Instructions for Application and Use of the Confidentiality Agreement Template

When conducting human participant research, the Principal Investigator (PI) may employ the services of individuals to help with data entry, manipulation, and management. These persons would NOT be considered key research personnel and would be peripheral to the conduct of the human participant portion of the research. Examples of these types of individuals may include transcribers, translators, data entry personnel, and persons aiding with coding/analysis/interpretation of the data. These individuals would not be considered engaged in the research because they are not involved in the conduct or design of the research. In general, persons performing these roles for the research would not be required to complete human participant protections training, as their role in the research does not involve direct interaction or intervention with the participants, recruitment or enrollment of participants, or obtaining consent from participants. For these reasons, it is believed that completing human participant protection training would not add protection to research participants.

The Confidentiality Agreement template is a document that should be used to establish an agreement between the PI and the person providing the service for the research. The agreement outlines the need to maintain confidentiality of the information or data and any restrictions on the further release or disclosure of the research data or information. The agreement template is a starting point and should include discussion between the PI and the service provider about specific measures in the IRB approved protocol to ensure confidentiality is maintained (i.e. how data should be stored and where). Additionally, the PI should discuss with the service provider any special measures that should be used for transmission or communication of data between the researcher and the service provider (i.e. only send encrypted files, hand deliver, or deliver with receipt.).

During the review process, the Institutional Review Board (IRB) may request the use of the confidentiality agreement, when the protocol submitted by the PI clearly includes plans for the use of personnel providing these types of services. The IRB would request a copy of the final agreement that will be used (signed or unsigned), once it is available (may be submitted via an amendment if this agreement is created after the initial submission). The original signed agreement should be kept in the investigator's research files for a minimum of three years after the completion of the research (similar to the other research related documentation).

If you have any questions regarding the use of the Confidentiality Agreement template, call Susan Loess-Perez, Director of Research Protections at 312-362-7593 or email her at sloesspe@depaul.edu.