Consent Clauses for Genomic Research

Preamble

This work is part of a broader project that aims to bring together all of GA4GH consent work within 3 different paths: genomic research consent clauses, national initiatives (biobanking and population studies) consent clauses and clinical consent clauses in the context of whole genome sequencing. A typology of familial clauses will also cross these categories. This 2020 update of genomic research consent clauses was primarily designed for genetic/precision medicine research studies. Examples below may need to be adapted to different research and legal contexts. This table is available to serve as a resource for researchers when drafting consent forms so they can use language matching cutting-edge GA4GH international standards. This tool does not include clauses for clinical genomic studies, familial clauses or biobanking and population studies as this work is ongoing and will be addressed in tools to be launched later this year.

Additionally, when consulting the consent clauses specific to data sharing and data linkage, researchers have the opportunity to articulate these clauses in a machine readable way to promote efficient and accurate data sharing. For further guidance, please see the Machine Readable Consent Guidance.

To date, the Consent Task Force of the Regulatory and Ethics Workstream (REWS) has prepared WGS template clauses for: genomic research, large scale initiatives (biobanking and population studies) and clinical genetic testing. A typology of clauses specific to familial testing, rare diseases and pediatrics has also been prepared. They all cross the categories listed above.

Methodology

The 2020 update of the 2015 GA4GH genomic research consent clauses is a natural part of the Consent Policy review which was undertaken in 2019. The 2015 standardised consent clauses were updated in light of the greater influence of genetics and genomics in biomedical research. For this review, recent consent forms from groups working within the GA4GH were examined to determine the categories of

information that were addressed in patient information sheets. The consent clauses contained in these forms were analyzed, distilled and standardized. They were further categorized under questions and the resulting list was presented to the Consent Task Force, the REWS members teleconference, the Genomics in Health Implementation Forum (GHIF) virtual meeting and the REWS roadmapping session at the GA4GH virtual meeting. Attendees were invited to identify gaps in the list and whether additional categories were needed. Following comments and a comparative analysis with the 2015 version, further edits were made. The table was shared to the broader GA4GH community and the public to receive feedback on the clauses themselves. Further modifications were made following this comment period. Obvious editions in the 2020 version include text to help explain the collection and storage of DNA and more details on DNA sequencing; a greater emphasis on methods for protecting the confidentiality of personal data; details on how data will be shared, to whom and for what purposes; and whether or not research results will be returned to individuals.

Readability-level

Please note that, ideally, the language below should be adapted and sense-tested before implementation. (i.e., readability-level and culturally nuanced). The table was reviewed so it would align with the empirical public data collected within the Your DNA Your Say study of global attitudes towards genomic data sharing. This work was delivered specifically for GA4GH in order to offer a public voice to policy, such as those around consent. The Your DNA Your Say study was initiated by the Participant Values Task Team, part of the Regulatory and Ethics Work Stream, back in 2016 and has been collecting patient attitude data up to 2019. With 37,000 completed surveys from 22 countries, gathered in 15 languages, there are clear recommendations to come from this work that relate to the information participants need in order to trust the data sharing process. A number of these recommendations have been integrated into the table below (i.e., use of the term “DNA information/data” instead of “genetic/genomic information/data”).

List of Consent Elements:

Background information and participant's engagement

- **Who is the study intended to benefit, and how will this benefit be achieved?**
- **Who has funded/reviewed this study?**
- **Why have I been invited?**
- **What am I being asked to do?**
- **What is DNA and what does data sharing involve?**
- **Why is data sharing between non-profit and for-profit organizations as well as between doctors and scientists necessary?**

Sample processing and access restrictions

- **What actions will be taken regarding my [DNA/sample/information]?**
- **What about samples I've already given for other purposes?**
- **Where will my samples be sent for processing?**
- **What information about my [DNA/sample/information] will be collected?**
- **Who can have access to my information? [Authorization/quality control]**
- **How will you protect my privacy when sharing my data?**
- **How/Where will my samples/data be stored and for how long?**

Risk assessment

- **What are the risks for me to participate in this study?**
- **What are the benefits for me to participate in this study?**
- **Will I be paid for participating in this study?**

