Policy Rationale

Within the broader context of social science research, classic history, oral history, biography, and some qualitative interviews do not always meet the definition from the federal regulations of research involving human subjects. Increasingly, however, the application of qualitative research methodologies may render studies that typically would not have required IRB review and approval to be submitted for IRB review or, at least, to require a determination from the IRB as to whether the study is subject to human subjects protection regulations.

According to federal regulations, there are two basic premises upon which the protection of human research subjects rests: first, that the data gathered from the subjects renders them identifiable, either directly or indirectly. While history, oral history, biography, and some qualitative interviews usually fall squarely within this premise, they typically do not meet the second basic premise of human subjects research (i.e., the regulatory definition of research). To meet the regulatory definition of research, data must be gathered and analyzed for the purpose of publishing and/or presenting knowledge that may be generalizable, or can be applied, to a broad segment of the population.

Based upon the narrow specificity - or non-generalizability - of history, oral history, biography, and some qualitative interviews, a substantial segment of historical work would not be considered human subjects research. The federal Office of Human Research Protection (OHRP), having taken current socio-historical practices into consideration, has provided the following guidance to the field in an effort to help distinguish when it may be necessary to submit social science studies involving historical, oral history, biographical, and qualitative interview methodologies to IRB review.

Data-gathering practices that serve to document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings would not constitute "research" as defined by the federal regulations. One example given is an oral history video recording of interviews with Holocaust survivors where the sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust, and to provide a venue for Holocaust survivors to tell their stories.
The purpose for which the data will be gathered and the methodology(s) applied to the data are key to the determination of whether the study may be subject to human subjects protection regulations. If substantially the same Holocaust survivor data as above were used to draw conclusions, inform policy, or generalize findings, OHRP would consider the study subject to federal regulations and require IRB review. For example, by applying qualitative methodologies to interviews with Holocaust survivors, researchers might analyze how alienation from official Nazi German culture was expressed and draw generalizable conclusions or develop policies regarding the amelioration of sub-group alienation from any “official” or hegemonic cultural standards. The collection of oral histories, biographies, and qualitative interviews for the purpose of creating an archive or repository for future research (that is, from which future researchers may test hypotheses, draw conclusions, inform policy, or contribute to generalizable knowledge) is particularly likely to be considered research, thus subject to federal regulations and IRB review.

In keeping with OHRP guidance, the UIC OPRS requires that any research involving humans, including social science studies incorporating historical methodologies, oral history, biographical methodologies, or qualitative interviews, be submitted for a human subjects research determination by the IRB.

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