An investigator may request a waiver of the requirement to obtain a signed consent form. A waiver of documentation may be appropriate in some instances (e.g., online research, mail surveys, special populations, international studies). The IRB may waive the documentation requirement by determining that the regulatory criteria for a waiver of documentation are met. The applicable criteria must be met for the IRB to grant a
waiver of documentation. When the documentation requirement is waived, the IRB may require that the investigator provide subjects with a written statement regarding the research. The IRB may require language in the written document (e.g., online research, mail surveys) such as "By completing this survey, you indicate your voluntary agreement to participate."

Researchers may propose a consent process that involves obtaining oral consent from subjects (e.g., telephone surveys, situations in which written consent is deemed culturally disrespectful or inappropriate). To approve oral consent, the IRB must find the criteria for a waiver of documentation are met. The IRB must review the language that will be used in obtaining oral informed consent. Researchers proposing to obtain informed consent orally must include a script of the oral consent language and content with their IRB application. Oral informed consent must include all the elements of informed consent unless an alteration of consent is approved and should be given to subjects in writing. See HRPP Manual 6-4-B, "Waiver or Alteration of Informed Consent" for alteration of informed consent criteria. Investigators should keep a log documenting the oral consent process throughout the duration of the study.

Investigators requesting a waiver of documentation must submit the information that will be provided to the subject or legally authorized representative (e.g. oral script, written document). It is the investigator’s responsibility to inform and educate the IRB about any special cultural situations.

**Review and Documentation**
Review and approval of waiver of documentation follows the procedures as required by the level of review. See HRPP Manual 8-2 “Expedited Review Procedure” and/or HRPP Manual 8-3 “Full Board Review Procedure” for policies and procedures on review and documentation required to waive documentation of consent.