

OHRP has received requests for guidance and clarification regarding whether scholarly or journalistic activities need to satisfy the requirements of the regulations. The 2018 Requirements more specifically address this question. The 2018 Requirements at 45 CFR 46.102(l) provide a definition of "research" and identify scholarly and journalistic activities that focus directly on specific individuals as one of four categories of activities deemed not to be research. The definition of "research" and the relevant category of activities deemed not to be research are described as follows:

1. (l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
 1. (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

Guidance

The 2018 Requirements explicitly clarify that a category consisting of certain scholarly and journalistic undertakings are not included in the definition of "research", and do not fall within the scope of the regulations. This category concerns scholarly and journalistic activities often conducted in various fields that focus directly on the specific individuals about whom information is collected and used, without extending that information to draw generalizations about other individuals or groups. This category of activities was removed from the regulatory definition of "research" to resolve longstanding debate and uncertainty in the research community regarding whether these activities are considered research for the purposes of regulatory oversight.

The objective of the activities in this category is to provide an accurate and evidence-based portrayal of the individuals involved, and not to develop generalizable knowledge. In some cases, these activities can be designed to affect those individuals' reputations, and to deliberately expose the individuals to public scrutiny or even possible harm, such as losing their positions or employment. The human subject protection regulations were not intended to cover individuals who are the focus of such scholarly and journalistic activities. Consequently, the protections afforded by 45 CFR part 46, including the requirement that risks to subjects be minimized, are inappropriate for these activities. For example, a journalist or a biographer might collect and present factual information to support their presentation of the character of an individual to show that the individual does not deserve the positive reputation he or she enjoys in society. Such fields of inquiry generally have their own codes of ethics. In contrast, if the activity involves collecting and using information about individuals for the purpose of drawing generalizations about such individuals or a population of which they are members, then the activity does not fit the parameters of this exception, and the activity may fall within the 2018 Requirements' definition of "research."

The 2018 Requirements at 45 CFR 46.102(l)(1) cite examples of academic fields and methodological traditions to illustrate the areas in which these activities may be carried out. The regulatory language explicitly cites those fields and traditions as examples in order to clarify that the focus is on scholarly and journalistic activities that collect and use information about specific individuals themselves, and not on generalizing the information or findings to other individuals, and that such activities occur in various fields of inquiry and methodological traditions.

Questions have frequently arisen in the areas of oral history, journalism, biography, and historical scholarship. As a result, these areas have been explicitly cited. Literary criticism is included as an example because, while a piece of literary criticism might focus on information about the author(s) of the piece of literature, it would typically focus on those specific author(s) of interest, and not on authors more generally. Legal research is included as an example because it would often focus on the circumstances of the plaintiffs or parties involved in a specific case. It is not the particular field that removes the activity from the definition, but rather that the purpose and design of the particular activity is to focus on specific individuals and not to extend the activity's findings to other individuals or groups. So, for example, a medical case report could fall within this category, if the point of the report were to describe an unusual and interesting case-specific medical complaint and its treatment. The list of examples of types of scholarly and journalistic activities is not exhaustive; there could be other such activities if they focus directly on specific individuals about whom the information is collected.

In contrast, although activities described in the category at 45 CFR 46.102(l)(1) may sometimes be performed in such academic fields as anthropology or sociology, a significant portion of the activities that are characteristic of these fields fall outside of the category and therefore remain within the scope of 45 CFR part 46. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals, but also of the community or group to which they belong, would not meet the category found at 45 CFR 46.102(l)(1). The purpose and design of such studies or activities is to reveal something about the community or group – that is, to develop generalizable knowledge. Because the purpose of such studies or activities is not to limit the inquiry to knowledge about the particular individuals being observed, the protections provided by the requirements of 45 CFR part 46, such as the requirement to minimize any harm to the specific individuals from which the information was collected, are appropriate. Such activities would continue to fall within the scope of the definition of "research" under the 2018 Requirements.