RAPC DNA/Genetic Testing Informed Consent

The purpose of a separate DNA Consent form is to help ensure that a person who is asked to give a DNA sample for a human research study is providing a knowing, intelligent, and voluntary consent for collection of the sample. To this end, a subject should be given specific information about the study's use of the genetic sample and profile that is *unambiguous, impartial, thorough, and comprehensible at an eight-grade reading level* so that the subject is able to evaluate the personal risks and benefits of providing a DNA sample.

A DNA Consent form that appropriately describes how genetic samples and information will be used, shared, safe-guarded, and retained not only addresses legal and ethical obligations to research subjects, it also helps protect the integrity of the research, which depends upon samples that are validly obtained.

RAPC DNA/Genetic Informed Consent Checklist
1. DNA sample as a required or optional component of study participation
a. State whether provision of a DNA sample is a requirement for being in the study, or if it is optional.
b. State whether a subject who is required to provide a DNA sample for the main study can opt out of providing a DNA sample that can be shared with and between other studies and researchers.
2. Description of DNA
a. Provide a clear description of DNA and its function (including an explanation of genes, information about inherited diseases, and the ability of DNA to identify individuals).
b. State whether genetic sequencing tests will be performed, and what this means.
c. If whole genome sequencing may be conducted, also explain what whole genome sequencing is in plain language, and what kind of information about an individual whole genome sequencing can yield.
3. Purpose of the study
a. State the research purpose of collecting a DNA sample in this study and place this purpose statement immediately after the purpose of the overall study so that any distinct DNA research purpose is clear to the subject, and the subject can understand why DNA collection is a study requirement or is optional.
b. State the immediate and long-term goals of the DNA collection.
4. DNA collection procedures
a. Set forth the process for DNA sample collection and whether blood, saliva, or some other type of biological specimen will be collected.
b. Set forth the amount of blood, saliva, or other biological material that will be collected, and when it will be collected during the study.
5. DNA study design
a. Explain the DNA study design.
b. State what kinds of data will be generated from the DNA sample analysis or from the DNA samples combined with other information from the individual.

c. State whether the study will provide the subject with any study results, either generally, or specifically related to the individual, including whether the study will release the results of whole genome sequencing to the subject who provided a DNA sample (if such sequencing is done).
6. Present and future use of a subject's DNA sample, DNA profile information and whether a subject's DNA and personal medical information can be shared with other researchers, institutions, and companies, or placed in publicly accessible data bases
a. Explain the uses for the DNA information that will be collected in this study, including whether and how any known diseases, medical conditions, biological traits, ancestry, and the functionality of the study drug may be studied through a genetic analysis.
b. Explain whether confidential medical information released in the HIPAA form can be released and used in conjunction with the subject's DNA information, and whether the study can continue to access a subject's medical record indefinitely along with the indefinite use of a subject's DNA sample.
c. Set forth whether the subject's DNA sample and/or whole sequenced genome *can be used for a purpose unrelated to the study for which the DNA sample is collected*, and if so, provide examples of such other purposes, and state whether any subsequent use of the subject's DNA sample is limited to health-related research (and not other concerns such as primary investigations into ancestry).
d. Set forth any restrictions on the use of the DNA sample and DNA profile information in the study or subsequently if the sample or profiled information is shared with others.
e. State who will have immediate and long-term access to a subject's genetic samples and data and health information and records, including whether a subject's DNA sample, DNA profile, and medical history and genetic information can be provided to and shared beyond the study with other researchers, academic institutions, commercial entities and ventures, etc.
f. State whether the study will recontact a subject and seek a subject's consent before the study shares a subject's DNA sample, DNA profile, and health-related information with other researchers.
g. Explain to what extent, and for how long, a subject's genetic information and data may be shared with others.
h. State specifically whether a subject's genetic information, including phenotypic data, can be shared with or placed in any publicly available databases, or in any general academic institution or commercial databases, or biobanks, and if so, whether access to or use of these databases is restricted in any way, such as by a neutral oversight board that reviews access to use of genetic samples.
i. State what other information about the subject, including, but not limited to gender, age, geographic, ethnic or racial group or sub-group information, criminal history record, participation in addiction research or other studies, and confidential disease or health information, may be made available to others when a subject's DNA sample, genetic data, or DNA profile information is shared among researchers or in public databases, etc.
j. State whether a subject's genetic information can be sold by the study or given to commercial entities or affiliated companies for their unrestricted use and profit, and, if so, explain what this means.
7. Confidentiality of genetic and personal Information
a. Explain the specific measures instituted to protect a subject's DNA sample and genetic information.
b. State whether, and to what extent, a subject's genetic and health information are "anonymized," and provide detail on how this is accomplished and ensured.
c. State whether only "anonymized" DNA samples and profile information are shared with other persons, entities, biobanks, and public or institutional databases, commercial ventures, etc.
d. State the restrictions, if any, the study places on use of a subject's genetic samples and personal information when that is shared with or provided to any persons, entities, biobanks, public or institutional

