

Resource for Secondary Research with Data and Biospecimens: Points to Consider and Sample Language for Future Use and/or Sharing for Informed Consent

KEY POINTS:

1. The use of this resource is **completely voluntary**.
2. This resource provides points to consider and sample language for informed consent documents of research studies which plan to store and share data and/ or biospecimens for future use.
3. This resource does not address collection, storage, or sharing of data or biospecimens initially obtained in a non-research context, for example, collected during the course of clinical care.
4. This resource addresses only consent **for the storage and sharing** of data and biospecimens collected during a primary research protocol, for the purposes of future secondary research. The approval for use of these data and biospecimens in new research studies that are outside the scope of the primary protocol and consent (i.e., secondary research) will need to be met through other means. This may include IRB approval of the secondary research project, and if necessary, re-consent, or a waiver of consent, even if participants have indicated their agreement to storage and sharing for future use (45 CFR 46.111, 46.116). Note that under the Common Rule, the consent document for the primary protocol (herein referred to as the “primary consent”), should address requirements for notifying research participants that identifiers may be removed and that the data and samples may be used for future research without additional consent (45 CFR 46.116(b)(9)(i)).
5. The sample language provided in this resource does not alone satisfy the regulatory requirements of the broad consent provision of the 2018 revised Common Rule at 45 CFR 46.116(d) and therefore does not provide consent for the future use of collected biospecimens and data under the exemptions at 45 CFR 46.104(d)(8). Meeting the additional regulatory requirements will be needed to enable the use of data and biospecimens for future research under the broad consent provision of the 2018 revised Common Rule.

I. Introduction:

As a steward of the nation’s biomedical research enterprise, NIH is dedicated to ensuring that data and biospecimens are shared for research ethically, securely, and with respect for the privacy, autonomy, and well-being of research participants and the communities to which they belong. Sharing increases the scientific utility of the data and biospecimens collected and reduces the burden on research participants who may be asked to donate data and biospecimens multiple times as part of different research studies. As part of this commitment, NIH [sought input](#) from stakeholders to identify best practices to obtain effective consent from prospective research participants about data and biospecimen sharing for future research, including the potential risks and benefits. The following resource was developed with [substantial input](#) from a wide range of stakeholders and outlines suggested points to consider when addressing data and biospecimen storage and sharing for future use in consent language and provides supplemental sample language that could be modified as needed when developing informed consent documents. Of note, **the sample language provided below is**

designed to be incorporated into a primary research consent document. The use of the sample language by itself does not address federal, state, local, tribal, or international requirements that may apply to the primary research. Furthermore, this resource is designed for research consent documents; it does not address the storage and sharing of data and biospecimens initially collected for clinical purposes. Use of the information provided in this resource, including sample language, is completely voluntary.

II. Instructions for Use:

This document presents points to consider, instructions for use, and optional sample language that is designed for informed consent documents for research studies that include plans to store and share collected data and biospecimens for future use. The use of the suggested language does not obviate the need for IRB review and approval of any non-exempt secondary research. The sample consent language provided in the resource does not supplant the primary study's informed consent document, but rather is intended to be incorporated into the primary study's consent document. **This resource is not a comprehensive informed consent document, nor is it presented in any specific order.** Not all of the components will need to be included in every informed consent document. The sample language will need to be tailored to institutional and study specific requirements. The sample language does not address all possible scenarios for which informed consent may be needed for data and biospecimen storage and sharing. It is the responsibility of researchers and institutional review boards (IRBs) to determine the appropriate use of the sample language including which components, if any, are relevant to a primary consent and the most appropriate section to incorporate the sample language. Researchers should carefully select language appropriate for the study, and IRBs should ensure that the study's primary consent meets all applicable regulatory and policy requirements, including federal, state, local, Tribal, and international requirements.

Use of this sample language is completely voluntary. This language is being provided as a resource for the research community, and there are no requirements or expectations that any portion of the language be used in an informed consent document for NIH-supported or -conducted studies.

The scope of this resource encompasses consent for storage and sharing of individually identifiable and deidentified data and biospecimens. "Data and biospecimens" includes information collected from, or about a research participant during the course of a primary study (e.g., surveys, medical images, electronic health records, wearable device information) as well as human material (e.g., blood, tissue, urine, extracted DNA).

This resource addresses only consent **for the storage and sharing** of data and biospecimens collected during a primary research protocol, for the purposes of future secondary research. The approval **for use** of these data and biospecimens in new research studies that are outside the scope of the primary protocol and consent (i.e., secondary research) will need to be met through other means. This may include IRB approval of the secondary research project, and if necessary, re-consent, or a waiver of consent, even if participants have indicated their agreement to storage and sharing for future use (45 CFR 46.111, 46.116). Note that under the Common Rule, the primary consent should address requirements for notifying research participants that identifiers may be removed and that the data and samples may be used for future research without additional consent (45 CFR 46.116(b)(9)(i)).

