Beyond One Million Genomes

1+MG Consent Recommendations

Recommendations for the content of 1+MG consent forms

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B1MG PROJECT, WP2, Task 2.2.

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1. Introduction

1.1. Purpose

The 1+MG initiative aims to promote responsible cross-border access and secondary use of genomic and related-health data across Europe for research, healthcare, and policy-making purposes. This document provides consent recommendations for prospective data collections intending on secondary use of data for research purposes (without a specific project in mind), including making data available cross-border.[1] The guidance focuses primary on consent *content* elements, as consent models and processes[2] may vary across countries and contexts. These content elements can also be used to design information for re-consenting or notifying individuals of secondary use (research purposes) including cross-border access.[3]

1.2. Nature of the Recommendations

Recommendations are made that 1+MG adopt 1) minimum requirements (MUST); 2) best practices (SHOULD); and 3) points-to-consider (non-directive). If a minimum requirement is missing, this may mean that a Data Holder cannot legally or ethically make data available through 1+MG, or can only do so subject to special data and access and use conditions. Best practices may also reflect in some cases national legal requirements.

The recommendations are informed by the requirements of the European *General Data Protection Regulation* (GDPR)[4], the interpretive guidance of the European Data Protection

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[1] Secondary use for healthcare and policy-making will be addressed separately. The use case for policy-making purposes must be more fully developed before relevant consent guidance can be provided.
[2] This document focuses on consenting adult populations. Additional considerations for minors and other vulnerable populations are addressed in the 1+MG Special Subjects Policy.
[3] A future checklist will be developed outlining minimal requirements when assessing existing consents to determine if legacy data collections can be used for further research purposes and accessed cross-border.
[4] Whole genome sequence data and related-health data included in 1+MG will generally be treated as pseudonymised data (which is personal data).

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Board (EDPB), research ethics principles[5] and guidelines, as well as ethical and legal data governance principles, such as those outlined in the draft *Data Governance Act*, and implemented in the 1+MG Data Inclusion Policy. Justifications and explanations are provided. Legal consent requirements depend on the legal basis selected under the GDPR art. 6 and art. 9. The guidance provided is largely independent of the legal basis, with caveats provided where a consent legal basis may require less flexibility in information, interpretation of what counts as "freely given" as well as in consequences of withdrawal.[6] Legal consent requirements may also depend on national laws[7]. Some illustrative examples are provided. National advisory bodies (e.g., ethics committees) are expected to provide additional, nationally-tailored consent guidance. Some 1+MG best practices may in fact be minimum requirements in certain national settings. It is the ultimate responsibility of the organizations involved in collecting data to identify and comply with all norms applicable to their activities.

This guidance is agnostic to different collection and sequencing contexts across Europe[8], including: population databases, genomic research projects, precision medicine clinical trials, genomic medicine initiatives, as well as clinical care (such as predictive, diagnostic or confirmatory genome sequencing). Some practical implementation examples are provided to facilitate application of the guidelines in specific contexts. The guidance is designed generally for any organization who plans to collect and/or generate genomic and related-health data, with the intention[9] to process the data for further research purposes (and/or secondary healthcare use) covering cross-border access. The guidelines are not specific to use of the 1+MG infrastructure per se. The guidance does not distinguish between further research purposes led by the collecting organizations and further research purposes of external researchers accessing data (except to ensure the consent covers the possibility of the latter). This is both to simplify communication, and because the publicly-funded 1+MG infrastructure is designed to support non-discriminatory access to data.

1.3. Background

The collection/generation of genomic and related-health data and widespread use for research and healthcare raises a number of ethical issues around informed consent. This includes the risk of privacy breaches; psychological distress due to the type and amount of personal data being processed and shared; risks of harm if data are misused or misinterpreted; the handling of results and incidental findings that have implications for the health of participants and/or their families, including capacity limits of health care systems to provide adequate follow-up care; and issues of vulnerability (e.g., to discrimination) related to factors including cultural,

