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Consent Clauses for Large Scale Initiatives

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Consent Clauses for Large Scale Initiatives: Context and Use

This work is part of a broader project that aims to bring together all of GA4GH genomic consent work. 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.

The Consent Clauses for Large Scale Initiatives is a table of a large variety of consent clauses from around the world. They are organized in different categories from biobanking and population studies, including personal genome biobanks. Each subcategory reflects the types of clauses actually in use in different countries but some of them might not always fit your local requirements. The Table is not limited to national initiatives as we have consulted other large scale initiatives for the purposes of this document. Such initiatives are not only larger in size but may span many years and serve as a resource for other researchers. The examples found under the various categories of clauses may need to be adapted to different research and ethico-legal contexts.

This Table is available to help researchers when drafting consent forms so they can use language that matches cutting-edge GA4GH international standards. This tool builds on the other categories of template clauses mentioned above. While the language in this document is largely genomic, it can be substituted and adapted for epidemiology or other studies.

Additionally, when consulting the consent clauses specific to data sharing and data linkage in particular, 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 available on the GA4GH website.

We used and adapted the 2020 update of Consent Clauses for Genomic Research categorisation to fit biobanking and population studies consent clauses in the categories of information usually found in patient information sheets. These categories were formatted into questions and the resulting list was presented to the Consent Task Force, the REWS, the Genomics in Health Implementation Forum (GHIF) virtual meeting and the REWS roadmapping session at the 2020 GA4GH meeting. Gaps were identified in the list and additional categories were suggested. Following comments, further edits were made. Finally, the concluding Table was shared with the broader GA4GH community and the public to receive feedback on the categories and clauses themselves. Further modifications were made following this comment period.

Table: Consent Clauses for Large Scale Initiatives

This document presents a range of existing consent clauses from different studies and countries with choices that can be customized for individual use by researchers.

LARGE SCALE INITIATIVES CATALOGUE: BIOBANKING AND POPULATION STUDIES	
Consent Elements	**Consent Clauses**
What is the purpose of the study? What is this study about?	If you join, we will gather health and personal data about you. We will combine it with data from other people who join. Researchers will remove identifiers from your data and use it for lots of studies in the future. By looking for patterns, researchers may learn more about what affects people's health.
	The purpose of the study is to see which genes make a difference in a patient's treatment. We will use information collected as part of the research.
	We hope to create a publicly accessible database containing [name of the research project] participants' self reported medical information, physical traits, DNA sequence, and related epigenetic information. The goal of this study is to aid [researchers, clinicians, health care services and/or commercial companies] around the world make [health-related] discoveries.
	We invite you to be a part of the [name of the research project]. We are studying DNA from different types of human cells. Many samples are needed because some parts of the human genome sequence only function in specific tissues or organs, such as [identify type of sample, e.g., the blood or liver]. Our goal is to identify the function of most of the genes and variants in the genome. We expect researchers who use this information will mostly study health and disease, but there may be other uses as well. Sharing information from [name of the research project] widely may benefit the public by helping researchers make discoveries more quickly.
	The purpose of the [name of the research project] is to identify most of the genetic variations that exist in people. We will do this by studying the DNA in [identify type of sample] samples collected from many people whose families were from different parts of the world, and then putting all of this information in scientific databases on the Internet. These scientific databases will be kept for a long time, and many [researchers, clinicians, health care services and/or commercial companies] from around the world will use them to help find genes and genetic variants related to health and disease.

	The [name of the research project] is collecting tissue from volunteers to help scientists and doctors from around the world understand how genes function and affect health. This could help in the development of medical tests and cures for many common diseases such as cancer, heart disease and diabetes.
How long will the research study take?	Your data will be stored and used for research for [number] years.
	This research study will last for at least [number] years. If you join, you will have a [number] hours visit, and follow-up visits once every [number] years.
	This research study will last for many years. It does not have an end date.
Who will take part in the study?	This project will involve at least [number] people whose families are from various parts of the world in order to understand genetic variation across different populations. [Insert a note explaining why this group is targeted or specifically sampled must be included given the research context.]
	We plan/aim to study/recruit up to [number] volunteers/participants.
	We hope that [number] people or more will join [name of the research project].
	No two people have the exact same DNA except identical twins. The differences in DNA are called genetic variations. But there are differences in how common some variations are across groups. We are inviting you to join because you are either a [country] national or long-term resident.
Who has funded this study?	[Name of the research project] is a health research program funded by the [private organization/public agency/government]. You can learn more information about this program here: [website].
	Researchers in several countries are working together to develop this resource, including [institution(s)]. Several agencies are funding the project, including [list]. You can learn more information about the organization of this project at [website].