Data sharing

- **What results will I receive and how will I receive them?**
- **What about secondary or incidental findings?**
- **Who will use my data and samples and how?**
- **How will my information be shared? (possible future clinical treatment)**
- **How will my information be shared? (international sharing "reference" databases)**
- **Will my information be linked with any other data?**

Capacity, third parties and future studies

- **What happens if I die or am unable to make my own decisions?**
- **What about insurers?**
- **Can I have access to the data you have on me?**
- **Will you contact me again? (for future research studies)**
- **Can I change my mind? How can I cancel my participation?**
- **If I withdraw, will all my data be deleted or not?**
- **Who can I contact if I have questions or concerns?**

Consent Clauses for Genomic Research

This document presents a range of sample consent clauses with a range of choices that can be customized for individual use by researchers. They are presented in the form of questions posed in a standard Personal Information Sheet.

Consent Elements:	Sample Clauses:
Who is the study intended to benefit, and how will this benefit be achieved?	This research project is looking at how useful DNA testing is for the diagnosis and/or management of a number of medical conditions and to determine how it affects patient care. DNA is the information in all of us that tells the body how to grow, develop and function. There are several different words that are often used interchangeably in relation to DNA testing (e.g. genetic-, genome-, whole genome sequencing), but all of these basically relate to the same thing, which is the ability to look at DNA to see it offers clues into why disease occurs. This study will help to determine the most appropriate and cost-effective way of providing DNA testing to patients in the future.
	We invite you to be part of the [name of project]. This project collaborates with researchers from around the world in studies approved and monitored by [research ethics review committee]. An ethics review committee checks that the research is properly conducted and deemed safe for you to participate in. This project is guided by the Framework for Responsible Sharing of Genomic and Health-Related Data [cite URL for relevant website]. The purpose of [name of project] is to [description of project].
	Scientists and doctors compare DNA and medical data between people so that they can identify patterns to understand more about health and/or disease. Thus, the purpose of [name of project] is to [description of project].

Who has funded/reviewed this study?	This research is being led by [organization], a collaboration of major research institutions, universities and clinical services across [country]. It is funded by [organization]. The study doctors and researchers are employees of the major collaborating institutions, universities and clinical services.
	The ethical aspects of this research project have been reviewed by [committee]. This project will be carried out according to [national/international policy on responsible research/ethics review]
Why have I been invited?	----------You have been invited to take part in [study] because you have a condition or disease for which no clear cause has yet been found.
	We are asking you to take part because you are a close relative of someone who does have one of these conditions: [list of relevant conditions]
	You have been asked to take part in the study because you have one of the conditions for which we are trying to determine if DNA testing is useful. [include explanation on the usefulness of DNA testing]
What am I being asked to do?	[To be completed by the study] *We are not providing sample language for this item because each study will vary substantially in its study procedures, and therefore require very different language pertaining to those procedures; harmonization along this dimension is not possible.*
What is DNA and what does data sharing involve?	All of us have DNA in our bodies; this is the instruction manual that tells our body how to grow, develop and function. It is also a biological code that can be used to identify us and can say who we are related to. This is the code we pass on to our children that influences how they grow, develop and function. DNA can play a part in our health and disease; scientists and

	doctors often use a DNA test to see if the DNA is altered in some people, which could be linked to current or future disease.
	DNA is of particular interest to scientists and doctors who explore whether medical conditions are inherited in the family. There are several different words that are often used interchangeably in relation to DNA testing (e.g. genetic-, genome-, whole genome sequencing), but all of these basically relate to the same thing, which is the ability to look at DNA to see if it offers clues into why disease occurs. Being able to test a person's DNA also helps scientists and doctors understand how to predict disease and potentially treat it. Because there are similarities in the DNA of different people, the results of testing one person can help the interpretation of a disease in another person.
	The best way to explain your genome is to say it is your body's 'instruction manual'. It contains nearly all the information needed to make you, run you, and repair you. You inherited it from your parents and in turn you pass it on to your children. Therefore, the outcomes of any DNA test may be of interest to not only you but people you are related to.
	In order to understand the links between changes to DNA and disease, scientists and doctors across the world need to share patient datasets with each other. The way they do this is usually to make their datasets accessible online; unless you are asked to specifically consent to your name being attached to this, it is usual to 'de-[identify/personalise]' the DNA information. This means that your name, address, date of birth and any other identifying information is kept separated from your DNA information, so it should not be possible to identify you personally. The database that your DNA information sits in might be accessible to a very restricted number of people or may even be publicly available. It may be accessed and shared by academics, doctors and researchers working in pharmaceutical companies doing clinical trials of medicines. It is usual within DNA research for data to be shared between both not-for-profit and for-profit organisations as both are needed for collaboration to create medicines.

