IRB Appendix G - Genetic Testing

Rev. March 2015

Complete this form to request the use of genetic testing in the proposed research.

Principal Investigator:

Project Short Title:

1. What type(s) of genetic testing will be performed?

- ☐ Germline (inherited mutation or genotype)
- ☐ Somatic (non-inherited mutation expected to be present only in the tissue being studied)
- ☐ Unknown

2. Which gene(s) will be tested? If micro-array is used, summarize the *types* of genes to be tested.

3. List any genes (being tested) that are known to cause hereditary diseases if present as a germline mutation.

4. Specify the purpose of the gene testing.

5. Are any proposed tests also clinically available assays?

- ◯ Yes
- ◯ No

If **Yes,** please specify:

6. Could proposed testing result in incidental (i.e., unintended) findings?

- ◯ Yes
- ◯ No

If **Yes,** please explain:

7. Will participants be informed of gene testing results?

Yes
No

Explain why or why not:

If **Yes,** also complete the following:

a. Describe the plan for informing participants of gene testing results.

b. Specify the procedure that afford participants a way to opt out of receiving their gene testing results.

c. Will the results have clinical significance for participants?

Yes
No

If **Yes,** please explain:

d. Could the results have implications for others (e.g., family members)?

Yes
No

If **Yes,** please describe:

8. Will counseling, pre- and/or post-, be provided to the participants?

a. If **Yes**, describe and specify who will perform counseling and the counselor's qualifications.

Yes
No

b. Will the participants (or their insurers) incur any costs for the counseling?

Yes
No

9. Will participants be informed of new developments?

Explain why or why not:

Yes
No

10. Will family member(s) (or their data) be involved in the research?

Yes
No

If **Yes**, complete the following:

a. Will family member(s) be readily identifiable?

Yes
No

Explain why or why not:

b. Will the primary participant be asked to provide any private information (e.g., health status, health or behavior history) about his/her family member(s)?

Yes
No

If the answer to both of the above questions (10a and 10b) is **Yes**, complete the following section.

c. Specify methods for recruiting family (e.g., how, when, where and by whom).

d. Specify methods for obtaining the informed consent of family member(s) (e.g., how, when, where and by whom).

e. Specify data and/or specimens to be collected and proposed collection methods (e.g., how, when, where and by whom).