JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 13, No. 10, October 2017 "Happy Trials to You"

Nine Questions for an IRB to Ask About Clinical Studies That Involve Genetic Testing

By Dennis J. Mazur and Norman M. Goldfarb

Clinical studies can assess the accuracy of a genetic test to diagnose a disease. Clinical studies can also assess the usefulness of genetic tests in, for example, determining the likelihood that a person will respond to a medical treatment. Genetic tests can also be used to screen people for participation in a clinical study of a medical treatment.

Genetic data is often highly sensitive, so the use of genetic tests requires adequate protections for each participant's privacy, as addressed in a previous article. Genetic tests, like any tests, are also subject to the possibility of false positives and false negatives.

The following nine questions can assist IRBs in reviewing a study that involves genetic testing:

1. Is the study designed to develop a genetic test, use a genetic test as a marker, or both?
2. Will the study population include people of different genders, ethnicities, and any other relevant subgroups?
3. What, if any, are the investigator's expectations of the prevalence of genetic variation across genders, ethnicities or other subgroups?
4. What is known about correlations between the marker and its physiological, mental or other manifestations?
5. How useful is the genetic marker likely to be as a diagnostic test, given the prevalence of the marker, the prevalence of the indicated condition, and the marker's predictive value?
6. Will the results from the diagnostic test be actionable by participants, e.g., will certain results indicate the need for medical treatment or lifestyle changes?
7. Will the results of the genetic tests be disclosed and their implications explained to participants (and how, when and by whom)?
8. Will the results of the genetic tests have implications for family members or others and, if so, will these results be communicated to them (and how, when and by whom)?
9. Will the results from the diagnostic test, if and when published, be of an especially sensitive nature to anyone?

Authors

Dennis J. Mazur, MD, PhD, is the author of *Evaluating the Science and Ethics of Research on Humans: A Guide for IRB Members,* published by the Johns Hopkins University Press, Baltimore, Maryland, 2007. Contact him at mzrdj11@gmail.com.

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.