[5] Including respect for persons, beneficence, and justice with a focus on the main ethical concerns raised by the informed consent process in the context of genomics.
[6] E.g., depending on national law or authoritative interpretations, this may include greater specificity of purposes and recipients; more details about the scope of data subject rights (especially for data are accessed by downstream controllers); and potential power imbalances between controllers (public bodies) and data subjects precluding consent.
[7] E.g., National, regional or sectoral data protection law, medical research law, health law, bioethics law, biobanking law, health research regulations.
[8] The territorial scope is primarily focused on national, regional or institutional data collections established in Member States of the European Economic Area (EEA) who are signatory to the 1+MG Initiative. It is possible that other countries outside the EEA (e.g., UK, Switzerland) are also permitted to contribute collections. Data access may be provided to researchers across the EEA and globally, under appropriate conditions.
[9] The intention to pursue further purposes triggers transparency requirements under the GDPR (Art 13((3)).

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linguistic, and socio-economic considerations.[10] Ethical issues in genetic/genomic research include the risk of therapeutic misconception; the risk of misunderstanding the purpose and design of this type of research as compared to clinical trials testing medical interventions; and misunderstanding of the risk–benefit ratio.

Additional legal and ethical issues arise where genomic and health-related data are made available to broad communities of users and organizations for secondary use. Sharing sensitive and potentially identifiable genomic and related-health data raises concerns about increased risk of privacy breaches, affecting the rights and interests of data subjects and their families. Countries outside the EEA may not provide equivalent legal protections or ethics oversight mechanisms. Moreover, the specific purposes, recipients of data, and associated risks cannot be fully specified at the time of an initial consent, raising issues about the informedness and specificity of consent. Even where the scope of consent is made clear and understood, there are concerns about the effectiveness of oversight and enforcement mechanisms to ensure data are only used for consented purposes. In short, transparent information is needed to enable individuals to make informed decisions about cross-border access and secondary use of genomic and related health data, combined with robust governance frameworks to ensure data are processed responsibly.

1.4. Methods

We have analysed ethics literature on practical and ethical challenges raised by the process of consent in the context of biobanks, genomic/genetic research, precision medicine, genomic medicine initiatives, and clinical care. (see References) In our search in the PubMed databases and other relevant specialized journals, we have privileged two types of publications :

- findings and recommendations based on empirical studies, where conclusions of the study were drawn from concretely empirical evidence (e.g. qualitative and quantitative studies, e.g. assessment of research participants' perceptions of research based on the information provided through the consent form/notice, etc.,)
- recommendations, reports, guidelines, models of consent developed by key leaders and initiatives in the field

We have also used conclusions from project workshops organised in the course of the B1MG project as well as the B1MG use cases. We have also reviewed GDPR requirements, European Data Protection Board Guidance (EDPB). A sample of national data protection law implementations applicable in the research and healthcare sector were reviewed and reported in the appendix.

2. General Guidelines

Consent processes typically include an "information sheet" that clearly describes what an individual can expect when participating in research or undergoing healthcare - containing sufficient information to make an informed decision - linked with a "consent form" to record the consent process and individual agreement.

[10] See 1+MG Special Subjects Policy.

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1. The information sheet and consent form SHOULD present the information overall concisely, using clear and plain language to promote comprehension.[11]
2. Where the information sheet becomes too long and complex, the structure SHOULD be layered, presenting the most important and legally required information first and providing additional information in optional sections.[12] Consider implementing e-consent tools that facilitate comprehension e.g., by including visualisations, hyperlinks, and self-directed review of information.[13]
3. All data protection information SHOULD be easily found in one place (e.g., one section within the information sheet).[14] Some information is highly relevant from both a research ethics and a data protection perspective (such as information on purposes, data types, categories of recipients, withdrawal rights). A layered structure permits key ethics and data protection information to be prominently presented first, with references to a subsequent section covering all data protection aspects.
4. Consider using separate consent forms for the primary purpose (research project/healthcare test); further research purposes (without a specific research project in mind); and any additional purposes (e.g., secondary healthcare use), so as to be more clear and transparent. Some overview may be needed to make the big picture clear. If a single consent form is used, consider using separate sections corresponding to the different purposes.
5. The information sheet SHOULD explain basic concepts such as genomic versus genetics, biosamples, genomic data, genetic variants, precision medicine, genomic research, biobank, data repository, coding.[15]
6. Given that aspects of data sharing like the exact purposes and recipients cannot be fully known at the time of consent, it is justified to use indefinite language (e.g., may) where necessary in consent and transparency information, as long as this does not undermine the fundamental rights of data subjects.
7. The contents of information sheets and consent forms provided to the participants may change over time. The version used for each participant MUST be documented, which is facilitated by proper versioning of these documents.
8. The consent form MUST obtain confirmation from the individuals that they have read and understood the information sheet, and/or that the content was explained to them (e.g., as a tick box). The consent form SHOULD obtain confirmation the individual had the opportunity to ask questions.
9. The cultural, linguistic, and socio-economic context SHOULD be considered when preparing the informed consent (e.g. religious beliefs that may not accept certain types of genetic/genomic tests, potential for stigmatization of vulnerable groups, etc.).