	Genes are the basic "instruction book" for the cells that make up our bodies. All genes are made of DNA. The DNA of a person is more than 99% the same as the DNA of any other person, but people do not have exactly 100% the same DNA except for identical twins. The complete set of DNA in your body, including all its genes, is called your genome. Although our DNA is very similar to each other, your DNA data is entirely unique. Variations in the genome explain some of the physical differences between people, and partly explain why some develop diseases like cancer, diabetes, asthma, and depression, while others do not. At present, it is not always possible to predict which changes in DNA lead to disease or health.
	Phenotype refers to a person's observable characteristics and traits and differences in phenotype may be affected by one's epigenetic state. As such, examining epigenetic changes can provide valuable information in addition to whole genome sequencing analysis.
	Epigenetic information refers to chemical additions to DNA, which can affect the effects genes have. The environment we live in can affect the epigenome and some epigenetic changes can be inherited. It is well known that these epigenetic states can contribute to phenotypic variation, including disease.
	This section is not limited to the language defined. Researchers are encouraged to provide further definitions and explanations to participants (i.e. the distinction between germline and somatic sample; personal and familial health/privacy implications) while keeping in mind meeting relevant readability-levels.
Why is data sharing between non-profit and for-profit organizations as well	It is only possible to develop medicines based on insights learnt about DNA, through a collaborative effort of data sharing between doctors, non-profit researchers and for-profit researchers. Because we all have so many genes and there are a great many variations that exist between genes, it is not feasible to expect that one research institution or one company will be able to solve the scientific understanding of how DNA links to health and disease. This requires a global,

as between doctors and scientists necessary?	collaborative effort, where agreements are reached to share and distribute data so that we all have the opportunity to benefit from advances in science.
What actions will be taken regarding my [DNA/sample/information]?	We will extract DNA from your [blood/saliva/other]sample. We will then send some of the DNA for testing. This is usually done in [country] but, rarely, it can be sent to international facilities. We will store your DNA and any other samples in a secure 'bank' called a biorepository in [country]. We will label your samples with a unique barcode instead of your name. We use the code to keep track of your samples. Laboratories we have approved may analyse your samples. They look for clues to help understand more about how genes work. There may be new ways of doing this in the future and the results will go into our data centre. Your samples could be stored for many years. If we use them up, we might ask you for more. If you don't want to give more, you don't have to. [consider including information on how and by whom participants will be re-contacted]
	A healthcare professional may discuss with you the outcomes of DNA testing including: · Finding an alteration in the DNA that is the cause of the condition. · Finding an alteration in the DNA that cannot be interpreted with current scientific knowledge; this may change over time as scientific knowledge improves, in which case you need to ask your health professional if they will get back in touch in the future [with all results or with results that might be helpful to prevent or treat your disease]. · DNA alterations cannot explain all inherited conditions. Reasons for this include: o the variant causing the condition cannot be found by the test; o the gene causing the condition was not tested; o the gene causing the condition is not yet known; o the condition may not have a genetic cause. o several DNA alterations, possibly in different genes, are required to have a condition.

What about samples I've already given for other purposes?	In some cases, we may be able to use the samples you have provided for your medical treatment or initial DNA testing. If there are available samples, we will contact the laboratory storing them directly. We will provide the laboratory with your consent to this study to access them and you will not be required to fill out another consent form. If you are having surgery, we may also access those tissues.
	We recommend using this clause with caution. This clause has to be exercised in accordance with the participant's previous consent, if any, for further use of the participant's samples and/or data. Further, considering that samples used in laboratories are pseudonymised, researchers may have to re-identify the samples to verify the above-mentioned consent conditions.
Where will my samples be sent for processing?	The laboratory used to test your sample is in [country]. If you are not living in [country] then you are agreeing to allow your sample and your data, which could include your personal information, to be sent to [country] or as part of the testing and analysis performed by [company]. [consider precising if the samples and data will be sent pseudonymised in accordance with local regulations]
What information about my [DNA/sample/information] will be collected?	As part of your consent, we will gather information about your health care (such hospital visits, medicines prescribed, etc). Researchers may also ask you directly for more details. This will allow us to access healthcare information about you: your condition, tests you have had, treatments you have received, any other health problems and history of related health problems in your family. This helps us to determine whether DNA testing might be useful for you, or for those living with your condition. The collection of this data does not affect anything related to your healthcare.
	This study will request access to your hospital and emergency records that are related to your condition. The collection of this information is usually required by law and is securely stored by the service or agency that collects it. In brief, we will supply the data linkage agency with some of your identifying information such as your name, date of birth, and address.

