An Institutional Review Board (IRB) is able to waive the requirement to obtain signed informed consent in two situations:

- The only record linking the participant and the research would be the consent document;
- The principal risk would be potential harm resulting from a breach of confidentiality;
- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; and
- The research is *not a clinical investigation* subject to FDA regulations.

OR

- The research presents no more than minimal risk of harm to participants and
- The research involves no procedures for which written consent is normally required outside of the research context.

Researchers interested in obtaining a waiver of written (signed) informed consent should make sure that their research qualifies for one of the above options, and should address how the research qualifies for each of the option's requirements in the Appendix P of the electronic IRB Application.

In cases where the documentation requirement for informed consent is waived, the IRB often requires the researchers to provide participants with a written statement regarding the research. This written statement requires prospective IRB approval. The template Study Information Sheet can be used as a guide. The written statement is presented to the prospective subject as part of the informed consent process. As part of the verbal consent process, the researcher should:

- Explain the study to the prospective subject including a discussion of the study purpose, procedures, risks, benefits, compensation, and alternatives to participation, but above all, that participation is completely voluntary;
- Provide the prospective subject the Study Information Sheet for review, when applicable;
- Allow the potential subject sufficient time to ask questions;
- Assure that the prospective subject understands the research procedures (e.g., ask open ended questions);
- Answer the prospective subject questions and obtain the subject’s verbal agreement to participate in the research.

A Note About Online Research: When administering the Study Information Sheet via an online method, consent is assumed if the participant starts the study procedures (e.g., online survey).
There is no grace period extending the conduct of research beyond the expiration date of IRB approval. The study expires at midnight of the date specified on the approval letter and the informed consent document.

If the IRB does not re-approve the research by the specified expiration date, study activities must cease (note: this includes access to identifiable data), pending re-approval of the research by the IRB.

Once notified of the expiration, if the Investigator feels that stopping ongoing research-related interventions or interactions would jeopardize the rights or welfare of current subjects, the Investigator must immediately submit to the IRB Chair a list of research subjects for whom expiration of the research would cause harm.

The Investigator may work with HRP Staff to facilitate the communication with the IRB Chair.

The IRB Chair reviews this list and allows individual participants to continue participating in the research interventions or interactions only when the IRB determines that it is in their best interests. However any information collected during the lapse in approval may not be used for research.

Remember: submit a continuing protocol application at least 30 days prior to expedited review and at least 60-90 days prior for full committee review.