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[11] GDPR Rec 58; Art 13; Art 7 - where consent is the legal basis; EDPB 05/2020, para 60.
[12] EDPB 05/2020, para 69.
[13] GDPR Rec 58.
[14] Article 29 Working Party, Guidelines on transparency under Regulation 2016/679, paras 11, 33. This includes information on the identity of the controller, data protection officer (DPO) contact, categories of data, purposes, recipients or categories of recipients, etc.
[15] See e.g., US National Institutes of Health, "Fact Sheets"; Torpy JM, Lynm C, Glass RM. Genetics: the Basics. *JAMA.* 2008;299(11):1388. doi:10.1001/jama.299.11.1388.

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10. Consider involving community groups to ensure such issues are appropriately communicated in the consent documents.

3. Consent to Further Research Purposes

1. The information sheet and consent form MUST state that genomic and related-health data will be used for further research purposes.[16]
2. The information sheet and consent form MUST specify a well-described area of further research purposes (e.g., health and biomedical research).[17]
    a. Consider giving individuals the option to limit their consent to a narrower area of research where this choice is likely to allow certain members of the recruitment population to respect important personal preferences (e.g., disease-related research v.s., health and biomedical research).[18]
3. Further research purposes MUST be distinguished from the primary purpose (e.g., research project/healthcare test), and any additional purpose (e.g., secondary healthcare use) including material differences about data processing[19] or ethical issues.[20] This may be facilitated by using separate sections or consent processes for each purpose.
4. The consent form MUST give individuals separate choices to agree to the primary purpose (e.g, research project/healthcare test), to further research purposes, and [where applicable] to any other purpose (e.g., secondary healthcare use).[21]
5. The information sheet and consent form MUST state further research purposes may involve sharing data with researchers at categories of external research organizations (e.g., academic research institutions, healthcare institutions, pharmaceutical companies, bioinformatics and health technology companies).[22] I.e., the information

[16] GDPR Art 13(1)(c); Art 6(1)(a) - where consent is the legal basis.
[17] GDPR Rec 33; EDPB 05/2020, paras 155-160.
[18] If such choices are given, these categories SHOULD be aligned with a controlled vocabulary of administrative (rights) metadata across 1+MG, to ensure both that individual consent and choices can be tracked and enforced, and also that data can be meaningfully integrated and re-used. See e.g. GA4GH Machine-readable Consent Guidance, coding the GA4GH Data Use Ontology.
[19] GDPR Art 13(1)(c).
[20] A full description of the primary purpose should include the identity and location of any partner organizations participating in any project-specific data sharing. Additional considerations for genetic research include the following: In order to avoid any misconception or confusion for the research participant as to the purpose of research and the expected clinical relevance of its results, explain what is different about a genomic research project as compared to a classical clinical trial (e.g., not to evaluate a treatment but to better understand the cause and mechanisms of the participant's condition). Indicate if the research project requires recruitment of family members (e.g., for direct collection of their genomic or health-related data), why this is necessary, and if so, how family members will be recruited (e.g., asking participants' help to identify and/or initiate contact with relatives).
[21] GDPR Art 7(2)(b) - where consent is the legal basis.
[22] The 1+MG Data Inclusion Policy requires that access to data for secondary use be provided on a non-discriminatory basis. This recommendation is driven by the general ethical and legal principle of non-discrimination applied to data sharing, as well as the principle of maximizing the benefit of research participants' contributions. Especially in the case of publicly funded sequencing and the use of publicly funded infrastructure, access should be made available to any qualified and trustworthy researcher able to advance science. Data protection compliance processes should not be designed to lead to the de facto proprietary

