Request for Letter of Determination Guidance and Template Letter

Investigators conducting research that that has been determined to not involve human subjects may qualify for protocol approval by Letter of Determination (LOD). Investigators must first review worksheet HRP-310, Human Research Determination prior to requesting approval by LOD. Specific guidance and step by step instruction in determining qualification for a LOD may be found in Worksheet 310. A representative from Human Research Protection (HRP) will make a final determination upon review of the request and provide administrative approval as warranted. Examples of the types of Protocols that may qualify for a Letter of Determination are described below.

1. Secondary analysis of an already existing deidentified data set to which the PI has no access to any code or links that may be used to re-identify the subjects.
2. Anonymous survey/questionnaire oriented protocols that seek a subject's opinion regarding a topic (other than about them personally), or experience with receipt of a service, provided absolutely no personal information or identifiers are collected and responses cannot be traced back to the source subject. Questionnaires and surveys cannot seek responses that are "about" the subject.
3. Program evaluations and improvements; such as when an investigator is given authorization to access an agency's or health clinic's records, data sets or employees and PI will evaluate services provided, customer satisfaction or in general quality improvement. PI would provide study data results to the agency or health clinic, data would not be made available as "generalizable knowledge".

Email completed application to HRPP@drexel.edu

COPY AND PASTE THE TEMPLATE BELOW TO CREATE YOUR APPLICATION REQUEST

Request for Letter of Determination

Human Research Protection
Drexel University
1601 Cherry Street, Ste. 10-444
Philadelphia, PA. 19102
215-255-7857

Date:
PI and Student names:
Protocol title:

To whom it may concern:

The PI and student as noted above request a Human Research Protection review of the subject protocol described below for approval as Letter of Determination.

1. Protocol overview and purpose:

2. Procedures:

3. Investigation site or source of data: (Include signed permission letter for access to site resources and/or data):

4. Data collection tools (survey/questionnaires/Excel spreadsheet):

Signatures: PI/Advisor _____

Student: _____