



## 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" .

Attachment	Add   Delete
Click the 'Add' button to add 'Attachment'	
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: Consents/Assents /Recruitment/Participant Materials	