Responding to Stipulations and Conditions

Administrative review of applications to the IRB often result in requests for required information such as documentation of CITI training or letters of collaboration. As well, IRB reviewers often need additional information in order to make determinations required by the regulations at <u>45CFR46.111</u>.

Sometimes requests for documents or information are couched as stipulations and other times as conditions, but in all cases, *review cannot proceed without a response*.

All responses, including additional documents or revised applications, should be accompanied by a memo that includes the following items:

- 1. Date of response.
- 2. Protocol number and title.
- 3. Name of person submitting the material.
- 4. Subject: Response to {request for information; stipulations; conditions}
- 5. Point-by-point response to the requests, stipulations and conditions.

rsb: 3-Oct-16