

**Format for IRB Full Committee Modification Review
(Outside of the Continuing Review process)**

- Please review the following formatting instructions that are applicable to your modification submission. For example, if your modification did involve changing the consent form, please omit reviewing the below consent form formatting instructions.
- Exception: Full Board modification reviews **always** require a revised project summary provided in the manner described below.
- Place one copy of the Full Board modification email notice on top of the 25 copies prior to delivery to the IRB Office.

Please provide 25 copies of the following documents, collated and stapled or binder clip:

IRB Modification Form, signed by the Principal Investigator (Form MOD).

Revised Project Summary – additions underlined and deletions marked through.

Revised Project Summary – clean copy.

Revised Consent Form – additions underlined and deletions marked through.

Revised Consent Form – clean copy.

Other document(s) (i.e., sponsor letters, regulatory letters, page(s) of listed changes).

Please provide 2 copies of the following documents:

Revised Protocol – additions underlined and deletions marked through.

Revised Investigator's Brochure – additions underlined and deletions marked through.

Protocol Amendment.