**Model Consent Content for Genome, Exome**

**and Other Genomic-Related Analysis**

**(v.4-14-2015)**

**Background**

This resource is intended to provide guidance to investigators as they develop protocol and consent documents for research projects integrating genomic-related research objectives. Investigators who include genome, exome or other genomic-related research in their protocol must address the following issues as they develop the protocol and study consent document: .

* Biospecimens, genetic/genomic data, and phenotyping information can be stored and used indefinitely for broad secondary research aims unrelated to the original study.
* Genomic analyses can reveal results of analytic and clinical validity and clinical utility that are not related to the test indication or research aim(s).
* Data can be reinterpreted and change in clinical significance over time.
* Privacy concerns can arise in part because of the risk of identification and re-identification.
* Findings may be relevant not just to the research participant but also to the biologic family members, ethnic and cultural communities, and for reproductive decision-making.
* Adherence to the NIH Genomic Data Sharing Policy will be required of all intramural investigators as of August 2015.

Investigators utilizing genetic and genomic technologies need to consider the following issues and incorporate them into the protocol and consent documents as applicable.

1. **Scope of the analysis**
   1. What type(s) of genomic analysis is included in the study? (i.e. genome or exome sequencing)? Somatic versus germline analysis? Even somatic analyses may reveal germline mutations[1](#_ENREF_1).
   2. What type of tissues will be used in the research (tumor, blood, other tissue)? Somatic analysis may identify constitutional genetic variation that could have clinical relevance for both the research participant and their close relatives.
   3. Will specimens and/or data be stored for future genomic analysis?
2. **Identifiability in genomic research**
   1. Will the data generated from a research participant be overtly identifiable, potentially identifiable by deduction or completely unidentifiable? For example, how likely could an unidentified sample (a sample collected without identifiers of any kind) be linked to an existing DNA repository that has personal identifiers such as the criminal justice system or the armed services?
3. **Incidental and/or secondary findings**

a. The Presidential Commission for the Study of Bioethical Issues report on incidental findings established nomenclature (see Table 1) to classify results from genomic analysis in part to facilitate decisions about notification of the research participant’s findings[2](#_ENREF_2).

Table 1: Genomic Analysis Result Nomenclature[2](#_ENREF_2)

|  |  |
| --- | --- |
| **Result Taxonomy** | **Description** |
| **Primary Finding** | A result associated with the indication for the test. |
| **Incidental Finding:** Anticipatable | A finding that is a rare but a known possible outcome from the test, i.e. misattributed paternity. |
| **Incidental Finding:** Unanticipatable | A finding not anticipated based on the current evidence, i.e. new evidence that reveals a health risk not known at the time the test was originally performed. |
| **Secondary Finding** | A finding actively sought but not associated with the indication for the test. |
| **Discovery Finding** | An extensive test in which anything of interest is reported. |

b. In 2013, the American College of Medical Genetics released a policy statement specifying that laboratories conducting clinical exome and genome sequencing seek and report germ line mutations in 56 genes associated with 24 different disorders[3](#_ENREF_3).

1. **Returning research results**
   1. The following points are to be considered by investigators when developing a plan for returning research results (primary, incidental, secondary, or other):

* Potential for results to affect both the subject and their close biologic relatives
* Have an established process for evaluating whether findings (incidental or otherwise) meet established criteria (analytic validity, clinical validity, clinical utility) to offer research results to individual participants
* Whether or not it is appropriate to return research results as “group results” via newsletter, publication, website or as individual research results
* Process of offering and delivering results
  + The process of identifying and disclosing research results should involve healthcare professionals with the appropriate expertise required to provide the participant with sufficient interpretive information (i.e., experts in the field, geneticist, genetic nurse, genetic counselor)
  + The research participants’ right to not know certain test results
  + A mechanism to confirm the research result in CLIA-approved laboratory
  + The process of returning research results is in compliance with evolving professional standards of disclosure of genetic and genomic information for healthcare decision-making

**V. Data Sharing**

a. The NIH Genomic Data Sharing (GDS) Policy establishes expectations and responsibility to ensure broad and timely genomic research data sharing.

b. The GDS applies to all intramural supported investigators

c. Data for required reporting includes (but is not limited to) both human and non-human genomic data, genome sequence, transcriptomic, epigenomic, and gene expression data.

* A Trans-NCI Genomic Data Sharing Workgroup has been established to facilitate policy implementation, guidance for investigators, compliance, and data sharing support for investigators.