What am I being asked to do?	**Overview**	In order to take part [name of the research project], you must [select all applicable/add more]: o be at least [applicable age of majority] years old; o be willing to give a sample of blood so that researchers can read out all of your genetic information from it (a process called "sequencing"); o be willing to have some of your cells grown from the [identify type, e.g. blood or saliva] sample that will make it possible for researchers to get an unlimited amount of genetic material from the sample for a long period of time; o be willing to have your de-identified genetic information put into secure public scientific databases available on the internet. This means identifying information such as your name, date of birth and other identifiable information has been removed before your genetic information is uploaded. o be willing to have many researchers around the world study your de-identified genetic material and data from your sample for a long time, and to have the results put in scientific databases on the Internet, shared with research and clinical communities as well as in conferences and publications; o [add any relevant step the participant must undertake to take part in the study].
	Complete paperwork	Through the [name of the research project] website [or during your visit], we will [select all applicable]: a. Ask you to read and sign this consent form b. Ask you to provide us with your contact information. This will allow members of the study team to get in touch with you directly [should mention later in the document that only the study team will contact the participant and no one else]. c. Ask you to make a decision about making your de-identified data publicly available. d. Ask you to tell us about your medical history. e. Ask you where your grandparents were born, and [where appropriate] what language(s) they spoke. This information is important because we want to collect samples from people whose grandparents came from [geographic region/ethnic group]. f. Ask you if any of your relatives have already given samples for this project. We need to collect samples from people who are not closely related to each other, so we do not want to include more than one member from a family. g. [may need to include additional topics here, as applicable] h. Ask you to complete a short multiple choice quiz.
		At [number of months/years] intervals, and at the end of your participation in the study, we will ask you to give us feedback on your experience participating in this study.

	Undergo medical examination	If you agree, you will receive a health check as part of this study. You will also be asked to provide a blood or saliva sample for long-term storage and analysis of your DNA. At the health check we will carry out the following procedures: [select all applicable] - Physical measurements We may ask you to go to a local clinic to be measured. If you say yes to being measured, it will take about [number of minutes]. Our trained research staff will do the measurements. We will measure your height, weight, hips, and waist. We will check your blood pressure and heart rate. We may ask you to have other measurements over time [such as…]. - Samples We may ask you to go to a local clinic to give a blood sample. If you say yes to giving a sample, we will use a needle to draw about [amount in ml/tablespoons] of blood from your arm. We may ask you to give a urine sample. We may ask for other samples, like saliva. […] Researchers will use many methods to study your samples. Because [name of the research project] will last for [number] or more years, some of the methods may not even be invented yet. - Fitness trackers If you have a fitness tracker (like one to count the steps you take in a day), you might be able to share data from it with [name of the research project]. If you don't have a fitness tracker, we may ask you to use one that we give you. - [may need to include additional topics here, as applicable] If you are asked, you can decide yes or no for each of the procedures above. You can say no and still take part in [name of the research project].
	Give access to my electronic records	- Electronic health records If you have electronic health records, we may ask for access. If you are asked, you can decide yes or no. You can say no and still take part in [name of the research project], but it might limit what other data we ask to collect from you. For example, if you say no, you might not be asked to give samples. There will be a separate form called the [name of authorization form required by local laws or government bodies] for you to sign if you decide to give us access.
		[Name of the research project] would like to monitor your health throughout the study and link health-related events to your medical record. Other health administrative data that is held by your health service provider will also be linked. This will allow us to get information that is difficult to obtain using questionnaires or at a clinic. We are very careful to keep all your information confidential. But if you do not want us to link your records you can tell us.