The sample language provided in this resource does not alone satisfy the regulatory requirements of the broad consent provision of the 2018 revised Common Rule at 45 CFR 46.116(d) and therefore does not permit the future **use** of collected biospecimens and data under the exemptions at 45 CFR 46.104(d)(8). Meeting the additional regulatory requirements will be needed to enable the use of data and biospecimens for future research under the broad consent provision of the 2018 revised Common Rule.

Some sample language below includes embedded instructions to fill in specific information pertaining to the research study. These embedded instructions are identified in **[grey bold text]** and will need to be removed after study-specific language is inserted.

III. General Points to Consider:

- There may be separate storage and/or sharing procedures for data versus biospecimens. Some protocols may require separate consent language to specify how data versus biospecimens are stored and shared.
- Those writing and approving informed consent documents are always encouraged to consider the reading level of the entire informed consent document, including any additional language addressing the storage and sharing of data and biospecimens, with the goal of creating understandable language that conveys the necessary information to the research participants. The sample language in this resource was crafted to ensure a broad comprehension reading level (with an overall goal of not exceeding an ~8th grade reading level). There are several third-party resources that help with creating understandable consent language, including the National Cancer Institute (NCI) guide to [evaluating readability](#). Researchers may also consider using supplemental strategies to assist with comprehension (e.g., interactive videos).
- Studies that involve a category of participants who are considered vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons may require additional considerations regarding the storage and sharing of data and biospecimens. Likewise, additional considerations may need to be taken into account for studies that involve pregnant persons, fetuses, or neonates. It is strongly encouraged to seek consultation with the appropriate experts to determine and take into consideration the applicable laws, policies, and regulations relevant to studies involving these populations.
- It is strongly encouraged to seek consultation with the appropriate experts to determine and take into consideration the applicable laws, policies, and regulations relevant when considering assent for participants under 18 and the subsequent need for obtaining the participant's consent when the minor reaches the legal age of majority.
- Some cultural, donor, and/or sovereign groups may have preferences or requirements regarding how data and biospecimens are handled, including the disposition of biospecimens. For example, sovereign Tribal Nations may have laws, policies, and/or regulations governing research that may impact the [storage and sharing of data and biospecimens](#). It is strongly encouraged to seek consultation with the appropriate contacts to determine applicable regulations, policies, and cultural preferences or Tribal laws that will need to be taken into consideration prior to storage and sharing of data and biospecimens.
- Additional considerations may be applicable for research studies that include the storage and sharing of genomic data. It is recommended that those writing and approving informed consent

documents review community standards, such as NIH resources provided by the National Human Genome Research Institute (NHGRI) on [informed consent](#) and the [NIH Genomic Data Sharing Policy](#), as well as international standards on genomic data sharing, such as [The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use- E18 Genomic Sampling and Management of Genomic Data Guidance for Industry](#).

- If the primary study limits the future use of data and biospecimens in any way, the specifics of those limitations should be outlined in the primary consent language.
- As coding and deidentifying technologies advance and capabilities for linking disparate data together evolve, consider the implications for reidentification, privacy, and confidentiality and adjust language as appropriate.
- Consider whether the data and biospecimens may be particularly sensitive and ensure that appropriate privacy safeguards are in place and communicated in the informed consent document.

IV. Sample Language Components:

Introduction-Description

Considerations: The Introduction-Description component is meant to provide prospective research participants with an introduction to, and description of the planned storage and sharing of data and biospecimens.

- Consider the appropriate timeframe for data and biospecimen storage. For some, the appropriate timeframe may be indefinite, while others may have a clear, limited timeframe.
- If identifiers will be retained, deidentification of the data and biospecimens is not feasible, or there are circumstances in which re-identification may be possible, adjust language as appropriate.
- If there are circumstances under which a code key may be used to re-link identifying information to data and biospecimens, consider including language to address this.
- If there are plans to share datasets with unrestricted access, adjust language to reflect this. Consider including the phrase: *“Your data and biospecimens will be shared in a way where anybody around the world can gain access to them without review.”*

Instructions: Adjust language as needed. To use this sample text, include the first two paragraphs then choose either Option #1 or Option #2. Replace embedded instructions identified in **[bold grey highlighted text]** with specific information pertaining to the study. Remember to remove the “Option” information identified in **[bold grey highlighted text]**.

Sample Language:

This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and biospecimens for [Insert time frame as indicated in the study protocol].