**VI. Resources**

* 1. The following resources and reference materials can be useful to investigators considering these issues:

**Consent Guidance**

National Human Genome Research Institute Informed Consent Elements <http://www.genome.gov/27026588>

National Human Genome Research Institute Consent Form Examples and Model Consent Language <http://www.genome.gov/27559024>

**Incidental/Secondary Findings**

Clayton, E.W., et al. (2013). Managing incidental genomic findings: Legal obligations of clinicians. Genetics in Medicine. 15, 624-629. Privacy

Fabsitz, R.R., et al. (2010). Ethical and practical guidelines for reporting genetic research results to study participants: Updated guidelines from a National Heart, Lung, and Blood Institute Working Group. Circulation Cardiovascular Genetics, 3, 574-80.

Green, R.C., et al. (2013). ACMG Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing. <http://www.acmg.net/docs/ACMG_Releases_Highly-Anticipated_Recommendations_on_Incidental_Findings_in_Clinical_Exome_and_Genome_Sequencing.pdf>

Jarvik, G.P. et al. (2014). Return of genomic results to research participants: The floor, the ceiling, and the choices in between. American Journal of Human Genetics, 94, 818-826.

McGuire, A., et al. (2010). Informed consent in genomics and genetic research. Annual Review of Genomics and Human Genetics, 11 361-381

Presidential Commission for the Study of Bioethical Issues, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*. 2013, <http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf>

Wolf, S., et al. (2012). Managing incidental findings and research results in genomic research involving biobanks and archived data sets. Genetics in Medicine, 14, 361-384.

**Genomic Data Sharing**

NIH Genomic Data Sharing Policy <http://gds.nih.gov/03policy2.html>

**Privacy**

Rodriguez, L.L., et al. (2013). Research ethics: The complexities of genomic identifiability. Science, 339, 275-6.

**Somatic Testing**

Catenacci DV, et al. (2015). Tumor genome analysis includes germline genome: Are we ready for surprises? Int J Cancer, 136:1559-67.

**Informed Consent Elements**

Adopted from the National Human Genome Research Institute, Informed Consent for Genomics Research. <http://www.genome.gov/27026588>

**Description of the research related to genome, exome or other genomic-related analysis**

It is important that research participants understand what they will experience as research participants. Dividing the research procedures into stages may make the information easier to understand. The description should cover topics including::

* Purpose of the research.
* What analyses will be performed and what could be learned.
* The process for the collection of samples (blood or other tissue) and health information.
* How samples and health information will be coded and stored.
* Whether there will be access to a research participant's medical record and, if so, the process for accessing them (e.g., one-time vs. ongoing collection of information from medical records).
* The duration of storage of biospecimens and participant data.
* Whether and how samples and health information will be shared with qualified investigators for appropriate research use both during the study period and after the study ends.
* A general description of the types of researchers who will have access to samples and data (e.g., academic, industry, government)
* Whether and how future contact (i.e. re-contact) is planned.

**Purpose of [genome, exome sequencing or other genomics-related analysis research]**

Potential participants should be given a succinct explanation of why they have been approached for the proposed study. This section should include topics such as a brief description of the underlying scientific justification for the research project, the study design, the diseases(s) or condition(s) being studied, and the immediate and long-term goals of the research project. Use of simplified language that is not overly technical may help potential participants understand the rationale for genome sequencing, exome sequencing or other genomics-related analysis.

**Example Language**

***Why is this research study being done?***

*We are requesting your permission to perform [specify type of analysis, i.e. genome and/or exome sequencing] on your [specify type of specimen, i.e. blood and/or tissue samples] and link this to your medical and/or family history]. Your blood and tissue samples contain genes, which are made up of DNA (****d****eoxyribo****n****ucleic* ***a****cid) which serves as the "instruction book" for the cells that make up our bodies. Sequencing [specify type of analysis, i.e. genome and/or exome] will determine the exact order of the base pairs (chemical letters) in [the tumor being studied, or blood]. Your sample(s), [specify any correlations, i.e. medical and family history information] will help us study how genes [specify purpose of analysis].*

**Data Sharing**

One of the main factors that distinguishes genomic-related research studies from other studies involving human research participants is that large datasets of genomic and health information are generated and will be deposited in data repositories for sharing with the broad biomedical research community. These data repositories may be fully open or accessible only with the permission of a Data Access Committee (*e.g.* [database of Genotypes and Phenotypes (dbGaP)](http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap) ), depending on the nature of the data, local policies, and other factors.

