1. **PURPOSE**

1.1. This guidance document describes the process for closing out an approved study via Study Closure Form (HRP-206).
1.2. The Study Closure Form (HRP-206) updates the IRB on the conduct and outcomes of the study, any new risks, safety issues or problems that may have arisen since the last study renewal, and informs the IRB of the final disposition of research records and data.

2. **GUIDANCE**

2.1. The Study Closure Form (HRP-206) should be submitted to the IRB within 30 days of completion or termination of all research activity, even if the current approval period has expired or if the IRB has administratively closed the study.

2.1.1. Failure to submit a Study Closure Form for all closed studies, including those that have expired or lapsed, will result in the IRB postponing the review and approval of future research protocols conducted by the PI until a study closure form has been submitted for all outstanding studies.

2.2. The PI must submit a Study Closure Form to end the IRB’s oversight (via Form HRP-206) when:

2.2.1. **All** the following apply:

2.2.1.1. The protocol is permanently closed to enrollment;
2.2.1.2. All subjects have completed all protocol related interventions and interactions;
2.2.1.3. No additional identifiable information about the subjects is being obtained;
2.2.1.4. Analysis of identifiable information is completed.

2.2.2. The study has expired or been administratively closed by the IRB;
2.2.3. The PI intends to depart the university and the research will not continue at the university.

2.3. The GW IRB may administratively close a study without investigator approval when:

2.3.1. It is determined that the investigator is no longer affiliated with GW;
2.3.2. The PI has not submitted a Continuing Review form or a Study Closure form, the approval period for the research has expired, and the IRB has not permitted ongoing research procedures for the safety of continuing subjects;
2.3.3. The investigator has not responded to the IRB’s requests for revisions and/or clarifications within a reasonable timeframe, usually 30 days, and an extension has not been requested;
2.3.4. IRB approval has been terminated.

2.4. The IRB will notify the Principal Investigator once a study is closed, administratively closed, or expired.

2.5. If after a study is closed, the PI seeks to engage in an activity that meets the definition of human subjects research, he or she must submit a new protocol for IRB review and approval.

2.6. Once a study is closed, the PI must follow “Investigator Guidance: Investigator Obligations (HRP-800)” for the maintenance of research records.
3. REFERENCES

3.1. 21 CFR §56
3.2. 45 CFR §46