GUIDANCE ON DATA SHARING

The George Washington University, Committee on Human Research, Institutional Review Board (the GWU IRB) adopts, in its entirety, the National Institutes of Health (NIH) Data Sharing Policy and Implementation Guidance, available at http://grants1.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm, as it relates to human subject protocols associated with NIH applications of $500,000 or more in direct costs in any single year. Pursuant to the NIH Data Sharing policy, such NIH applications must include a plan for data sharing or state why data sharing is not possible, e.g. the study involves restricted data. The GWU IRB recommends that all principal investigators consider applying the NIH Data Sharing Policy to all human subject protocols, regardless of funding source.

Pursuant to this GWU implementing policy, all non-restricted final research data, associated with studies undergoing IRB review and approval, e.g. clinical studies, biological specimen studies, surveys/questionnaires, etc., should be considered for data sharing for subsequent research purposes, e.g., secondary analysis studies by non-GWU researchers. Such data should be made available as soon as possible while safeguarding the privacy of subjects and protecting confidential and proprietary data.

Final research data is defined as recorded factual material commonly accepted in the scientific community as necessary to document, support, and validate research findings. This definition does not include summary statistics or tables; rather the definition includes data on which summary statistics and tables are based.

Restricted data is defined as datasets that cannot be distributed to the general public because of participant confidentiality concerns, third party licensing or use agreements, or national security considerations etc. e.g., data associated with a pharmaceutical sponsored study in which GWU entered into a data use agreement.

Non-restricted data consists of datasets that can be distributed to the general public given that distribution of the data does not introduce participant confidentiality or national security concerns or interfere or run counter to third party licensing or use agreements.
As part of the IRB review process, the GWU IRB will assess the appropriateness and adequacy of a study’s proposed data-sharing plan (or the justification as to why data sharing is not possible) based on the following criteria:

1. When and how data will be stripped of direct and indirect identifiers. Prior to sharing final research data with individuals outside the GWU research team, the data should be stripped of all direct identifiers that could identify individual research subjects i.e., the 18 elements of data outlined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) de-identified data provisions, and indirect identifiers. Indirect identifiers are defined as variables/items of data that could lead to the deductive disclosure of the identity of individual subjects, e.g., a rare population/condition noted in a small geographical area.

2. The proposed plan to minimize the risks of unauthorized disclosure of personal identifiers, direct or indirect.

3. The timeliness of the planned data sharing. The GWU IRB anticipates that such sharing of final research data should occur one year following the date of publication of the main findings from the final dataset; however, the actual time will be influenced by the nature of the data collected.

4. The justification for limiting or not having data sharing. The GWU IRB recognizes that data sharing may be complicated or limited in some studies for a variety of reasons. In such situations, the GWU IRB expects the principal investigator to explain such limitations in the data-sharing plan, e.g., explain why the data constitutes restricted data and thus cannot be shared with the general public for subsequent research purposes.