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sheet and consent MUST NOT limit sharing for further research purposes to specific recipients (e.g., partner organizations/joint controllers only).[23] Consider if choices should be given to limit categories of recipients to certain sectors.[24]

6. The information sheet SHOULD state that data will be stored in a secure database, and identify the location and host organization (where known). This is a legal requirement if the recipient organization is a controller for storing and making data available.
7. The information sheet MUST NOT limit the geographical location of recipients to certain countries within the EEA.[25]
8. The information sheet and consent MUST state whether or not there is an intention to share data with research organizations based in third countries outside the EEA, where an equivalent level of privacy protection can be ensured if data are to be used globally.[26] (See more in the Data Protection section). Failure to mention this may mean data must be specially restricted to the EEA.
9. The information sheet SHOULD explain the reasons for data sharing, (e.g., to enable qualified researchers across the EEA and around the world to collaborate, check each other's results, and ask new questions, which can accelerate research, helping us to better understand and address disease).
10. The consent MUST explain how detailed information about future research projects will be offered/made available to the data subject (e.g., direct communication; website, newsletter, and/or on request), and at what time (e.g., periodically, in advance of each access grant).[27]
11. Consider if the individual will be given an opportunity to opt-in or opt-out to subsequent, specific research projects (i.e., dynamic consent).[28]

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treatment of data. Practically speaking, necessary recipients cannot reasonably be predicted in advance for further research purposes. For public bodies who will be subject to the proposed *Data Governance Act*, non-discriminatory access will be a legal requirement (Art 5).

[23] If you plan to rely on consent as a legal basis, however, ensure your national law or regulations do not require the identity of all recipients to be specified (Rec 42).

[24] Sector-specific limitations on access are generally discouraged, as it is hard to predict which sectors are necessary to advance research, and it is hard to track, interpret and enforce these requirements. Exceptionally, such limitations may be justified where a sequenced population has significant trust issues with a particular sector.

[25] Note there is no legal requirement to mention cross-border access within the EEA, though there is nothing wrong with explicitly stating this.

[26] The 1+MG does not foresee enabling access to researchers in third countries outside the EEA without equivalent privacy protections, as derogations (e.g., consent) are exceptional (GDPR Art 49).

[27] EDPB 05/2020 para 161 "A lack of purpose specification may be offset by information on the development of the purpose being provided regularly by controllers as the research project progresses...". Consider if national law or authoritative guidance requires direct notification of data subjects in advance of processing for any specific research project, i.e., in advance of granting access (Art 13(3)).

[28] Whether or not such a model is ethically appropriate and practically feasible will depend on the context. The practical feasibility of this model will at a minimum require effective communication platforms and processes, as well as the strong, ongoing engagement of sequenced individuals.

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4. Categories of Samples and Data

1. The information sheet MUST describe the categories of biological samples that will be collected (e.g., blood, saliva, tumor).[29]
2. The information sheet MUST mention that biological samples will be used to generate (whole genome) sequence data revealing the individual's genetic make-up.
3. The information sheet MUST mention all the special categories of personal data that will be processed for each respective purpose including health and genetic data.[30]
4. The information sheet and consent forms MUST distinguish the categories of (pseudonymised) genomic and related-health data that will be used for further research purposes.
5. The information sheet SHOULD describe the types of data that will be collected (e.g., demographic data, clinical data, family health history, lifestyle, mobile health data etc.).[31]
6. The information sheet MUST clearly describe the categories of existing biological samples and personal data that will be obtained from existing sources and what are those sources (e.g., samples accessed from existing biobanks, data collected in the context of medical care, and linkage with electronic health records) and specify the categories of data providers (e.g., medical centres, government databases). Clarify in particular if linkage to electronic health records will be obtained periodically, and if so, over what period of time.
7. The information sheet SHOULD describe the methods and procedures used to collect the biological samples and the data (e.g., interventional procedures such as blood sampling, biopsies performed in the context of clinical care or research; data collection through surveys, quality questionnaires, mhealth apps etc.).
8. The information sheet MUST clearly distinguish between any collection of samples and data as part of standard clinical care [where applicable], and collection solely for research purposes.

