

## Research subject consent/assent document approval stamp policy

All consent and assent documents must have the official HSIRB approval stamp and signature before they are presented to subjects.

Steps for obtaining and/or using a consent document:

1. Investigators develop the final version of the consent documents to be used in the research project and submit them to the HSIRB exactly as they are to be presented to the subject.
2. The HSIRB reviews the consent documents as a part of the proposal review process.
3. If any changes are required in the consent documents, the HSIRB will notify the investigators, who will make the needed changes and return them to the HSIRB for final approval prior to initiation of the research.
4. When approved by the HSIRB, the consent documents will receive the following approval stamp:



5. The stamped and signed consent documents will be returned to the investigators with written notice of HSIRB approval of the research project. A copy of the documents will be maintained in the HSIRB files. The investigators will copy the consent documents that bear the original stamp for distribution to potential research subjects.
6. After recruitment, research subjects should receive a copy of the consent document. Only consent documents bearing the HSIRB approval stamp may be used to obtain consent.