databases, commercial ventures, etc., and specifically set forth: (i) whether those who will have access to a subject's DNA samples and profiles are bound by any confidentiality agreements on how the DNA sample and profile information can be used; and (ii) whether the study has any express prohibitions on the re-identification of samples and information by any means, including genetic genealogy.
e. State whether a subject is, or could be, identified by name, description, initials, image, or otherwise, in a research paper, or in a published article, or in information shared with other researchers, or placed in the public domain.
f. State whether samples and profiles can be provided to researchers and companies in other countries and/or sold internationally, where privacy protections may be different.
g. State whether there are any audits, institutional reviews, or other mechanisms in place to help ensure that genetic information and samples are retained in a confidential manner, and identify who performs these reviews or audits.
h. State whether the study has obtained a Certificate of Confidentiality, and if so, explain what this means in terms of the genetic information the study collects.
i. Set forth the government and organizations, such as the Research Advisory Panel of California, that may have access to a subject's records.
8. Data storage and retention
a. State how long DNA samples and DNA profile information and a subject's associated health records will be retained.
b. Explain how DNA samples and profile information will be stored and secured.
c. Set forth whether and under what circumstances DNA samples and profile information will be destroyed, how any sample and profile destruction is confirmed and documented, and how anonymity of samples and information is ensured in the destruction process.
d. Set forth whether the subject's samples, data, or other information will be destroyed or transferred if the study site or sample repository closes, or the researcher retires or ends the study.
9. Risks/Discomforts
a. Explain any risk or discomfort from the collection of biological samples.
b. State whether any genetic information discovered as a result of this or future studies may become part of a subject's health record, and whether this may be accessed by commercial entities.
c. Explain any risk of unauthorized disclosure of personal DNA-related information from the main study.
d. Explain any risk related to sharing of a subject's personal and sensitive genetic information with other researchers.
e. Explain any risk associated with the re-identification of personal information and the ability of DNA to be used to identify a subject and a subject's family members (even if it is disassociated from a name), and to discover a family's genetic propensity to disease.
f. State any risk of identifying information or disease-related information being released to unauthorized persons, and/or researchers or companies who are not bound by confidentiality restrictions.
g. Explain any potential for misuse of information and genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.
h. State whether the study will contact the subject if there is a significant data breach involving the subject's personal genetic information, or if substantive new risks are discovered.
10. Discontinuing study participation
a. State how a subject can request to be discontinued from the genetic portion of the study.

b. Explain what happens to existing genetic profile information and data created if subjects request that their DNA or blood samples be destroyed (e.g., does the study keep all test results and genetic profile information generated up until the subject's request to destroy samples).
c. State specifically, as applicable, whether and to what extent, upon a subject's request, the study is able to withdraw and discontinue use of the subject's DNA samples and health and genetic data from on-going genomic studies, and shared use locations including, but not limited to: bio-banks, publicly-accessible databases, restricted-access databases, and from any commercial research databases kept by the study sponsors and its affiliates and business partners.
11. Financial reimbursement, costs, compensation, benefits to the subject
a. Set forth whether there are any costs to the subject for participating in the study.
b. Explain whether the study compensates subjects for providing a DNA sample for use in the main research study.
c. Explain whether the study compensates subjects for the on-going or future use of their DNA samples and genetic and health information, as applicable, either by the study investigators, or when the study shares the subject's sample and data with others, including other researchers, companies, affiliates, etc.
d. State whether the subject will receive any non-financial benefit from providing a DNA sample.
e. State whether the subject will share in any monetary profit derived from the commercial or institutional use of the subject's DNA sample or genetic information.
12. Discussion of DNA sample collection with family members
Inform subjects that they may wish to discuss their provision of a DNA sample with family members given that any risks of providing a sample may also affect a subject's family members, and emphasize this, if applicable, by placing in bold face type, a statement such as, "The risks of your providing genetic information may also affect members of your family. You may want to discuss your participation in this genetic study with your family."
13. Language requirement
Include a separate language comprehension section to the DNA ICF form (e.g., at the end of the consent form, add a statement in the appropriate language such as "I have read this information, which is printed in English. This is a language that I read and understand"), with a signature block for this separate section.