INFORMED CONSENT CHECKLIST FOR GENETIC/GENOMIC TESTING

NOTE: This checklist covers language specific to genetic/genomic testing and is intended to supplement the CPHS Informed Consent Checklist and the CPHS Biomedical Template Consent Form. For basic elements of informed consent, refer to the Informed Consent Checklist above.

As genomic technology advances, research participants' samples, genomic data, and associated health information are being stored and shared to maximize the benefits achieved through research. It is essential that the rights and interests of research participants (i.e., human subjects) who contribute samples and health-related information to these projects are respected throughout the research process.

ELEMENTS OF INFORMED CONSENT FOR GENETIC TESTING	YES	NO	N/A
Purpose: Is there sufficient, clear description of the underlying genomic science (e.g., an explanation of "genes" and/or "DNA" in lay language), the study design, the diseases(s) or condition(s) being studied, and the immediate and long-term goals of the study in simple, non-technical language?			
Procedures: Have the following been described? (*as applicable*) • The process for collection of samples (blood, saliva, or other tissue) and personal/family health information.			
• Whether researchers will have access to a research participant's medical records, and if so, by whom and through what process data will be collected (e.g., one-time versus ongoing collection of information).			
• What DNA sequence or other experimental data will be generated from the samples and/or data.			
• Information related to storing, sharing, and future use of the samples and/or data.			
• (Statement of) Plans for dissemination of summary-level research results and possible return of individual research results.			
Risks/Discomforts: Have the following been described? (*as applicable)* • Psychological or social risks that may occur through receiving information that is unexpected or unwanted by the participant. If results are to be returned, the uncertainty of findings, and personal and sensitive information about disease and disability risk, paternity, or ancestry may be difficult for participants to understand and may sometimes be upsetting to participants.			
• Privacy breach due to possible re-identification or other loss of confidentiality.			
• Unauthorized use of data due to computer security breaches or other unanticipated distributions.			

Risks/Discomforts (continued): Have the following been described? (*as applicable*) • Information about participants in some cases might extend to relatives or identifiable populations or groups, the latter of which could result in potential discrimination or stigmatization.			
Confidentiality: Is information provided about legal protections for participants' genomic data, including protection against genetic discrimination? • The Genetic Information and Nondiscrimination Act of 2008 (GINA) prohibits the use of genetic information, including family history, for most health insurance and employment purposes.			
• The Affordable Care Act of 2010 (ACA) prohibits issuers of health insurance from refusing coverage to patients or altering their premiums because they have "pre-existing conditions," including genetic diagnoses.			
• Certificate of Confidentiality (if approved by NIH)			
For studies receiving NIH Funding (subject to NIH Genomic Data Sharing Policy): • Does the consent form contain language to ensure that samples and data are available for storing, sharing, and use in future, unspecified research (i.e., secondary research)?			
• Does the consent form include information about the sharing of genetic or genomic data and associated phenotypic data in the NIH Database of Genotypes and Phenotypes (DbGaP: http://www.ncbi.nlm.nih.gov/gap)?			
For studies depositing samples and/or data into open or controlled-access databases: Does the consent form contain the following information?: • Who will have access to the samples and/or data.			
• What information will be made available along with the sample.			
• How long the sample and/or data will be made available (usually an unlimited period of time).			
Discontinuing Study Participation (use of samples and/or data): *As applicable:* • Does the consent form clearly explain that for genomic studies that involve bio-banked samples or storage of individual-level genomic, demographic, or health data in unrestricted or controlled-access databases, complete withdrawal of samples and data may not be possible once samples or data have been distributed to other laboratories?			
• Is it possible to withdraw samples or data from future distributions? If so, the consent form and the informed consent process should include a full explanation of the extent to which withdrawal of samples or data is possible or not possible and what the process is.			
Financial Reimbursement, Costs, and Commercialization: • Is there a clear explanation of any compensation, including reimbursement, that will be provided to participants, or expenses that might be incurred by participants as a result of their involvement in the research?			

Financial Reimbursement, Costs, and Commercialization (continued): • Is the Moore Clause (required by UCOP regarding the ownership of specimens) included? Recommended language similar to the following should be used: "Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them."			
Future Contact: *For studies receiving NIH funding:* If applicable, does the consent form contain language that allows for contact regarding participation in future research even if the contact schedule has not yet been determined?			