Attachment 5: DOCUMENTATION FROM THE NIH OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

Email about IRB and Evaluation

From: OHSR (NIH/DDIR)
Sent: Monday, May 13, 2013 4:22 PM
To: Burroughs, Adrienne McGill (NIH/NINR) [E]
Cc: Matose, Takunda (NIH/OD) [C]
Subject: FW: IRB question for evaluation survey

Good Afternoon Adrienne,
Nice to speak with you again about your new program evaluation* for "Palliative Care: Conversations Matter". Generally Program Evaluations are not considered human subjects research as defined by 45 CFR 46.102 and do not require approval by this office if the results of the evaluation will be shared with the program or entity in which the program operates. As we have indicated before, if the results of a program evaluation warrant dissemination to professional or groups outside the organization or program being evaluated that prior OHSRP or IRB approval is required.

You may wish to edit your description slightly to avoid confusion about the nature of the project (program evaluation versus research):

"Survey Design: Conduct qualitative and quantitative ~~research (via~~ online surveys) with ~~identified~~ selected participants…"

Best of luck with your project.

P.S. If you do believe that you should obtain our determination regarding this activity, please complete the Request for Determination- Interview Survey or Other which may be obtained from the OHSRP website: https://federation.nih.gov/ohsr/nih/index.php (NIH login required), look in the column, "Investigator Resources" and select "Forms and Templates".

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*Program evaluation information highlighted in yellow below.

DRAFT FROM POLICY – REPRESENTS OHSRP CURRENT THINKING AND PRACTICE

The NIH Office of Human Subjects Research Protections (OHSRP) has authority to make certain determinations pertaining to NIH research activities, in lieu of an NIH IRB. Many NIH research activities are not categorized as human subjects research and do not require any type of approval, but some of these activities involving data and specimens do require a formal OHRP determination. Certain activities fall under the exempt categories, set forth in 45 CFR 46, meaning they are human subjects research, but do not require IRB approval. The purpose of this website is to guide NIH resesearchers through NIH policy and procedures.

NIH ACTIVITIES WITH CERTAIN TYPES OF DATA AND/OR SPECIMENS DO NOT REQUIRE APPROVAL EITHER FROM AN IRB OR OHSRP:

A. NIH policy is that research with the following types of specimens/data do not require any type of formal determination. Activities in this group include:

- Human specimens/data from deceased individuals.
- Human specimens/data from commercial repositories that do not contain information which can identify the providers of the specimens.
- Human specimens from established cell lines that are available to qualified scientific investigators, provided that they are not identifiable to NIH researchers and provided that NIH researchers do not have access to a code linking the cell line to the individual from whom the line was derived.
- Derivatives of materials originally obtained from humans if those materials are either (1) not identified or (2) coded but none of the NIH researchers will be given access to the code.

B. NIH policy is that some activities with data and/or specimens are NOT characterized as research, consequently 45 CFR 46 requirements do not apply. Activities in this group include:

- Use of Specimens/data for diagnostic purposes only.
- Single case reports, if the report meets three (3) criteria: 1) the information is compiled by person(s) already involved with patient care; 2) the information is presented in de-identified form; and 3) no changes are made in the patient's care or diagnostic testing for the sake of reportability.
- Program evaluations in which the results of the evaluation are shared only within the program or entity in which the program operates, i.e., the data from the activity are produced by the program and returned to the program.