Managing incidental findings in human subjects research

June 25 2008

Article offers first major consensus recommendations for IFs

An incidental finding (IF) is a finding concerning an individual research participant that has potential health or reproductive importance, is discovered in the course of conducting research, but is beyond the aims of the study. IFs are an increasingly common byproduct of research using powerful technologies that generate "extra" data. Because IFs can potentially save lives but also cause alarm, the decision on whether or not to disclose them to research participants has been a major dilemma. Little guidance currently exists on how to approach this problem. A two-year project supported by the National Human Genome Research Institute at NIH has now published the first major recommendations for how to anticipate and manage IFs in genetic, genomic, and imaging research, suggesting broader application to other research domains. This project, led by Prof. Susan Wolf at the University of Minnesota's Consortium on Law and Values in Health, Environment & the Life Sciences, involved a multidisciplinary group of leading experts from the U.S. and Canada. The project has published a 17-article symposium including the consensus paper, which appears in the Summer '08 issue of the *Journal of Law, Medicine & Ethics*.

The project members concluded that it is essential to address the possibility of IFs in the consent process. Researchers should set up a process for recognizing IFs and verifying whether there is indeed a suspicious finding of concern. Researchers should take steps to validate an IF and confirm its health or reproductive importance before offering the finding to a research participant. A researcher who lacks the

expertise to make this assessment may need to consult a clinical colleague. The consensus paper also addresses the vexing problem of IFs discovered in reanalysis of archived data.

The consensus article distinguishes among three categories of IFs to determine when they should be disclosed. IFs with strong net benefits -- ones revealing a condition likely to be life-threatening or revealing a condition likely to be grave that can be avoided -- should be offered to research participants. An IF that offers possible net benefit -- one that may offer more benefit than burden to the research participant -- may be disclosed in the researcher's discretion. An IF that has unlikely net benefit or whose net benefit cannot be determined should not be offered to the research participant, because disclosure may well present more burden than benefit.

"The problem of IFs is important and deserves broad discussion among researchers, research participants, institutional review boards, funders, and oversight bodies," the authors conclude. "Handling IFs responsibly requires clarity about the difference between research and clinical care, coupled with attention to the ethical duties of researchers when faced unexpectedly with information that could save a life, significantly alter clinical care, or prove important to the research participant."

Source: Wiley-Blackwell