5. Voluntary Participation and Withdrawal

1. Individuals MUST be informed that participation in further research purposes (i.e., in the research repository) is entirely voluntary, and that they may discontinue participation at any time, without any penalty or disadvantage.[32]
2. The information sheet SHOULD provide instructions on how to withdraw from participation in further research purposes (e.g., contact the research team).

[29] GDPR Art 14(1)(d).
[30] GDPR Art 14(1)(d).
[31] GDPR Art 14(1)(d).
[32] GDPR Art 7(3) - where consent is the legal basis. CIOMS Guidelines II(2). To respect this requirement, any withdrawal process must separate choices to withdraw from the primary purpose, the further research purpose, and other purposes (e.g., secondary healthcare use).

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3. The information sheet or information provided at the time of withdrawal MUST offer separate choices to withdraw from the following processing operations[33] related to further research purposes (where applicable):
    a. the continued storage, sharing and use of already collected data and/or biological samples;
    b. future active participation/ provision of data (e.g., continuing to undergo physical procedures, site visits, providing longitudinal survey or mhealth data); and/or
    c. future linkage to electronic health records.
4. The information sheet SHOULD indicate what would happen to data and/or biological samples should they withdraw (e.g., samples/data will be destroyed and/or anonymised).
5. The information sheet MUST explain and justify limitations on the right to withdraw from further research purposes, namely:
    a. it MAY not be possible to withdraw data that is already being accessed and/or analysed as part of an ongoing research project.[34]
    b. it WILL not be possible to withdraw data archived after completion of a research project until the end of the archiving period, to ensure the integrity of completed research projects.

6. Benefits and Commercialisation

1. The information sheet SHOULD explain that the main aim of research is scientific progress, i.e., to advance our understanding of disease. Ultimately, this could lead to new approaches and products to prevent, diagnose and/or treat people with a similar condition.
2. The information sheet MUST explain, where applicable, that research aims at general knowledge and is not likely to benefit the individual and/or their family members directly. In some rare disease sequencing, diagnosis of individuals and families may be a clear goal and foreseeable outcome.[35]
3. The information sheet MUST explain that research results may lead to commercial products, and that the individual will not have any monetary rights in these products.[36] It may be helpful to provide illustrative examples, such as drugs, clinical decision support systems, etc.

[33] GDPR Rec 43.
[34] There may be exceptions where data is not kept in an identifiable form (GDPR Art 11), or where consent is not the legal basis. Even where consent is the legal basis for collection and storage, and for the collecting organizations further research purposes, it may not be the legal basis relied upon by the research organizations accessing pseudonymised data.
[35] CIOMS Guidelines II(11).
[36] CIOMS Guidelines II(11).

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4. To avoid therapeutic misconception, descriptions of any usual care activities and associated direct benefits (e.g., clinical testing) MUST be clearly distinguished from any research activities and associated (lack) of direct benefits.

7. Risks

1. The information sheet MUST clearly distinguish between risks associated with the primary purpose (e.g., research project/healthcare test)[37], and the risks of further research purposes.[38]
2. The information sheet SHOULD explain that sharing data with researchers from other institutions may increase the risk of privacy breaches, especially considering there is always some risk of being re-identified from genomic and related health information.
3. Some of the external researchers accessing data may be based in third countries, but this will only be done where privacy protections are equivalent and/or where appropriate safeguards are in place to offer an equivalent level of protection.
4. The information sheet SHOULD explain that ongoing progress in science and technology makes it possible to perform unanticipated forms of research on genomic data that may turn out to be controversial.

