

## **Guidance for Required attachment of PDF documents for IRB approval:**

**\*Effective 8/27/14 all documents requiring an IRB stamp must be submitted as a PDF\***

Documents that you attach (e.g., non-Rascal consent forms, recruitment flyers, study instruments) can now be stamped by Rascal, after approval of the submission to which they are attached. **This feature is only compatible with documents that are attached in Rascal in a PDF format.**

Going forward you will need to ensure that all document(s) which require an IRB stamp of approval are **attached in Rascal in a PDF format.** This includes any document that will be given to, used with, or read to a participant as recruitment material, a consent form, or a data collection measure. Please note: CRFs that are completed by the study team with no input from the participant do not require an IRB approval stamp.

Below, please find instructions for facilitating an organized submission and quick processing of your stamped materials:

- Documents may be converted to PDF through use of Adobe Professional or Microsoft Office software, or through scanning.
- The Rascal generated stamp requires a 1-inch high by 4-inch wide space in the lower right-hand corner of your PDF document. Every effort should be made to ensure that your document is big enough for this stamp and to leave this space open when formatting your study materials. Note: the stamp has been designed to be translucent if information cannot be removed from this area of your document.
- When attaching documents to your Rascal submission, please name documents in such a manner that the type of document (e.g., consent form), and when applicable, version date, are clear, e.g., “consent form v3”. The ‘Document Identifier’ is the information that will be listed in approval correspondence and letters from the IRB to identify the document that was approved.
- Note: documents that will not require a stamp (e.g. external protocols, documents demonstrating tracked changes, etc.), which are not intended to be approved, are not required to be submitted in a PDF format.

### **In future new protocol submissions and modifications:**

Please make sure that all documents which require stamping are uploaded as PDF documents meeting the formatting specifications listed above. All previously attached documents that are being superseded with the new documents included in a submission or resubmission should be deleted/archived from RASCAL.

### **In your next renewal:**

Please replace all previously approved non-PDF documents that are still required for the continued conduct of the research with PDF documents meeting the formatting specifications listed above. *A renewal that includes “replaced” documents should also include a clear delineation (either in the modification section or as a separately attached external document) of which documents are new with the renewal and which documents are simply PDF versions of previously-approved, unchanged, non-PDF documents being replaced to facilitate stamping.* All previously-approved documents that are being superseded with or replaced by the new documents included in a renewal should be deleted/archived from RASCAL. Documents that are no longer necessary for the conduct of your research should also be removed/archived.