Many of these datasets are useful beyond the particular aims of the study for which they were originally collected, especially as various diseases turn out to have biologic mechanisms in common. Thus, the value of these data can increase when they are allowed to be shared with the broader research community and are not restricted in use to particular diseases or for a limited period of time.

This section should describe the mechanism(s) that will be used to store and share the data in compliance with the NIH Genomic Data Sharing Policy and should also indicate whether samples and genomic data will be shared with the broader research community both inside and outside the sponsoring institution.

Example Language

**Storage and release of samples, genomic data, and health information**

Portions of your samples, genomic data, and health information will be stored for an unlimited period of time to be used in future research. [If appropriate] As part of this project, your samples will be used to create cell lines that will keep reproducing and can be used for many purposes. We will store the cell lines and other samples and data in a "cell bank," so that other researchers and companies can apply to use the cell lines in their own research. The cell bank will only release cell lines to researchers and others under certain conditions. [Specify the terms of release established by the repositories, such as approval by a governance committee.]

**Unrestricted access databases:**

The information from this study will be freely available in a public, unrestricted database that anyone can use. [For example], the public database will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

**Controlled access databases:**

Your individual genomic data and health information will be put in a controlled-access database. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database have agreed not to attempt to identify you.

**Incidental and Secondary Findings**

In 2013, the American Colleges of Medical Genetics (ACMG) issued recommendations for reporting incidental findings in clinical exome and genomic sequencing. This guidance specified that **clinical** laboratories performing exome and genome sequencing interrogate the genome and report germ line mutations in 56 genes associated with 24 different disorders [3](#_ENREF_3). There is no consensus as to the application this guidance to analyses performed in a research context. However, the National Heart, Lung, and Blood Institute of NIH has issued guidance on the return of genomic incidental findings of clinical utility in the research setting[4](#_ENREF_4).

In 2014, the ACMG incorporated the option for individuals undergoing testing to opt out of receiving findings that are not associated with the primary test indication. In 2015, the ACMG confirmed the previous policy statements, began using the nomenclature established by the Presidential Commission on Bioethics, and highlighted the key components to be included in a genome testing consent. ACMG specified that the consent should include a description of the limitations of the interpretation the test results, how patient privacy is maintained, the implications of the test results for family members, the possibility of generating results that are not associated with the primary test indication, including test results which have clinical utility[5](#_ENREF_5).

Investigators performing genome or exome sequencing in their protocols need to describe a plan for the management of incidental and secondary findings within the protocol and consent. This plan should address the type of results to be disclosed and include plans for the following:

***Results for disclosure***

* No results for disclosure and justification for this approach.
* Current ACMG list. This list is considered the minimum list and investigators can add to this list[3](#_ENREF_3).
* Medically preventable conditions.
* Medically relevant results with unclear treatment implications.
* Results without personal health implications, but which may be useful for reproductive planning.
* Results of uncertain significance.
* Whether the investigators will update participants if future research changes the clinical significance attributed to results at the time of the initial investigation.

***Process for return of results***

* How genetic education and counseling by a trained genetic healthcare professional will be provided.
* How CLIA confirmation of research results will be performed, including the mechanism of payment for CLIA laboratory confirmation..

***Disclosure to children***

* Whether or not results for adult-onset disorders will be disclosed to children or the parents of minor participants and the rationale for either choice.
* If applicable, a plan for return of results when pediatric research participants reach the age of majority.

**Example Language**

***Incidental and Secondary Findings***

*Gene changes will be identified that are not related to this research study. These include*

* *Changes in genes that are related to diseases other than cancer*
* *Changes in genes that are not known to cause any disease. These are known as normal variations.*
* *Changes in genes that are new and of uncertain clinical importance. This means that we do not know if they could cause or contribute to a disease or if they are normal variations.*

*If we find a change in a gene that is important to you or your family’s health, the results will need to be confirmed in a clinical laboratory.* ***[specify how long you will look for other relevant genetic changes, i.e. one time only, for a period of time]*** *If you want this to be done, we will draw an additional blood sample and send it for confirmatory testing. Once the results are available, if you would like to receive your results we will offer to have you come to NIH (at our expense) to have genetic education and counseling to explain this result.*

*If you do not want to come to NIH, we will help you find a local genetic healthcare provider who can explain it to you (at your expense).*

*Please let us know your preference by initialing one of the following statements:*

*\_\_\_\_ I DO NOT want to be recontacted if genetic variants with potential health implications are discovered.*

