Representing Data Sharing in Informed Consent

Guidance for Researchers at the University of Illinois at Urbana-Champaign

Purpose

Obtaining appropriate consent is critical to data sharing and to reuse in future research. This guidance provides models and advice to consider when creating or revising informed consent language.

Many major US funding agencies (for example NIH, NSF, etc.) now strongly encourage data sharing and reuse and may even require it as part of grant award. Similarly, many academic publishers also encourage data sharing. In fact, articles have been retracted because of the author's inability to provide the underlying data when a study's validity has been questioned.

Best practices to future-proof your research

- Accounting for data sharing and reuse in the original informed consent process is critical to avoid future complications and negative consequences.
- Because the re-consent process is arduous and sometimes impossible, you are encouraged to use the most permissive consent language that allows for future sharing and reuse without hampering recruitment.
- There are three basic approaches to informed consent that anticipate data sharing and reuse. Note for all cases, some officials *must* be allowed access for legal or policy purposes.
    1. **Widest sharing and reuse** - Allows data to be used in future research projects by the original research team or others through controlled access to identifiable data and/or release of publicly available de-identified data.
    2. **Limited sharing and reuse** - Allows for reuse and public data sharing of de-identified data but does not allow for reuse of identifiable data either by the original research team or others in the future.
    3. **No sharing or reuse -** Only the research team is allowed access, and data use is limited to the specific project under consideration with an expectation that identifiable data will be destroyed at a defined date. This scenario does not allow for reuse of identifiable data in the future or sharing de-identified data.
- Public data repositories often allow for the data to be reused by anyone so this language is required if you plan to publicly deposit data.
- Modular construction of the informed consent language allows you to add or remove text to increase or decrease future data sharing possibilities. It also allows you to obtain separate consent signatures for different uses, which potentially encourages participation.
- Store documentation about the informed consent process in the same location as the data so subsequent users know what participants agreed to. Some repositories, such as NIH's BioLINCC, require consent forms to be uploaded with data deposits.

Example Text For Data Sharing and Reuse in Informed Consent

The examples below reflect the three basic approaches outlined above. These examples are meant to help researchers choose language about privacy, reuse, and sharing that is best for their circumstances. Alternatives for the privacy paragraph are also provided below and additional examples are available from the IRB.

Most Permissive – Widest Data Sharing and Reuse

> We will keep private information about you confidential to the extent allowed by laws and university policies. When researchers publicly discuss or publish the results of this research, they will not tell anyone that you were in the study. However, government or university officials who are responsible for monitoring this study and journal staff who review the research results for accuracy may see information that identifies you, including your signed consent form.
>
> If you give us your permission, we will use or share data from this study and your personal information [and "type of biological specimen" sample] for use in future research studies. We will not ask for your additional informed consent for these studies. The future research may be done here or at another place. The research may be similar to this study or completely different. To use your information future researchers must agree to follow the same laws and policies to protect your private information. They will not tell anyone that you were in their study. If you allow us to use or share your personal information for future studies, you can change your mind later and ask us to remove it. However, please keep in mind that we cannot take back information that other researchers have already used.
>
> We will submit data from this study to a public access repository [and sample repository for biological specimens]. All private information that could identify you will be removed or changed before data [or samples] are put in a public repository. Anyone can use information from a public access repository for any purpose.
>
> *(Flesch-Kincaid Reading level = 11.8)*
>
> *Pros:* This consent allows for future research, including reuse of identifiable data, by the original research team and by others as long as they agree to maintain confidentiality. It also acknowledges that others may need access to check research results and accounts for public dissemination of a de-identified dataset. This level of data sharing is consistent with many funder and publisher expectations.
>
> *Cons:* For highly sensitive research topics, this consent may seem too risky to participants.

Moderately Permissive – Data Sharing and Reuse Only of De-identified Data

We will keep private information about you confidential to the extent allowed by laws and university policies. When the researchers publicly discuss or publish the results of this research, they will not tell anyone that you were in the study. However, government or university officials who are responsible for monitoring this study and journal staff who review the research results for accuracy may see information that identifies you, including your signed consent form.

We will submit data from this study to a public access repository [and sample repository for biological specimens]. All private information that could identify you will be removed or changed before data [or samples] are put in a public repository. Anyone can use information from a public access repository.

(Flesch-Kincaid Reading level = 14.7)

Pros: This consent allows for future research, including reuse of identifiable data, by the original research team and by others as long as they agree to maintain confidentiality. It also acknowledges that others may need access to check research results.

Cons: For highly sensitive research topics, this consent may seem too risky to participants. This is essentially "on request" data sharing, which may or may not be accepted by your research funder or the journals in which you wish to publish.

Least Permissive – No Data Sharing and No Reuse

We will keep private information about you confidential to the extent allowed by laws and university policies. When the researchers publicly discuss or publish the results of this research, they will not tell anyone that you were in the study. However, Government or university officials who are responsible for monitoring this study may see information that identifies you including your signed consent form.

(Flesch-Kincaid Reading level = 13.8)

Pros: This consent is as restrictive as possible while still being truthful in terms of who might need to access personal information. For highly sensitive research topics, this example may seem the least "risky" of the three examples.

