BACKGROUND
Federal and state guidelines are non-specific as to which documents must be IRB stamped approved. To ensure consistency, the IRB has developed this guidance document to clarify which study documents receive the IRB approval stamp.

This applies to Full Board and Expedited studies. This does not apply to exempt studies unless there is a HIPAA Complete Waiver.

STAMPED
- Informed consent documents, Assents *
- HIPAA waivers
- Any items that will be given to or viewed by participants, e.g.:
  - Letters to participants (or their LARs)
  - Recruitment materials (flyers, add texts, information/recruitment pamphlets, etc...)

NOT STAMPED
- Investigator Protocol
- Sponsor protocols
- Drug brochures
- Diaries
- Surveys, questionnaires
- Miscellaneous checklists, documents
- Package inserts
- Eligibility screening scripts
- De-briefing scripts

* If re-consenting of subjects is necessary, current stamped informed consent documents will be issued. Studies closed to enrollment will not receive stamped informed consent documents (unless pediatric subjects will be turning 18 years of age).

For Questions and Additional Information contact the IRB:
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