

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.

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(a)(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