	The data linkage agency will then create a unique ID for you and send it to the hospital custodian. Your hospital and emergency records will be merged with the unique ID and be provided to us.
	Because any of your data could benefit approved research or future healthcare, we are asking to access electronic copies of records deemed necessary from [healthcare provider] and other organisations. This includes information about any illnesses or stays in hospital – even ones that you may not think are related to [condition]. The data are from different sets of records, including hospital or clinic records, medical notes, social care and local or national disease registries. The data includes images from your [medical] records, such as [MRI scans, X-rays or photographs]. To get this data, we'll need to send some details about you (for example, your name and date of birth [include others, if any]) to the organisations holding this information. This will allow them to find the health data they hold about you.
	We may use your data to study many different medical conditions, not just ones that affect you. Once we've received your health information from the organisations holding it, only our clinical team and authorised people involved in the project have access to your name and other personal information. We need to maintain this information so we can return your results to you. We may let your healthcare provider, or other medical staff who look after you, know you are taking part.
Who can have access to my information? [Authorization/quality control]	Besides authorised persons from the study team, your [personal information, health records and any information collected and stored by the study doctors during the research project] might be accessed during audit and inspections by other bodies, such as regulatory authorities. This is to ensure that the study team is complying with the approved study design and procedures. This review may be done by the ethics committee that approved this research project, regulatory authorities, or as required by law. In these circumstances, these parties will review only, not collect or record, your personal information. By signing the consent form, you indicate that you are aware of these access/review requirements.
How will you protect my privacy when sharing my data?	Your privacy is very important to us, and we will take appropriate measures to protect it. We will not disclose any information about you like your name, your address, or your contact information to unauthorised persons. All personal identifying information will be replaced with a unique code.

	Before researchers have access to your data, we [anonymize/code/de-identify] it. This means we take out names, dates of birth [include others, if any] and other personal details and replace them with a code. This process for de-identification of data is called pseudonymization.
	Your participation in this research project and any information obtained within this research project that can identify you will remain confidential, except as required by law [circumstances in which confidential information can be released by law should be explained to the participant].
	Your [coded/pseudonymized] information and sample will only be shared when safeguards are in place to protect your privacy. Personal identifiers will be removed (including your name, date of birth, and address) and stringent security measures will prevent unauthorized access or misuse. Data sharing will also involve the minimum, necessary information. These safeguards make it difficult to know whether the information is about you or other people; however, there is always a very small chance that you might be re-identified. Given that the potential to identify you is significantly reduced, you are unlikely to directly benefit from this sharing.
	We will not identify you at conferences/meetings, nor in any publications or dissemination activities.
How/Where will my samples/data be stored and for how long?	All study data will be stored in secure, controlled-access databases that meet international security standards and [country] laboratory accreditation requirements. Only the study doctors, study researchers and personnel working directly with this study will have access to the database. However, if it is an option, you may choose to have information about your participation in this research project recorded in your health records.
	Your data is stored in a secure data centre in [country]. Its security level meets national data standards.

