator (label with PI’s Name)
- FCOI Plan for (insert name of individual)
- Letter of Support 1 from (label with entity’s name)
- Letter of Support 2 from (label with entity’s name)
- Participant Letters
- Flyer (#1, #2, #3 etc...)
- Advertisement (#1, #2, #3 etc...)
- Recruitment Script (version dated 1/1/2018)
- Data Collection Tools: Study Diary, Assessment, or Questionnaire for (label with document’s name, date, and/or version)
- Protocol (label with protocol version number and date)
- Investigator Brochure for (label with drug’s name, version number, and date)
- Package Insert for (label with drug’s name and version number)
- Administrative Approvals: Karmanos PRMC Approval, DMC Approval, Radiation Review/Approval, Psychiatry etc.

### Amendment Submissions

For amendments include a **highlighted copy** and a **clean version** of the documents being revised. Please attached documents per the instructions indicated above.

### Continuation Submissions

If no changes are being made to the consent, assent, recruitment materials or participant documents please provide a **clean version** of the documents. These continuation documents must be attached at the end of the continuation form under “Attachment”.

<table>
<thead>
<tr>
<th>Attachment</th>
<th>Add</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Click the 'Add' button to add 'Attachment'.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please attach a 'clean' of all Consent/Assent/Participant document(s). A "clean" unstamped copy of all documents that are due to expire should be included. Consent/Assents/Recruitment/Participant Materials.