Your data and biospecimens may be shared with researchers around the world. However, the decision to share your data and biospecimens is controlled by [indicate which entity has control]. To get your data and biospecimens, future researchers must seek approval from [indicate which entity has control]. The researchers must agree not to try to identify you.

Option #1: If the data and biospecimens are coded and can be linked back to the identity of the participant:

We will protect the confidentiality of your information to the extent possible. Your data and biospecimens will be coded to protect your identity before they are shared with other researchers. [indicate which entity has the code key] will have a code key that can be used to link to your identifying information. The code key will be securely stored.

Option #2: If the data and biospecimens cannot be easily linked back to the identity of the participant:

Your name and identifying information will be removed from any data and biospecimens you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and biospecimens.

Voluntary Participation and Withdrawal of Consent from Storage and Sharing

Considerations: The Voluntary Participation and Withdrawal component informs prospective research participants about whether data and biospecimen storage and sharing for future research is voluntary or required for participation in the primary study. The component also describes what happens if the participant initially agreed to the storage and sharing of data and biospecimens, and then changes their mind about storage and sharing for future use.

Voluntary Participation Considerations:

- In general, participants should be given the choice about whether or not they wish to have their data and biospecimens stored and shared for future use. Providing options for participants to agree to data and biospecimen storage and sharing is particularly important in studies that offer the prospect of direct benefit to the participant. Requiring storage and sharing may be considered undue influence if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway to join a possibly beneficial research study.
- If the primary research study offers no prospect of direct benefit, it may be reasonable to consider requiring storage and sharing in the primary protocol (e.g., if the primary protocol is a repository protocol with the sole purpose being to collect data and/or biospecimens for future use). In this

case, there is no reason to participate if the participant does not want to provide consent for storage and sharing.

Withdrawal of Consent Considerations:

- Consider cultural sensitivities around the return and/or destruction of biospecimens when research participants withdraw their consent for the storage and sharing of data and biospecimens.
- If the data and biospecimens are being stored and shared for FDA-regulated research, adjust language to reflect that there are cases in which data and biospecimens may need to be maintained.
- If the entity that controls access to data and biospecimens is different than the entity responsible for holding the code key (e.g., an honest broker), consider adjusting language to reflect this.

Instructions: Adjust language as needed. Choose either Option #1 or Option #2. Replace embedded instructions identified in **[bold grey highlighted text]** with specific information pertaining to the study. Remember to remove “Option” information identified in **[bold grey highlighted text]**.

Sample Language:

Option 1: When sharing of data and biospecimens will be optional (e.g., for studies that have potential benefit):

It is your choice whether or not to let researchers share your data and biospecimens for research in the future. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study.

*If you change your mind and no longer wish to have us store or share your data and biospecimens, you should contact **[insert contact info]**. We will do our best to honor your request and to retrieve any data and biospecimens that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and biospecimens we will not be able to retrieve them. In addition, if the data and biospecimens have already been used for new research, the information from that research may still be used. We will **[fill in what will happen to the biospecimens after they are retrieved]** any biospecimens we have or are able to retrieve.*

*Please initial **[or sign depending on institutional practice]** next to your choice:*

- YES**, use my data and biospecimens in other research studies
- NO, do NOT use** my data and biospecimens in other research studies

Option 2: When sharing of data and biospecimens will not be optional (e.g., where sharing is integral to the purpose of the study):

Participating in this study means you agree to share your data and biospecimens. You can change your mind later, but researchers might still use your data and biospecimens if they have already been shared. If you do not want your data and biospecimens used for other projects, you should not participate in this study.

Risks & Benefits

General Considerations: The Risks & Benefits component describes the reasonably foreseeable risks and/or discomforts related to storage and sharing of data and biospecimens, and any anticipated benefits related to storage and sharing of data and biospecimens.

Considerations- Risks:

- If identifying information will be retained, include language that addresses the additional measures designed to safeguard participants' privacy (e.g., coding of identifiable information, access controls).
- Adjust language if there is a specific risk associated with loss of privacy due to storage and sharing, such as stigma or the ability to obtain certain types of insurance.

Instructions: Adjust language as needed. Remove **[Risks]** and **[Benefits]** unless needed as a section heading.

Sample Language:

[Risks] *We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.*

[Benefits] *You will not receive any direct benefit from sharing your data and biospecimens. However, sharing your data and biospecimens may contribute to research that could help others in the future.*

Commercial Application

Considerations: The Commercial Application component informs prospective participants about whether their data and biospecimens may contribute to products with commercial value.

- If research participants will receive any payments related to commercial or product development, adjust language in the last sentence to reflect this.

Instructions: Adjust language as needed.

Sample Language:

The use of your data and biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.