*\_\_\_\_ I DO want to be recontacted if genetic variants with potential health implications are discovered. (You will be given a choice to learn or not learn about a genetic change that we find.)*

***Research Results-non disclosure***

*We will not give you any individual results from your [genome and/or exome] sequencing. This is because it will probably take a long time for this project to produce health-related information that we will know how to interpret accurately. However, we will tell you if we find that you have a communicable disease that we are required by law to report. [Specify whether and how you will summarize research results for participants.]*

***Research Results-disclosure***

*When we have useful results from the genome sequencing we have done, we will contact you and ask you if you want to learn the results. We will ask you to come back to the NIH to learn the results. You will meet with professionals with the expertise to help you learn more about the risks, benefits and limitations of learning your research results. If you then decide to receive your results, the research team will explain the meaning of these results and any implications for your and/or your family’s health.*

**Benefits**

Potential benefits to the research participant and to others should be described in the consent form. It is important to include potential benefits for society, but investigators should be careful to distinguish between potential benefits to the individual research participant versus society.

**Example Language**

***Are there any benefits to participating in the project? No Benefit***

*You will not benefit personally from giving a sample for this project because this kind of research usually takes a long time to produce medically useful results. However, your participation will increase our understanding about cancer. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.*

***Are there any benefits to participating in the project? Benefit***

*Possible benefits to you could include: [include as applicable]*

* *Learning that a specific change in your genes is the reason for your personal history of cancer, which might help you to prevent or lessen future health problems.*
* *Information about the risks of cancer in your children and other close relatives which may help lower their risk by obtaining early screening or other risk management care..*
* *New and better treatments may be an option depending on the genetic result(s).*

*This study may increase our understanding about cancer. We think the information gained during this study may contribute to the medical care, treatment and prevention of problems for others in the future.*

**Risks**

Research participants need to be informed of the risks in any research project, including genomics research projects where large amounts of genomic- and health-related data may be generated, stored, and broadly shared with other qualified investigators for appropriate use. The risks related to genomics research and the extent to which we understand the risks should be discussed with research participants during the informed consent process. Both the likelihood of the risk as well as the severity of the risk should be discussed to help research participants understand the context of genetic and genomic risk. Genomic research study design varies considerable. However, the types of risk most commonly associated with genomic research are psychological and social risk to the research participant and their family.

Examples include:

* Risks related to types of research which some research participants might find ethically troubling and might not wish to promote with their own biological samples.).

Resources:

Tomlinson, T. et al. (2014). Do people care what’s done with their biobanked samples? [IRB,](http://www.ncbi.nlm.nih.gov/pubmed/25219068) 36(4):8-15.

Gornick, M.C. et al. (2013). Impact of non-welfare interests on willingness to donate to biobanks: An experimental survey. Journal of Empirical Research on Human Research Ethics, 9(4):22-33.

* Risks related to broad sharing of phenotype and genomic data (*e.g.* genotype, DNA sequence, expression profiles, etc.).
* Risks of the data sharing model for the study (*e.g.* the possibility that the coded data may be released to members of the public, insurers, employers, and law enforcement agencies).
* Risks of receiving information that is unwanted by the participant.
* Risks of computer security breaches or other unanticipated distributions arising from maintaining data in an electronic format
* Risks to relatives or identifiable populations or groups.
* The uncertainty of findings related to genetic risk for a given disease or trait.
* Privacy risks, both those known and those unforeseen at this time.
* Any physical risks, such as those associated with collecting blood or other tissues samples.

**Whether to include GINA**

Federal legislation (The Genetic Information Nondiscrimination Act, or GINA) was passed to provide protection against discrimination in employment and health insurances decisions across the nation. The federal protection against discrimination that is provided in GINA may be eclipsed by even more extensive privacy or anti-discrimination laws at the state level, so it is important to clearly present the issues to consider in the context of where the research is being done.

The NCI PDQ Genetics Editorial Board has provided a review <http://www.cancer.gov/cancertopics/pdq/genetics/risk-assessment-and-counseling/HealthProfessional/page6#Section_388> of GINA 2008which protects the provision of health insurance and employment against discrimination based on genetic information as follows:

* Prohibits access to individuals’ personal genetic information by insurance companies and by employers.
* Prohibits insurance companies from requesting that applicants for group or individual health coverage plans be subjected to genetic testing or screening, and prohibits them from discriminating against health plan applicants based on individual genetic information.
* Prohibits employers from using genetic information to refuse employment, and prohibits them from collecting employees’ personal genetic information without their explicit consent.
* Prohibits employment agencies from failing or refusing to refer a candidate on the basis of genetic information.
* Prohibits labor organizations from refusing membership based on a member's genetic make-up.

