



CANCER REGISTRY OF
GREATER CALIFORNIA

Change:

On January 19, 2017, the US federal government issued revisions to the Common Rule under which scientists who receive federal funding conduct research involving human subjects (Federal Policy for the Protection of Human Subjects, 82 Fed Reg 7,149 (2017) (to be codified at 45 CFR 46)). The revised Common Rule expressly addresses public health surveillance in relation to scientific research and the protection of human subjects (1). It will enhance the efficiency of activities including cancer registration and surveillance, and research that uses cancer registry data.

Cancer registration and surveillance is an evidence-based response to the demands of the citizenry that cancers be counted. It enables scientific findings that range from genetic markers to identification of behavioral and environmental factors that influence who gets cancer and why. These findings are made possible through research studies conducted to respect and protect research participants and especially cancer patients about whom identifiable data are access and used.

New Definitions, Categories, and Processes:

With the intent to modernize and strengthen its regulations, the government has issued revisions that resonate with the core aims of public health, and will better facilitate productive, scientific outcomes. These revisions include:

- ✱ The recognition and exclusion of public health surveillance activities, including the collection and testing of biospecimens, from Institutional Review Board (IRB) oversight;
- ✱ The requirement that a research study in which more than one institution located in the US is engaged be reviewed by a single IRB among these institutions with the others entering a relationship of reliance; and
- ✱ The expansion of exemption categories to include research involving the collection of identifiable human subjects data through survey and interview procedures.

In recognition of the value of genetic and molecular science to public health, the definition of public health activities extends to "the collection and testing of biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products)" (82 Fed Reg 7,261 (2017)).

Balancing Risks and Benefits:

The revised Common Rule offers an opportunity to reflect on the risks associated with research involving cancer registry data and the adequacy of human subjects protections. The more than 15 million cancer survivors and persons living with cancer in the US have shifted social and cultural perceptions of cancer itself.

Increasingly, physicians anticipate rendering some cancers curable and others more like chronic disease. Survival has become an attainable achievement and an everyday experience. As a result, some of the vulnerability associated with cancer research has been reduced. Risks of informational harms, however, are more specifically defined in medical privacy laws, and elevated by the use of information technologies in medicine and research.

Through consent documents and other study materials, researchers describe the nature and potential impacts of loss of privacy and breach of confidentiality, discrimination in relation to medical insurance and employment, reputational harms, and the implications of discovering genetic information, the sharing of which can impact not only individual research participants but also biological family members who may be unrelated to or non-participants in research.

Revised Regulations, Expanded Opportunities Human Subjects Protection and Cancer Research

Meaningful Oversight:

IRBs oversee risks that affect participant experiences. They may require researchers to signal risks such as recollection of trauma or distress, depression, or misperception of a disorder or other personal condition on the basis of research questions or inferences from one's own responses to research questions.

Broadly, these risks may be characterized as risks of informational harms. The revised Common Rule indicates that when these risks are appropriately conveyed and mitigated through data management and security procedures, many research activities present minimal risk and may be efficiently approved or granted exemption.

The Cancer Registry of Greater California is a program of the Public Health Institute.

For more information about cancer registry data and its use in research, or to request cancer data for your study, visit the Cancer Registry of Greater California.

<http://crgc-cancer.org/data-access-and-disclosure/>