8. Safeguards

1. The information sheet SHOULD describe in general terms the kinds of safeguards that will be adopted to protect personal data and/or biological samples (without being too specific so as to limit changes in the future). E.g.,
    a. data pseudonymisation, meaning all direct identifiers (such as your name, address, data of birth, ID number) will be stored separately and replaced with a unique identifier making it hard to trace the information back to you.
    b. controlled and managed access by qualified researchers to secure data repositories, with access being subject to monitoring and auditing.
    c. data access/use agreements for accessing parties limiting their use to pre-approved purposes (e.g., specific studies) and requiring them to refrain from deliberately identifying individuals.
    d. access to data and research projects will be subject to appropriate oversight by a data access committee and/or a competent research ethics committee.[39]

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[37] The primary purpose may involve different categories of risks e.g., risk of injury from physical research interventions; privacy breach from the collection, storage, use, and sharing of samples/genomic and related-health data as part of the primary research project (unauthorized access and re-identification, leading to potential discrimination, stigma, or worry). As genetic/genomic information might contain health information about biologically related family members, explain privacy risks for members of the family. In terms of psychological risks, genetic/genomic data may reveal information about possible family relationships, including non-paternity; indicate that some individuals would find this information distressing.
[38] This approach is consistent with the fact that study subjects will have the option to participate in the primary purpose while opting out of further research purposes.
[39] CIOMS Guidelines.

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9. Return of General Research Results

1. The information sheet SHOULD explain that general research results of future studies will be published in academic journals and presented at conferences.
2. The information sheet SHOULD explain how the general research results of future studies will be communicated to participants (e.g., list of publications on the data repository website, subscription newsletter, or upon request).

10. Return of Findings of Individual Health Relevance

Organizations who collect and/or generate genomic and related health data are normally required to have a plan in place for handling different kinds of findings with health relevance for individuals or their relatives as part of the primary purpose (e.g., research project/healthcare test). Findings of individual health relevance may include individual research results linked to the aims of a research project, or incidental findings outside the aims of a research project/healthcare test. For recommendations about how to handle findings of individual health relevance, see the 1+MG Incidental Findings Policy. Here, best practice recommendations address how these plans SHOULD be described in the information sheet and consent form for the primary purpose. These consent recommendations should also be sufficient to cover the handling of incidental findings from secondary use.

1. Explain whether or not findings of individual health relevance will be reported to participants and/or their families.
2. Explain where applicable if these findings include individual research results related to the study aims and/or incidental findings beyond the primary aims of sequencing.[40]
3. Explain the conditions under which findings of individual health relevance will be reported to participants and/or their family members e.g.,
   a. the level of clinical significance (e.g., life-saving, clinically actionable),
   b. the level of validation (e.g., in an approved genetic laboratory), and
   c. the time period (e.g., during the course of the study).
4. Offer participants the choice not to receive findings of individual health relevance, and explain any situations where preferences may be overridden by professional obligations (e.g., where there is a legal duty to warn family members of life-threatening conditions).
5. Describe the procedure for how findings of individual health relevance may be returned (e.g., reporting through a designated medical professional).

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[40] Note our recommendations for a 1+MG Incidental Findings policy consider all findings of individual health relevance in secondary use contexts as "incidental findings", and that any return of such findings through 1+MG should respect the initial plan and consent established at the time the data were collected.

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6. Explain if findings with shared health implications for biological relatives will be reported to them, and under what conditions (e.g., only with the participant's consent or after the participant's death).
7. To avoid therapeutic misconception, reiterate that the possibility of receiving individual findings of health relevance should not be equated with diagnostic testing or screening.

11. Will I Be Contacted in the Future and Why?

1. The information sheet MUST where applicable mention the possibility of future contact to collect additional samples/data as part of further research purposes.
2. The information sheet SHOULD mention the possibility of future contact to seek renewed consent to further research purposes (e.g., where necessary because of a substantial change in the scope of research aims or where technologies for analysing samples/data substantially change in an unanticipated and material way).
3. The consent form MUST where applicable offer a separate choice to future contact of the individual for the purpose of recruitment into future studies (e.g., precision clinical trials).
4. The consent form MUST where applicable offer a separate choice to receive findings of individual health relevance (see above).

