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Institutional Review Board Role When Returning Study Results to Subjects

We continue here with our coverage of an important series of recommendations and discussions issued in April by the Secretary's Advisory Committee on Human Research Protections (SACHRP). For example, last month we presented portions of the committee's recommendations on the controversial proposal by the National Institutes of Health (NIH) on the required (not optional) use in NIH-funded multisite studies of only one central Institutional Review Board (IRB) to review protocols from all the sites.

This month we turn to another topic addressed by SACHRP that we have not covered before; namely, proposed new policies on returning research results to subjects and/or to the general public.

"There is currently significant attention to the distribution of final study data and results, both to the subjects who participated in the research and to the public at large. SACHRP has determined that there are four aspects of returning research results to subjects and releasing the results publicly ...

- Return of incidental findings to subjects
- Return of individual study results to subjects
- Return of general study results to subjects
- Public release of study data" ("Recommendations Regarding Return of General Research Results," SACHRP, April; on the Web at http://www.hhs.gov/ohrp/sachrp/commsec/sharing_study_data_and_results.html).

Returning Study Results to the Public

"SACHRP partially addressed the issue of public release of data in December of 2013 by providing commentary in response to the June 4, 2013, Food and Drug Administration (FDA) Request for Comment relating to the availability of masked and de-identified non-summary safety and efficacy data. While this commentary was focused on the issues presented in the FDA request for comment, it also addressed some of the broader issues associated with the public release of study data.

SACHRP plans to address each of the remaining three topics in individual recommendations [in the future] in order to provide targeted assessments of the ethical, regulatory, and administrative issues raised by each ....

Currently there are several processes being implemented or considered for sharing study data publicly, including but not limited to the direct provision of general study results to research subjects. At the broadest level are public releases of study data in formats such as ClinicalTrials.gov and published medical journal articles.

This information is available to subjects just as it is to other members of the public, but does not involve a specific effort to provide the data direct-

NOTE #1: Quoted materials in this newsletter appear exactly as originally published in source documents, including any misspellings, grammatical errors, missing words, etc.

NOTE #2: Articles may be continued in subsequent issues.

Also In This Issue

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