	Your sample will be securely stored at the [name] biorepository in [name of hospital/research centre, country] for quality purposes.
	Data related to [identify datasets] will be stored on secured servers (located at [location]) and access to the data will be limited to authorized researchers in this study via assigned login password. All data related to [datasets] will be destroyed after [number] years from the publication of the final project report. Hard copies will be shredded and destroyed by secured destruction service provider. Non-identifiable data will be stored indefinitely as the economic model will be critically appraised by the scientific community. Updating and running of the model will require access to the non-identifiable data files.
	Data will be kept for a period of [number of years/identify period OR indefinitely] unless an ethics committee [or other oversight body] decides otherwise. [consider identifying the criteria determining the storage period]
What are the risks for me to participate in this study?	Risks of sharing DNA and health information include the possibility that you could be identified based on this information, and that it could be used for, but not limited to, insurability or employment discrimination or stigmatization (i.e., genetic discrimination). We believe that this is unlikely, though it is more likely if you or your family members have already shared your DNA or health information with public resources, such as genealogy websites. DNA information alone is not sufficient to identify a person. It needs to be matched with personal information available from other sources. [consider including language from local regulations in place to protect against certain types of genetic discrimination]
	Some people worry about being identified as someone taking part in the project. The chance of this happening is extremely small [consider including an estimation of such risk, such as “i.e., less than 1%”], and we will do everything we can to prevent this from happening.

	Much like fingerprints, it is possible to identify someone if certain pieces of information are put together. While we use very strict data security measures to protect your privacy, there is always a small risk that your data may lead to you being re-identified. As technology advances, there may be new ways of linking data back to you that we cannot foresee today. Like other medical information, this may one day affect your insurability or your employment. In [insert country] there are laws to protect against discrimination.
What are the benefits for me to participate in this study?	Some people wish to have DNA testing to help them understand their or their child's condition. A genetic diagnosis can also sometimes help families to access support and services that they need, and to plan for the future. A genetic diagnosis may also help health professionals manage a condition.
	DNA testing can lead to a diagnosis in 30-50% of people with unknown DNA conditions. If a diagnosis doesn't happen today, the DNA test result could be looked at in the future as scientific and medical understanding improves.
	It is important to remember that DNA testing is not a general health test and will not identify all gene changes that could contribute to health problems that may develop in the future.
	There may be no direct benefit to you from taking part in this research. The outcomes may provide valuable information about whether this test should be part of routine care for patients with your condition in the future.
	The research part of this study involves testing large numbers of samples from many different people to try to identify factors that influence disease. Findings often need many years of further research to prove whether and how they are important. You will be contributing to knowledge that may make it possible to improve care for patients in the future.

	You may or may not benefit from participating in this study. It is possible that the researchers will be able to identify the genetic cause of the [name the relevant health condition(s)] in your family.
Will I be paid for participating in this study?	You will not be reimbursed any costs you may incur, including traveling to or from any establishment that is taking part in this study. You will not be compensated for any loss of personal time associated with participating in this project.
	By participating in this project, you will be compensated [amount] for your time, travel and inconvenience.
	Some of the research done with the information stored in the databases may one day lead to the development of software, tests, drugs, or other commercial products. If this happens, you will not receive any of the profits.
What results will I receive and how will I receive them?	It will probably take a long time to interpret the data accurately. You can check the project's web site at [cite URLs for relevant websites] to read about the project's progress and to see if there are any general results. [consider including the local policy on return of individual health results/incidental findings and role of physician where applicable: if it is possible for participants to request results, and if so which ones, or if results will not be returned at all]
	Your individual DNA test result [either all results or only 'significant'/clinically actionable results] will be given to you by your [treating specialist/genetic healthcare professional or clinician]. Research results beyond the diagnostic report may be provided if available. This could include a summary of the impact of the DNA testing for the conditions that are being studied as part of this research. Before using a research result in the management of a health condition, the results will be confirmed in a clinically accredited laboratory first and you can ask your clinician to confirm that this has been done. [consider including foreseeability of genetic counselling]
	Doctors will explain and discuss the results with you. However, we cannot yet guarantee how long it will take to get these results, and there may be no results relevant for your treatment.