Note that ongoing contact or transparency about data access and general research results is addressed above.

12. Data Protection and Data Subjects' Rights

General

1. The data protection section MUST mention the identity of the controller (the initial data collecting organization) and the contact information of its data protection officer (DPO) [where applicable].[41]
2. The data protection section MUST mention the legal basis for the controller's processing (all or part) of the individual's personal data for further research purposes.[42] This purpose/legal basis MUST be distinguished from other purposes/legal bases.[43]

[41] GDPR Art 13(1)(a),(b). For the DPO contact information, a general DPO office is preferable to an individual who may change. To avoid confusion, it is preferable to highlight that the DPO is generally responsible for matters related to data protection, as opposed to scientific aspects of ongoing studies.
[42] GDPR Art13(1)(c).
[43] E.g., legitimate interests (Article 6(1)(f)) for archiving part of the data needed to establish audit trail and ensure reproducibility of research studies already conducted; Compliance with the law (Article 6(1)(c)) or Vital Interest (Article 6(1)(d)), when reporting of certain health-related findings are foreseen; etc.

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3. The data protection section MUST indicate how data subjects can obtain more detailed information (e.g. contacting the DPO, or accessing a dedicated document containing an exhaustive list of data processing activities).
4. [Where there is an intention to destroy the pseudonymisation table] The data protection section SHOULD mention that it may not be possible to exercise data subject rights where the link back to the individual's identity is no longer retained.[44]
5. The data protection section MUST explain that data subjects have the right to lodge a formal complaint with the competent Data Protection Authority (DPA); specify the relevant DPA the data subjects can contact for this matter.

Recipients

6. The data protection section MUST list the categories of recipients, namely research organisations, data hubs (i.e., data centres, repositories, registries), and secure computing facilities.[45]
7. The data protection section SHOULD mention that data may be processed in the future by other controllers (such as research databases and research organizations) who may base their processing on a different legal basis or who may base their processing on a different data protection law. This may curtail the scope of data subject rights (as explained below in the context of each right).
8. The data protection section SHOULD mention that data may be processed by other controllers (such as research databases and research organizations) for their own research purposes, who may base their processing on *different applicable laws*. This may curtail the scope of data subject rights (as explained below in the context of each right).

International Transfers

9. The data protection section MUST reiterate, where applicable, that there is an intention to share data with research organisations in third countries outside the EEA, and the transfer mechanism(s) foreseen (e.g., adequacy decision, appropriate safeguard).
10. The data protection section MUST indicate where more specific information on the nature of the transfer mechanism can be obtained.[46]

Data Subject Rights

[44] GDPR Art 11.
[45] If you plan to rely on consent as a legal basis, however, ensure your national law or regulations do not require the identity of all recipient controllers to be specified (Rec 42).
[46] GDPR Art 13(1)(f).

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11. Right to rectification. The data protection section MUST explain that data subjects have the right to request correction of inaccurate personal data and the completion of incomplete personal data, but that this right may be limited where necessary to achieve research purposes.[47]
12. Right to access information. Explain that data subjects have the right to access information on how their personal data is being used and shared, including the purposes of approved, ongoing, or completed research projects, the categories of personal data and the identities of the recipients involved (e.g., names of the institutions and/or principal investigators), and the existence of any international transfers and the associated legal mechanism, etc. . Explain that this information will be available on request, and may be available through additional means (e.g., website, by subscription to a periodic newsletter, regular notifications about new projects). Explain that this right may be limited where necessary to achieve research purposes[48] or to the extent it would affect the research organization's intellectual property rights.[49]
13. Right to access a copy of personal data. Explain that data subjects have the right to access a copy of their personal data[50], but that this right may be limited where necessary to achieve research purposes[51] or where other laws restrict communicating genetic or health data (e.g., genetic testing laws). When assessing the potential applicability of these limitations, it MAY be helpful to distinguish between access to the following types of personal data:
    a. Data directly provided by the data subject. This includes: contact information, past medical history details, answers to questionnaires, measurements done directly on the patient.[52]
    b. Data generated by virtue of the data subject's participation in research or undergoing the initial medical procedure. This includes raw genomic sequence data and any other data derived from biosamples.[53]
    c. Data inferred by analysing the raw data (individual research results).[54]
14. [Where consent is the legal basis] Right to data portability. Explain the individual has a right to receive personal information *they have provided directly* in a structured, commonly used and machine-readable format, or to have the information transmitted

