

## *Appendix B: Document Review*

This Appendix provides a general format of the Research Compliance Monitor's (RCM) process for conducting a Document Review.

### **Document Review**

The Document Review includes a thorough review of all of the approved and pending IRBNet research records and documents by the RCM. The PI does not need to be present during this part of the process. In general, this part of the PAM program takes place between the PI being randomized and up until the Second Meeting with the PI. Depending on the complexity and length of the project, this step in the process can take several weeks. This review enables the RCM to develop a comprehensive understanding of the research protocol, methods, and documents that have been approved for use on the project. The RCM will make note of any areas of question or concern to be discussed with the PI during the Second Meeting.

### **IRBNet Records**

Should include:

- Initial Submission
- Amendments and Modifications
- Continuations
- Adverse Reactions/Unexpected Events
- IRB and PI correspondence, including Project Mail and Approval/Exemption Letters
- Complete Research Protocol
- Informed Consent/Assent Documents
- Study Personnel List
- Surveys, Questionnaires, and Other Study Instruments

### **Other Records**

The RCM will also check to ensure that other records are current, such as:

- Faculty and Staff Conflict of Interest Disclosure
- CITI Training Certificates

### **Document Review Comparison**

The Document Review Comparison is the second phase in the Document Review process in which the RCM compares the Investigator Self-Assessment Form to the Document Review findings. This step allows the RCM to identify areas where they may be a potential lack of congruency, and to compile questions and areas for discussion based on congruency checks and investigator self-assessment comments, etc. Additionally, the RCM will utilize this time to review and organize any questions the PI has brought up during the Self-Assessment process. Any questions or areas of potential incongruous will be discussed with the PI during the Second Meeting.