What about secondary or incidental findings?	Other information analysed or revealed by researchers will not be returned to you, even if there is a possibility that it might have relevance for your health, or that of your family. This is because samples and data used in research will not usually be processed and analysed in a way that would reliably inform medical decisions. What the research results show may be of uncertain or unknown significance for your health at the time that the research is done, so results might not be fed back to you even if they later prove to be linked to your current condition.
Who will use my information and samples and how?	Your data will be stored online, in controlled-access databases. Only authorised researchers will have access. An independent committee will determine whether to grant researchers access to your data. These researchers can come from anywhere in the world and their research may be on nearly any topic. They may work for universities as well as commercial compagnies, such as drug companies. Your information may have commercial value and may contribute to commercial development efforts worldwide (i.e., development of new drugs for treatment of disease(s)). [consider including the lines above on potential commercial use, for transparency purposes]
	Researchers who wish to access the database will be required to apply to [Data Access Office] who will examine their credentials and data security plan. They will also make sure the proposed research project is consistent with your consent. You will not be identified if findings from your data are presented at scientific conferences or appear in scientific publications. [Data Access Officer] will notify you immediately in the event of a personal data breach.
	With your consent, we will share this specific individual information with other researchers from around the world who would use it to improve patient care or advance genetic knowledge, for clinical and/or general research purposes. Your information could be shared with others through different types of databases, including: ● Open-access databases: These are publicly available to anyone with internet access. General information, such as the health information reported by your doctor, age, race, or sex may be shared in these types of databases. ● Controlled-access databases: These are only available to approved users.

	Because of the broad nature of this data sharing, it is unlikely that you will be notified if your information is used, and unlikely that you will receive any results. You will not be paid for your participation.
	Providing consent for DNA testing also allows for the sharing of your sample, DNA data and related health information to advance scientific knowledge. Your information will be shared in a way that protects your privacy. This may include sharing of large databases to help improve understanding of related conditions by comparing your results to those from other people.
	Other doctors and scientists at this and other medical and research centres may use your de-identified health information, research data and/or sample in further research with the goal to improve health outcomes and develop new treatments. Results from research carried out by other approved researchers will not be returned to you as they will not have access to your identifying information.
	Researchers can only look at de-identified data inside this monitored environment and perform their analyses. Researchers can only access the answers to their questions (their results). They can't copy or take away any individual data or images. Nobody can access the data without any previous authorisation and we will carry out checks on them. The purposes of their research studies must be specific and disclosed prior to their access.
	We will monitor researchers looking at your de-identified data to check that they're doing what they are allowed to do and no more.
How will my information be shared? (possible	Your [coded, pseudonymized] data and samples will be shared. If needed, they can be re-identified. This will be important if there are findings from this research that have implications for your future clinical care, it may be possible to contact you, so that your result [can, will] be returned. However, this research does not guarantee direct benefits to you.

future clinical treatment)	
How will my information be shared? (international sharing "reference" databases)	[Project name] will work and collaborate with national and international researchers to find causes for unknown conditions. With your consent, we will share your personal health information with [name of database], an international database that has been created to support the sharing of data worldwide to advance research.
	With your consent, we will share the information you give us with a national database for DNA information, called […] which is controlled by [name of organization]. This database will be used in future studies about human health. The information in this database will be stored permanently. Other researchers must get permission from a Data Access Committee to be able to use the database. Traditional identifying information like your name, address, telephone number, will NOT be put into the database. The data and any medical information will have a code number.
	To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease.
	If you agree to take part in the [study/research/resource], some of your DNA and health information might be placed into one or more scientific databases. A researcher who wants to study the information must apply to the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people.

	The goal of [name of study] is to create a way for scientists to share and learn from each other. One of the best ways to do this for scientists is to share research data. Although the study you are being asked to participate is related to [name of disease], other scientists may like to use your samples and/or data to study other treatments or for other purposes (e.g. prevention, diagnosis etc).
	We would like your permission to share your health history, laboratory test results and your data with other scientists across the world. A special committee will look at each request to share data to find out what the researchers want to do and how they will protect your rights and choices based on the consent you provided. When we share this information, people will not know your name.
	If you agree, some of your de-identified data will be deposited in an international DNA database [name of database], reporting relationships among DNA alterations linked to specific traits. Once the data are in [name of database], they are available for unrestricted distribution.
	[Name of database] will share your coded health and DNA data with other international databases to better understand the causes of [disease].
Will my information be linked with any other data?	[Name of database] will link the [information] and [information] you have contributed as part of this study with your sequencing and other data.
What happens if I die or am unable to make my own decisions?	In the future it is possible that you may become unable to make decisions for yourself. If your clinical team believes that you can't make decisions about this project, at the time these are needed, they can look for a legally designated representative. This could be a friend or family member. If the person believes: · that you would still want to take part in the project, we will arrange this; or