However, GINA:

* Does not prohibit medical underwriting based on current health status which is especially relevant for people with a history of cancer, though the Affordable Care Act limits consideration of pre-existing conditions by insurers.
* Does not mandate coverage for medical tests or treatments.
* Does not interfere or limit treating health care providers, including those employed or affiliated with health plans, from requesting or notifying individuals about genetic tests.
* Does not prohibit occupational testing for toxic monitoring programs, employer-sponsored wellness programs, administration of federal and state Family and Medical Leave Laws and certain cases of inadvertent acquisition of genetic information.

GINA has several limitations.

1. Does not apply to members of the United States military, to veterans obtaining health care through the Veteran’s Administration or the Indian Health Service, because the laws amended by GINA do not apply to these groups and programs.
2. Does not apply to life insurance, long-term care, or disability insurance.

OHRP has issued the [Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards](http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html) <http://www.hhs.gov/ohrp/policy/gina.html> regarding consideration of GINA in the review of genetics protocols and informed consent forms.

**Efforts to protect privacy and confidentiality**

Genome-wide association studies, genome sequencing projects, and related genomics research studies typically generate rich phenotypic and genomic datasets that are often deposited in open access or controlled access databases (accessible only with the permission of a Data Access Committee), for storage and wide-spread sharing with the research community. This presents special challenges to privacy and confidentiality protections[6](#_ENREF_6). For a more detailed discussion of these challenges, see the Presidential Commission for the Study of Bioethical Issues. Privacy and Progress in Whole Genome Sequencing <http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf> .

As part of the informed consent process, it is important to discuss how the research team protects the research participant’s identity against undesired intrusions (privacy) and to limit the access to research and health information that could identify the research participant (confidentiality). This section of the consent document should describe the level of confidentiality that the research team plans to provide over the research data and the measures planned to ensure that confidentiality is maintained. Participants should know whether their samples will be anonymous/non-identifiable (i.e. personal identifiers will not be kept with their sample and the sample will not have a code number that can be used to identify the participant) or coded and considered de-identified (i.e. any identifying information such as name or social security number will be replaced with a code and only a few authorized people will have access to this code to link samples and data back to personal identifiers).

In special circumstances, such as for reportable conditions like HIV status and child abuse, absolute confidentiality may not be possible. If this or a similar possibility exists, then disclose the conditions under which information must be disclosed and to whom.

**Certificates of Confidentiality**

Certificates of Confidentiality are an important tool to protect the privacy of research study participants. The NIH encourages their appropriate use and has made information on their applicability and use available to investigators at the [Certificates of Confidentiality Kiosk](http://grants.nih.gov/grants/policy/coc/) [grants.nih.gov].

Certificates of Confidentiality are issued by the NIH to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality to participants.

If a Certificate of Confidentiality is in effect, it should be reflected in the protocol and the consent form. Participants should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted in the "Extent and Limitations of Coverage" section of [Certificates of Confidentiality: Background Information](http://grants.nih.gov/grants/policy/coc/background.htm) [http://grants1.nih.gov/grants/policy/coc/index.htm].

**Example Language**

***Psychological or Social Risks Associated with Return of Incidental or Secondary Findings***

As part of the research study, it is possible that you could learn that you have genetic risks for another disease or disability. This may be upsetting and, depending on what you learn, might create a need to make challenging decisions about how to respond.

Although your genomic information is unique to you, you share some genomic similarities with your children, parents, brothers, sisters, and other blood relatives. Therefore, learning your research results could mean something about your family members and might cause you or your family distress. Before joining the study, it may be beneficial to talk with your family members about whether and how they want you to share your results with them.