	Give access to my data collected elsewhere	- Data about your health from other sources We will add data from other sources to the data you give us. For example, environmental data and pharmacy records. This will give researchers more data about factors that might affect your health. There are two ways we will add data from other sources to your [name of the research project] record: a. *Based on where you live and work* We will add data about your area based on where you live and work. For example, we may add data about the number of people in your area. We may add pollution data. We may add data like how close you live to the nearest grocery store or park. b. *Based on data that identifies you* We will use data that identifies you like your name and date of birth to add data that is specific to you. For example, we may add data from pharmacy records or health insurance records. If you have had cancer, we may add data from cancer registries. If you have a [national identification number], we may ask you for it to help with adding data. It is optional. Even if we ask, you do not have to give us your [national identification number]. You can say no and still take part in [name of the research project]. These other sources can contain sensitive data. For example, they may tell us about your mental health, or use of alcohol or drugs. They may contain sexual or infection data, including HIV status. Because of this, we will ask the [name of the research project] ethics committee to review and approve each data source before we add it.
		We will also request health information about you from other institutions or registries that may have your health information. This may include any relevant governmental/administrative health data repository in your [country, province/state, institution] among other things.
	Other tasks needed during/after the study	[We will tell you if you are eligible to take part in this study based on the information you have provided to us. If you are eligible,] we will invite you to a face-to-face interview at the [name of the institution and location]. If you live far from our location, we will offer you a phone interview. The purpose of the face-to-face meeting or phone call is to discuss the study procedures and give you the opportunity to ask any questions.
		Please tell us immediately if you experience any health related unexpected events as a participant in this study. Such events should be reported to the principal investigator (PI) or study coordinator directly. [Provide contact info and emergency resources]
		You, as a participant of the [name of the research project] (ref numbers), are being asked to participate in this add-on study, [name of the additional ethically approved research project].
		In approximately [number of weeks/months], we will contact you to come and pick up the result of your clinic visit for the research study. If we find something abnormal, we will tell you during your visit. We may contact you for a revisit in approximately [number of months/years].

What actions will be taken regarding my [DNA/sample/information]?	If you agree to participate in this study, we will ask you to provide a blood or saliva sample which we will use to isolate your DNA.
	The only information we will include with the sample is the name of the ethnic or geographic group you come from (or that your ancestors came from), and your sex. Your name and your medical information will not be shared with researchers outside of the study team.
	You understand that the cells of some of your samples can be grown forever. Your cells can be stored and studied for many years. Also, your cells can be transformed into different kinds of cells to help researchers answer scientific questions. For example, skin cells could be transformed into nerve cells.
	The [name of the research centre/institution/repository] researchers may [select all applicable]: ● grow some of your cells from the sample you provided so that researchers can get an unlimited amount of DNA from it for many years, maybe even forever; ● share the DNA from the cell line with [any/specific/project] researchers [at our institution/in our country/around the world]; ● study your sample, including your DNA, in great depth using many different techniques, some of which may not even have been invented yet; ● share your sample with other participants of the [name of the research project] for additional studies; ● put all the de-identified data in open access (public) scientific databases on the Internet at [include website]; ● compare samples from different ethnic or geographic groups [we suggest adding a clause as to why this research would be allowed if including this bullet point]. ● [additional topics here, as applicable]
Access to my information? [Authorization/quality control]	Scientists (researchers and/or clinicians), health services and commercial companies from around the world will be able to use the samples and information in the DNA database for many kinds of [health-related] research. This database will be kept for many years, maybe even forever. Researchers may use it in many future ethically approved studies. Some of these analyses may not even have been invented yet.
	Access to this database will be controlled. Researchers will have to be approved by [name of the research project] to use this database.
	We will post information from the database publicly on the internet. The information we post will be about the group, not about individuals in our study.
	Once you join [name of the research project], we will post your DNA and self-reported medical data on a publicly accessible website/database. We will not include your name or other information that directly identifies you.

	If we sequence (read) your DNA, you will get to review the results before we ask you to make a decision about making your de-identified data publicly available.
	Regulators and people from [sponsor/institution] may review the notes and data we gather about you for this research project to make sure we are conducting this study correctly. By agreeing to participate in this research, you give permission for them to have access to your records.
	You will be able to see the data we collect about you. This includes: - Any data you give us, like your health data. - Your physical measurements [such as…]. - Available measurements from your samples. You will be able to share this data or question it if you so choose. For example, you might want to share your [name of the research project] data with your family, health care provider and/or other health professionals.
Will you take photos of me?	We may ask for your permission to take a picture of your face. If you say yes, you will be asked to sign a separate [photography consent form] as well.
Will you re-use my samples or data for other research purposes? [secondary research]	We may use any of your samples for ethically approved research about this topic or other topics. We may do any type of analysis, including laboratory genetic analysis. [We may do this even after you are unable to provide consent or your death].
	Your de-identified sample and genetic information may be used by [institution] for ethically approved research that may help others with a similar condition.
	We may store your samples indefinitely. We will use them for many different projects. For instance, there is a possibility that some of your samples may be used for ethically approved genetic research. For example, we could grow your cells forever from your sample, and they can be transformed into different types of cells that could be used to make medical products. We will not tell you about these projects or uses of your samples.
	If you choose to publish your DNA sequence data, the [name of the research project] may re-process your DNA sequence data from time to time as new data, information or techniques become available. This means that we may need to do additional analysis and testing of your DNA over time. If you gave consent to the publication of your original DNA sequence data, we will publish your updated sequence automatically. We will not ask for your permission to post your updated sequence. We will not give you an updated research report.