[47] Art 89(2) derogation where provided by Member State law (in one or more countries).
[48] Art 89(2) provides the possibility of a derogation where provided by Member State law.
[49] Art 63. Consider if the limit relating to risks to third parties applies, though this seems unlikely in this context (Art 15(3)).
[50] Art 15(3).
[51] Art 89(2) provides the possibility of a derogation where provided by Member State law. Consider if the limit relating to risks to third parties applies, though this seems unlikely in this context (Art 15(3)).
[52] This data MUST always be made accessible when consent is used as the legal basis. (Art 20 GDPR).
[53] In some cases, there may be national laws in place prohibiting the disclosure of genomic data outside the context of genetic counselling. The consent form must clarify if such additional conditions apply.
[54] This includes the analysis and interpretation of raw genomic data. (Providing access to this type of data is optional regardless of the legal basis, and should be based on the data controller's policy on the return of health-related findings).

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to another organization without hindrance.[55] Data provided directly includes those listed by 10a above, but does not typically include data generated from samples. Consider mentioning available formats for raw whole genome sequence data include e.g., BAM, VCF. Mention that the right does not apply beyond the data directly provided by the data subject, to the original controller.

15. [Where consent is the legal basis] Right to withdraw consent at any time State that data subjects can withdraw their consent to processing at any time.[56] Indicate that following the request, data will not be used for future research by the controller or by other controllers relying on consent. Mention this right will not apply where other controllers process the data under a different legal basis, though there will still be a right to object. (see below)
16. [Where public interest / legitimate interest is the legal basis for all or only downstream processing] Explain the individual has the right to object to processing.[57] Explain this right may be limited for compelling, legitimate grounds (e.g., where continued processing is necessary to ensure the integrity of ongoing or archived research projects).

References

Regulatory Guidance

EDPB, Guidelines 05/2020 on consent under Regulation 2016/679 at
https://edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf

Guidelines and Reports

ClinGen: Riggs ER, Azzariti DR, Niehaus A, Goehringer SR, Ramos EM, Rodriguez LL, Knoppers B, Rehm HL, Martin CL; Clinical Genome Resource Education Working Group. Development of a consent resource for genomic data sharing in the clinical setting. Genet Med. 2019 Jan;21(1):81-88. doi: 10.1038/s41436-018-0017-5. Epub 2018 Jun 13. PMID: 29899502; PMCID: PMC6292744.

Global Alliance for Genomics and Health's (GA4GH's), Consent Clauses for Genomic Research and Familial Consent Clauses, at
https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/

[55] Art 20.
[56] Clearly explain how the data collected and already used in past research projects will be treated following the receipt of a withdrawal request. For example, if a minimum amount of data are retained in order to establish an audit trail and enable study reproducibility, explain how this is done (e.g. the data will be stored in a segregated environment accessible only following a formal audit request; safeguards used to ensure data security and purpose limitation; the type of data retained; legal basis for the retention under the GDPR).
[57] Art 21.

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Global Alliance for Genomics and Health: Consent Policy, Sep. 2019, at https://www.ga4gh.org/wp-content/uploads/GA4GH-Final-Revised-Consent-Policy_16Sept2019.pdf

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National Institutes of Health, Special Considerations for Genomics Research https://www.genome.gov/about-genomics/policy-issues/Informed-Consent-for-Genomics-Research/Special-Considerations-for-Genome-Research#families

Examples

FINGEN, Information on the processing of personal data in the FinnGen study, at https://www.finngen.fi/en/data_protection/data-protection-statement.

Genomics ENGLAND, Frequently asked questions about Ethics and Consent at https://www.genomicsengland.co.uk/understanding-genomics/data/ethics-and-consent-faqs/.

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