



IRB eProtocol

Labeling Attachments for eProtocol

Label all files/attachments using the following format

■ New Submission

(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 1
 - 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 (revision dated 1/1/2018)
- Consent 2
 - 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)
- Adolescent Assent 1
 - Assent 1 for Treatment Group (revision dated 1/1/2018)
 - Assent 1 for Group A etc...(revision dated 1/1/2018)
 - Adolescent Assent (revision dated 1/1/2018)
- Adolescent Assent 2
 - Assent 2 for Control Group (revision dated 1/1/2018)
 - Assent 2 for Group B etc... (revision dated 1/1/2018)
- Oral Assent Script (revision dated 1/1/2018)
- CV/Resume for Principal Investigator (insert name)
- FCOI Plan for (insert name of individual)
- Letter of Support 1 from (insert entity's name)
- Letter of Support 2 from (insert 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 (insert document's name, date, and/or version)
- Protocol (indicate protocol version number and date)
- Investigator Brochure for (insert drug's name, version number, and date)
- Package Insert for (insert drug's name and version number)
- Karmanos PRMC Approval (insert IRB#) or DMC Approval (Insert IRB#)

Amendment

- Consent –current (revision dated 1/1/2018)
- Consent –revised (revision dated 3/2/2018)
- Protocol-current (then indicate version number and date)
- Protocol-revised (then indicate version number and date)

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