What are the risks associated with the study?	**To my physical person and/or as inconvenience**	*Inconvenience.* Joining this study will take [number] hours. We will ask you to fill in a pre-enrolment and enrolment form. We will ask you to read background materials and this consent form. We will [select which applies: "check that you have understood" OR "ask you to undergo a medical screening examination"]. Once you join, we will ask you to do [hours] of activities. We will ask you to travel to our clinic for a [number] minute medical interview [and blood draw/skin punch/other sample collection]. We will ask you to complete quarterly questionnaires that should take about [number] minutes each.
		Physical Discomforts. You may experience a small amount of pain, bleeding, and/or faint when we draw your blood. You may have temporary bruising and/or infection at the place where we draw your blood. We will collect [amount] of your blood. A person who is [trained/licensed] to draw blood will do this procedure.
	Potential genetic discrimination and/or stigmatization	Researchers will use information such as your ethnic group, and sex in their studies. This data helps researchers learn if the things that affect health are the same in different groups of people. These studies could one day help people of the same ethnic group, or sex as you. However, there is a risk that third parties could use this data to support harmful ideas about groups.
		Like other medical information, finding out genetic information about you may affect your insurance or employment.
	Unknown potential risks	The risks of taking part in this study may change over time as technology advances and new ways of understanding information are developed. For example, there may be new ways of linking information back to you that we cannot foresee now. Risks may come up in the future that we cannot predict now.
		Public genomics projects like the [name of the research project] are relatively new. For this reason, we don't yet know all of the risks of taking part.
		Taking part in [name of the research project] may have risks that we don't know about yet. We will tell you if we learn anything that might change your decision to take part.
Benefits associated with the study? (includes personal, societal and financial)		You may not benefit from being part of this study. That said, taking part may be interesting to you. You may learn new things. You may help others by taking part. For example, your de-identified data may help researchers better understand [DNA/health/disease].
		The goal of [name of the research project] is to increase the understanding of human biology, health and disease. This may lead to the development of new diagnostics and therapeutics, improve clinical decision-making, and positively impact global health. This project could have a significant impact on personalized medicine and pharmacogenomics (the study of how genes affect a person's response to drugs). However, you will not be receiving any part of the potential profits of the commercialization of such drugs.

	If you agree to participate in [name of the research project], you will receive a basic health-check as part of your visit. You will learn about your health. Other possible benefits include: early identification of health problems, disease risks, referrals to specialized clinics and sharing results with primary health care providers.
Limits/restrictions of this study?	Taking part in [name of the research project] is not the same as receiving medical care. Biomedical research looks at possible new ways of understanding human health. The information you receive, is not meant to replace professional medical advice, diagnosis or treatment. If you are concerned about your overall health or if you have a specific concern, please follow up with your regular healthcare provider.
	Do not use the information you receive from [name of the research project] for any medical or clinical decisions. These results need to be confirmed by a licensed health care professional before they can be used in your care.
	The [name of the research project] will give you research results. Research results are not the same as clinical results. We cannot guarantee the accuracy or completeness of the research results. Research results need to be confirmed/validated in an accredited clinical laboratory.
	The [name of the research project] is not responsible for any part of your health or medical care. You should continue to receive care from your regular medical care provider.
Will you contact my doctor?	Yes we will contact your medical care provider for more health information.
	No, we will not contact your medical care provider.
	We will not send your research records from [name of the research project] directly to your health care provider.
Can I withdraw from the study?	Yes you can change your mind. At that time, we will stop using your samples and/or de-identified data [OR] we will destroy your samples and/or data. We cannot retrieve samples and information that has already been given to other researchers or already used in research studies or presentations or conferences.
	The Community Advisory Group [for this project/for this community] may ask that everyone in [name] community's samples be withdrawn from [repository].
	Even if you decide to leave this study, we may securely keep your contact information in order to comply with local laws and regulations.