Cons: This consent does not allow the data to be used for future research outside of the original IRB protocol (by anyone, including the original research team). If it does not meet your obligations to your funder, you may be out of compliance. You will not be able to publish in journals where underlying data must be made available, either by default or because of an editorial inquiry.

Alternative Privacy Language for the First Paragraph in the Above Examples

> Alternative #1 We will use all reasonable efforts to keep your personal information confidential, but we cannot guarantee absolute confidentiality. When the researchers publicly discuss or publish the results of this research, they will not tell anyone that you were in the study. But, when required by law or university policy, identifying information (including your signed consent form) may be viewed or copied by: a) The Institutional Review Board that approves research studies; b) The Office for Protection of Research Subjects and other university departments that oversee human subjects research; c) internal and external auditors responsible for oversight of research; d) Federal agencies with some regulatory authority, such as the Office of Human Research Protections in the U.S. Department of Health and Human Services; e) [Funder's Name], the funder of this research; or f) journals in which study results are published.
>
> *(Flesch-Kincaid Reading level = 16.6)*

or

> Alternative #2 The information in this study will be used only for research purposes and in ways that will not reveal who you are. Any information that could identify you will be removed or changed before files are shared with other researchers or before results are made public. However, federal or state laws may require us to show information about you to university or government officials or sponsors who are responsible for monitoring this study. Similarly, journal policies may require us to show information about you to journal staff so that they can review the research data for accuracy.
>
> *(Flesch-Kincaid Reading level = 13.9)*

Models for Documenting Informed Consent to provide flexibility for participants

Not all participants will be comfortable with consent that allows for data sharing. Separating consent signatures from the different components privacy and sharing or completely separating components into different protocols of may increase participant comfort.

> **Model 1: One Protocol, One Consent Document**
> Consent to participate and sharing permission are integrated into one all-inclusive consent document. The consent form language such as *"As a research participant in this study, you consent to the use of your data for this study and future research by others."* or having participants initial in two places where they agree to: 1) use of their data for the study; and 2) use of their data for future studies." are options.
>
> **Model 2: One Protocol, Two Consent Documents**
> Consent to participate and permission to share data are considered completely separate choices and are recorded via separate signatures that are part of one research protocol.

Model 3: Two Protocols, Two Consent Documents
Permission to share data is the focus of a completely separate IRB protocol that covers multiple projects. Participants consent to participate in research via one protocol and share data in another, where the latter protocol specifies the type of data (e.g., identifiable) and any consequences that may result from sharing the data.

Tips for Informed Consent Language That Anticipates Sharing/Reuse

Include when anticipating future sharing or reuse:

- What identifying information will be retained
- Who will have access to identifying information
- That all reasonable efforts will be made to keep personal information confidential and provide exceptions (e.g., to the extent of the law)
- The conditions under which access to the data may be granted to others. For example, sensitive data can be safely shared through mediated/controlled access, specific user agreements, de-identification and custom approval by the original research team (e.g., by publication)
- How the data will be shared
- How data will be de-identified in practice (e.g., by removing all personal information that could directly identify an individual)
- How data will be anonymized, aggregated, or de-aggregatedIf desired, include provisions to allow data reuse in future research
- The participants' right to withdraw and how to do so
- When possible, aim to increase future flexibly by obtaining participants' consent to wider and more public data sharing

Avoid when anticipating future sharing or reuse:

- Terms such as 'fully anonymous' or 'strictly confidential' as they are often open to interpretation and impossible to achieve
- Terms used inconsistently or vaguely, such as "your data," "your study information," "all information collected about you," or "study results"
- Inadvertently implying that the research study or the participant's consent is time-limited
- Promises that the data will only be seen or accessed by the research team
- Language that mentions data will be secured in vague terms
- Language that neglects identifying how personal data may be re-identified through association with other data sets

Further Reading and Sources

Gilmore RO, Kennedy JL, Adolph KE. "Practical Solutions for Sharing Data and Materials From Psychological Research." *Advances in Methods and Practices in Psychological Science* (2018): 121-130. doi:10.1177/2515245917746500

Meyer, MN. “Practical Tips for Ethical Data Sharing.” *Advances in Methods and Practices in Psychological Science* (2018): 131 - 144. doi:10.1177/2515245917747656

Hunt S, Hofelich MA, Woodbrook, R. “Consent Forms Data Curation Primer. Data Curation Network” *University of Minnesota Digital Conservancy* (2020) https://hdl.handle.net/11299/218838

Utrecht University “Informed Consent for Data Sharing” https://www.uu.nl/en/research/research-data-management/guides/informed-consent-for-data-sharing

Inter-university Consortium for Political and Social Research (ICPSR) "Recommended Informed Consent Language for Data Sharing" https://www.icpsr.umich.edu/web/pages/datamanagement/confidentiality/conf-language.html

University of Michigan “IRB-HSBS General Informed Consent Template” https://research-compliance.umich.edu/new-irb-hsbs-general-informed-consent-template

Document History

Version	Date	Action	Authors
1	2022-01-24	Document created	Anita Balgopal (OPRS), Patty Jones (Beckman), Heidi Imker (RDS), Jan Novakoski (OVCRI), Phil Reiter (Privacy), Julie Robinson (SPA), Svetlana Vranic-Sowers (OTM)