

## **(1.2) Criteria for human subjects research**

You are conducting a small retrospective study of the CT findings encountered in a rare medical condition. You've identified approximately ten patients with the condition who underwent CT, and have a log that contains the accession number for each of the CT examinations, as well as a summary of the key findings. The log does not contain the patient's name or medical record number. You have completed your review of the imaging and are prepared to begin drafting the manuscript. However, you are wondering whether evaluation of the study by the IRB is required, as this study entails a limited retrospective imaging review and the captured data do not include the patient's identity. You recall hearing from a colleague that IRB regulations only apply to actual human subjects research, and you are unsure whether the human subjects criterion applies to the current activity. Does this study warrant evaluation by the IRB?

### **Commentary**

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 Services (DHHS). The Common Rule provides specific criteria for activities that are considered "human subjects research" and that would potentially fall under the purview of an IRB. Namely, such activities must both represent "research" and deal with "human subjects." "Research" refers to a systematic investigation that is intended to contribute to "generalizable knowledge," whether or not the activity was originally conducted for research purposes. Work that intends to extract conclusions that may be applied to other populations or extend beyond an internal program generally meet this criterion of contributing to generalizable knowledge and thereby representing research. "Human subjects" refer to living individuals about whom the researcher either obtains data through an interaction or obtains identifiable private information. Content of a medical record is considered to represent private information. However, it must be possible to identify the subject through such medical record data in order to meet this criterion.

In this case, the described activity attempts to provide generalizable knowledge and thus constitutes research. In terms of whether the activity deals with human subjects, no direct patient identifier (i.e., name, social security number, medical record number) is included in the data set. However, the description notes tracking of the accession number for the CT examinations. This accession number can be used to identify a specific patient, which in turn could be used to discover further medical information about an individual. On this basis, the described investigation deals with human subjects and constitutes human subjects research, thereby warranting oversight by the IRB. Any data element that could be used to identify the patient, such as a hospital account number, radiology examination code, or pathology specimen code, constitutes identifiable private information, such that the activity is considered to deal with human subjects based on the Common Rule. In comparison, research activities that do not deal with individual human subjects (for instance, a project comparing reimbursement policies of different insurance providers and that does not include any data at an individual level) do not satisfy this criterion and generally would not be subject to the regulations of the Common Rule. Therefore, the present study warrants submission for IRB evaluation, which should have occurred prior to beginning the investigation. Given the minimal risk of the study, the IRB may

deem it to be eligible for an expedited review process. Nonetheless, when unsure whether a given investigation meets the criterion for human subjects research, it is advisable to consult with one's local IRB for further guidance.

## 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](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.
- 4) United States Department of Health & Human Services. Code of Federal Regulations. <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> Accessed: December 23, 2015.