(1.3) Determination of IRB-exemption status

You have recently conducted an investigation comparing MRI findings with pathologic, laboratory, and clinical information in patients with a rare adrenal tumor. The project integrated findings from various institutional databases, including the primary EMR as well as pathology and radiology records. You initially assigned each patient a random anonymous identifier when beginning the investigation. Currently, your primary database contains this anonymous identifier for each patient, along with a summary of the imaging, pathologic, laboratory, and clinical data. You have a separate file serving as a key that contains a list of these identifiers, along with the patient's medical record number and the corresponding pathology and MRI case numbers. Only a single copy of the key exists. This file is password-protected and resides on a secure and encrypted hospital server that is approved for storing research-related private health information. In currently writing the manuscript, you consider how to indicate the IRB status of the study. As your current study solely entails a retrospective image review, and you have been careful to store identifiable patient information only in the form a key on the approved hospital server, you consider designating your current project as exempt from IRB approval. What concerns are raised in doing so?

Comment

Specific federal legislation (Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects; referred to as the "Common Rule") provides regulations that direct the conduct of IRBs. Such regulations are implemented by the Office for Human Research Protections (OHRP) within the Department of Health and Human Labor (DHHL). The Common Rule identifies general categories of human subjects research studies that are deemed exempt from the rule's regulations. These categories include, although are not limited to, studies performed within certain educational settings; food taste and acceptance studies; and studies related to public benefit or service programs. Of primary relevance to the present case is an exemption category for previously existing data sets in which the data are recorded in a manner such that the subjects cannot be individually identified. Importantly, the Common Rule indicates that this exemption category only applies if subjects cannot be determined either directly or indirectly through an identifier. Even if the study is retrospective and does not entail direct patient intervention, the usage of patient identifying information introduces a risk of loss of confidentiality, thereby potentially creating more than minimal risk. For the current study, the presence of a code that can be used to link study data to individual patients, although stored in a separate file on a secure server, results in the study no longer satisfying this category for exemption.

Also at issue in the present case is that, while the Common Rule does not explicitly state who is responsible for determining whether a study meets criteria for exemption, the OHRP strongly encourages that the investigator not make this determination. Such self-determination introduces a conflict-of-interest. Rather, it is suggested that this determination be made by an independent individual who is educated and trained in the Common Rule regulations as well as nuances of the exemption categories. Accordingly, many IRBs currently require that investigators submit their studies to the IRB to decide whether an exemption is appropriate. Therefore, in the present case, you should not have personally judged your study to be IRB-exempt but rather have followed the IRB's procedure for submitting the study for evaluation, at which point the IRB staff would make a judgment regarding possible exemption. For instance,

in the present case, the IRB could evaluate the manner in which private health data is being electronically stored, managed, and accessed, to guide its decision regarding possible exemption for the study.

In summary, the criteria for exemption must be individually determined for each investigation, a process that is best performed by trained IRB personnel rather than by the investigator. IRB exemption does not imply that a study does not require being brought to the attention of the IRB, but rather represents a status that is typically granted by the IRB following its own evaluation of the study. Thus, you should submit the study to the IRB to be evaluated for potential exemption. This IRB submission should have occurred prior to beginning the research investigation.

References

1) National Institutes of Health. Office of Extramural Research. Frequently Asked Questions from Applicants. Human Subjects Research – Definitions. http://grants.nih.gov/grants/policy/hs/faqs_aps_definitions.htm Accessed: December 23, 2015.
2) United States Department of Health & Human Services. Human Subject Regulations Decision Charts. http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html Accessed: December 23, 2015.
3) United States Department of Health & Human Services. Frequently Asked Questions About Human Research. http://www.hhs.gov/ohrp/policy/faq/ Accessed: December 23, 2015.
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