

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

Email about IRB and Evaluation

From: Bridge, Heather (NIH/OD) [E]
Sent: Monday, June 25, 2012 2:53 PM
To: Burroughs, Adrienne McGill (NIH/NINR) [E]
Subject: RE: IRB question for evaluation survey

You are correct the policy has not changed in regards to program evaluations*, if the results are only being returned to the program for the purposes of improvement. However, if you think you will publish the evaluation (not true in this particular case) then we would advise obtaining an determination from our office.

All my best,

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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 reseachers 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.