Guidance: IRB Approval Document Stamping			
DATE	AUTHOR	APPROVED BY	PAGE
11/18/2013	M. McFann	C. Kiel	1 of 1

BACKGROUND

The IRB Administration receives numerous requests for individualized documents to be stamped for varying reasons including investigator preference, sponsor documentation, and individual and particular site monitor recommendation. Federal and state guidelines are non-specific as to which documents must be IRB stamped approved. To ensure consistency throughout the Campus and Health System, the IRB Administration has developed this guidance document to clarify which study documents receive the IRB approval stamp and are returned to the investigator.

At initial submission, the Investigator Protocol, all recruitment documents, and informed consent documents should be submitted for IRB review and approval. At renewal, submit only those documents that are being modified for IRB review and approval. Upon approval, the following documents will be returned to the investigator, stamped as indicated:

ALL PAGES OF THE DOCUMENT

- Informed consent documents*

NOT STAMPED

- Investigator Protocol
- Sponsor protocols
- Drug brochures
- Separate protocols
- Diaries
- Surveys, questionnaires
- Miscellaneous checklists, documents
- Package inserts
- Flyers, ad texts
- Eligibility screening scripts
- Informational/Recruitment pamphlets/sheets
- De-briefing scripts

* If re-consenting of subjects is necessary, current stamped informed consent documents will be issued. Exempt studies and studies closed to enrollment will not receive stamped informed consent documents.

Questions and Additional Information for the IRB

The IRB Administration wants your questions, information, and feedback. Contact and location information for the IRB Administration is:

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