***Privacy Risks Associated with Return of Incidental or Secondary Findings***

*Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. While neither the public nor the controlled-access databases developed for this project will have information such as your name, address, telephone number, or social security number, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low.*

*Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives.*

*It is possible also that someone could get unauthorized access or break into the system that stores information about you. Every precaution will be taken to minimize this risk. There also may be other privacy risks that we have not foreseen.*

**Protections against misuse of genetic information**

Since some genetic variations can help to predict future health problems for you and your relatives, this information might be of interest to health care providers, life insurance companies, and others. However, Federal and State laws provide some protections against discrimination based on genetic information. For example, the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, GINA does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums. *GINA also does not apply to members of the United States military, individuals covered by the Indian Health Service, or veterans obtaining health care through the Veteran’s Administration. Lastly, GINA does not forbid insurance medical underwriting based on your current health status though the Affordable Care Act limits consideration of pre-existing conditions by insurers.*

***Certificate of Confidentiality***

*We have obtained a* ***Certificate of Confidentiality*** *from the Department of Health and Human Services. The Certificate is designed to prevent us from being forced to disclose identifying information for use in any federal, state, or local civil, criminal, administrative, legislative, or other court proceeding, even if faced with a court subpoena. You should understand, however, that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. We may not withhold information if you give your insurer or employer or a law enforcement agency permission to receive information about your participation in this project. This means that you and your family must also actively protect your own privacy.*

*The Certificate does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. Such disclosures will be made as described below.*

***The research team may share your information with:***

* *The Department of Health and Human Services (HHS), to complete federal responsibilities for audit or evaluation of this project;*
* *Public health agencies, to complete public health reporting requirements;*
* *NIH representatives, to complete NIH responsibilities for oversight of this study;*
* *Your primary care physician if a medical condition that needs urgent attention is discovered;*
* *Appropriate authorities to the extent necessary to prevent serious harm to yourself or others.*
* *[Insert any additional necessary language related to any applicable state mandatory reporting requirements (e.g., findings of STDs, TB, etc.]*

**Withdrawal from study**

Participants have the right to withdraw from the study at any time and the implications and consequences of withdrawal should be discussed in this section of the consent and as part of the overall consent process.

For certain genomic studies, complete withdrawal of samples and information may not be possible once samples have been distributed to laboratories and information has been posted for broad data sharing. In such circumstances, a full explanation of the inability to withdraw all samples/information should be provided.

If participant samples are being shared with other investigators and labs or there is the potential for sharing of these samples in the future, the consent form should clearly explain whether or not these samples can be destroyed and what the process will be.

For studies where individual-level genomic, demographic, and health data will be deposited in a public or controlled-access data repository for broad sharing with the research community, the consent should reflect the data repository policy. For example, a data repository may allow submitting investigators and their institutions to request removal of data on individual participants from the data repository if a research participant withdraws consent. These participants' data can then be excluded from future distributions, but data that have already been distributed for approved research use will not be able to be retrieved.

**Example Language**

***Withdrawal from the Project***

*You may stop your participation in this study at any time. If you decide to withdraw from this study you can contact [Insert Name & Contact Information of Principal Investigator] at [Insert Name of Institution] and he/she will destroy any remaining samples of yours that have been obtained for the study. [Use if applicable-*If cell lines have been derived from your samples, we will destroy the remaining cell lines stored in the (specify: laboratory or biobank)].  *However, the samples and data generated from your samples that have already been distributed to other research centers or placed in the research databases can****not*** *be withdrawn.*

**References**

1. Catenacci DV, Amico AL, Nielsen SM, et al. Tumor genome analysis includes germline genome: are we ready for surprises? Int J Cancer 2015;136:1559-67.

2. Presidential Commission for the Study of Bioethical Issues. Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts. Bioethics.gov: Presidential Commission for the Study of Bioethical Issues; 2013.

3. Green RC, Berg JS, Grody WW, et al. ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing. Genetics in Medicine 2013;15:565-74.

4. Fabsitz RR, McGuire, A., Sharp, R.R., Puggal, M., Beskow, L.M., Biesecke,r L.G., Bookman, E., Burke, W., Burchard, E.G., Church, G., Clayton, E.W., Eckfeldt, J.H., Fernandez, C.V., Fisher, R., Fullerton, S.M., Gabriel, S., Gachupin, F., James, C., Jarvik, G.P., Kittles, R., Leib, J.R., O'Donnell, C., O'Rourke, P.P., Rodriguez, L.L., Schully, S.D., Shuldiner, A.R., Sze, R.K., Thakuria, J.V., Wolf, S.M., Burke, G.L. . Ethical and practical guidelines for reporting genetic research results to study participants: Updated guidelines from a National Heart, Lung, and Blood Institute Working Group. Circulation Cardiovascular Genetics 2010;3:574-80.

5. ACMG policy statement: updated recommendations regarding analysis and reporting of secondary findings in clinical genome-scale sequencing. Genet Med 2015;17:68-9.

6. Rodriguez LL, Brooks LD, Greenberg JH, Green ED. Research ethics. The complexities of genomic identifiability. Science 2013;339:275-6.