Vivli
CENTER FOR GLOBAL CLINICAL RESEARCH DATA

Vivli Template Data Sharing Plan

As part of our ongoing efforts to support the broader research community, Vivli has provided the following template language for a data management plan, based on NIH requirements. The NIH suggests, *"Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement."*

Template:

The proposed research will include data from approximately (number of participants) participants recruited from clinical facilities in the (location) area with (population being studied; i.e. T2 diabetes). The final dataset will include (data included such as self-reported demographic and behavioral data from interviews with participants, and laboratory data from blood and urine specimens provided). We will share individual-participant level or IPD data. The data will be made available 1 year after completion of the study, in a de-identified format. In addition to the IPD data set, the researcher will share the (elements of the final data set and documentation to be shared, i.e. data set, data dictionary, statistical analysis plan, analytic code, and final protocol with amendments.)

In order to maintain appropriate managed access of the data, we will make it available via the Vivli platform (http://vivli.org/). Vivli is a non-profit clinical research data sharing platform that has been created to meet the needs of researchers who use and produce clinical research data worldwide. Using the Vivli platform, researchers can share or access de-identified data from completed clinical trials.. In order to access IPD arising from this project, users must complete the Vivli data request form and sign the Vivli Data Use Agreement, which limits subsequent use to the terms of the approved request and requires that users maintain data security, and refrain from any attempts to reidentify research participants or engage in any unauthorized uses of the data. In order to get access to the data, the user must submit a valid scientific question, include a statistical analysis plan, and complete all required fields on the Vivli data request form. Vivli will review the data request for completeness. Anyone who has submitted an approved data request and signed a data use agreement on Vivli will be given access to the data.

Vivli will then make the data available, without cost, to users for a set period of time. Vivli will maintain storage and access of the data for as long as it maintains scientific utility. Costs for sharing this project's data through Vivli are included in the proposed budget.