	· that you would **not** want to take part, you will stop being a participant. We will not ask for any more samples or information from you or your records. You would also stop being a participant if the clinical team can't find someone to advise for you. If you stop, information that has already been collected about you up until that point will still be available for researchers in the future while no more information about you will be collected. This is in line with your original consent.
	You have the option of allowing for the disclosure of the results to another person if you lose decision-making capacity or pass away before receiving all DNA results discovered during this study. Your DNA results may be important for your family members to learn as you may share similar DNA information.
	We will continue to access all your updated records [throughout your lifetime, for as long as you are in the project, for number of years]. [This includes information added after your death].
	Once the results you have authorized to be disclosed reach the noted recipient, that person may re-disclose them, at which time they may no longer be protected under [country] privacy laws.
	You give permission for long-term storage and use of your blood and urine samples for health-related research purposes (even after your incapacity or death), and relinquish all rights to these samples which you are donating to [name of project].
What about insurers?	You don't have to tell an insurer that you are part of the project, or about your results. They won't have access to your results. If you have any medical treatment or a diagnosis, you should tell your insurer about these if they ask.

	In [country], DNA testing will not alter your ability to get health insurance or your health insurance premiums. DNA testing in you or your child could affect how easy it is for you or other family members to get income protection, travel or life insurance, or the price of your premium.
	An existing diagnosis may already affect your ability to obtain these kinds of insurance. Industry regulation prevents insurers from asking relatives for your DNA test results, and you cannot be requested to have a test by an insurer. Your healthcare provider will not provide your results to an insurance provider without your permission.
	Like other medical information, this may one day affect your insurability or your employment.
Can I have access to the data you have on me?	Yes. You can ask for a copy of your data. There may be a charge for this. For more information, speak to the researcher running the research project or your healthcare professional or see our website at [web address].
Will you contact me again? (for future research studies)	In the future, your clinical team or the [study] project team may contact you. This could be to ask you for more information. Or to invite you to take part in future research, including clinical trials of new treatments. Or to ask you for your views on the project. It is up to you whether you agree to take part in these studies. We may also send you information about the progress of the project.
	We may like to contact you in the future about the possibility of participating in other ethically approved research projects. This is optional and you can indicate your willingness to be involved in such research on the consent form.
Can I change my mind? How can I cancel my	Your decision to participate is voluntary and will not change your medical care or affect your laboratory test. If you check “YES” below, your information will be shared indefinitely. You can change your mind at any time by contacting us at

participation and if I do, will my data be deleted or not?	[Institution]. If you let us know, we can stop your information from being shared in the future. However, data that has already been sent to other researchers or research databases cannot be removed.
	To leave the project at any time, ask your clinical team for a 'withdrawal form'. Fill this in and return it to them. There are two options for withdrawal, as shown below. You can get more information about these from your clinical team or in the withdrawal form. 1. No further contact, but continue to include my existing samples and information in the project. 2. No further contact and no further use of my samples or information.
	You are free to withdraw from the project at any stage. If you withdraw before testing and data is collected, we will not continue. If you withdraw after testing and data is collected we will use any information already collected unless you tell us not to. However, if your data has already been shared it may not be possible to retrieve or remove all your data.
	You can withdraw your data at any time by contacting [name of relevant person] free of charge at [information]. Data sent to other researchers around the world cannot be withdrawn if already used or published.
Who can I contact if I have questions or concerns?	If you have any questions or concerns, please contact [name of person] free of charge at [insert telephone number] or by mail/email at [insert mailing address and/or email address]. You can also contact [name of other members of the team: PI, researcher, health care admin] free of charge at [insert telephone number] or by mail/email at [insert mailing address and/or email address].
	If you wish to make a complaint about any aspect of this study at any time, please contact [name of person] free of charge at [telephone number] or by mail/email at [insert mailing address and/or email address]. We take all comments seriously and will get back to you as soon as possible. You can also contact [name of other members of the team: PI, researcher,

	health care admin] free of charge at [insert telephone number] or by mail/email at [insert mailing address and/or email address].

Deliverable Revision History

Deliverable Number/Version	Date Effective	Summary of Revisions
D 010 / v. 1.0	July 2020	Original document