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Seven Questions about Informed Consent for Clinical Studies of Genetic Tests

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There are three forms of genetic testing:

- **Diagnostic testing.** Does the patient have the genetically-linked disease or condition?
- **Predictive testing.** Is the asymptomatic patient, based on his or her family history, at risk for developing the disease or condition? Or, what is the prognosis for the symptomatic patient?
- **Carrier state testing.** Can the asymptomatic patient pass the problematic gene to his or her offspring?

Given the general public's unfamiliarity with the complex issues related to all these forms of genetic testing, IRBs should ensure that potential study participants and, if appropriate, their families, are well informed during the consent process. The following seven questions should be addressed:

1. How accurate and reliable is the test?
2. How will the results of the test be kept private?
3. Are there any guarantees that the information will not be seen by others, e.g., insurance carriers or employers?
4. What are the legal protections against discrimination, if there is disclosure?
5. Will the study participant's family be informed that he or she is in a research study?
6. Besides the study participant, will anyone in the study participant's family be informed of the test results?
7. Is the study population particularly sensitive to issues related to genetic testing?
8. If participation in the study or the test results will be shared with family member(s), will the study participant, the study participant's physician, the family member(s) physician(s), the principal investigator, another member of the research team, or a genetic counselor inform them and help them understand the issues?

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