

INSTRUCTIONS FOR SUBMITTING AMENDMENT DOCUMENTS:

The IRB will accept and review AMENDMENT documents ONLY UNDER THE FOLLOWING CONDITIONS:

1) The document (s) must be labeled with the *AMENDMENT NUMBER, DATE and IRB number printed on each page of document.

* Please keep in mind that, regardless of the VERSION number of sponsor's protocol, the original NEW YORK EYE and EAR INFIRMARY – APPROVED protocol and consent is considered to be the FIRST/ORIGINAL protocol version. For example, Sponsor company and PI submit NEW protocol labeled version 3.2, dated 1/1/08. ALL SUBSEQUENT AMENDMENTS/VERSIONS of this original protocol approved by NYEEI/IRB MUST BE LABELED AMENDMENT #1, 2, 3, etc., regardless of the SPONSOR companies version #, as the IRB is reviewing the FIRST, SECOND, THIRD, etc. change or amendment to that study.

2) The AMENDMENT must numerically follow any previously approved amendments. For example, if AMENDMENT number 1 was approved by the IRB on 1/1/08, the next amendment submitted on 6/1/08 MUST be AMENDMENT number 2. If the IRB receives an amendment out of order (for example, submitting amendment #3 when the IRB last approved amendment #1 without ever having reviewed or approved amendment number 2), the paperwork will not be accepted for review and will be returned to the PI.

A typical Drug company Sponsored protocol, for example, may look like this: **ACME co. Protocol #ABC12345, version 4.8, 1/1/08, IRB #91.12, Amendment #5.**

PLEASE BE SURE TO CONSIDER ANY CHANGES TO CONSENT FORM AND/OR RESEARCHER AUTHORIZATION (HIPAA) FORM AS THESE FORMS MAY ALSO NEED AMENDING, DEPENDING ON THE PARTICULAR AMENDMENT.