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Columbia University Irving Medical Center Response to:

NIH Request for Information: Developing Consent Language for Future Use of Data and Biospecimens
Notice Number: NOT-OD-21-131

Submitted on behalf of:

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III. General Points to Consider:

- Data and biospecimens may involve distinct storage and/or sharing procedures. Some protocols may require separate consent language to inform how data versus biospecimens are stored and shared.

- Those responsible for study conduct and oversight are encouraged to consider the reading level of the entire informed consent form, with the goal of creating understandable language that conveys the necessary information. The sample language in this resource was crafted to ensure an appropriate reading level (with a goal of ~8th grade reading level or below). Additional resources on evaluating readability can be found from the National Cancer Institute (NCI).

- 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, or research with pregnant women, fetuses or neonates may require additional considerations regarding the storage and sharing of data and biospecimens. Those responsible for study conduct and oversight are encouraged to revise the sample language to reflect these considerations. We strongly encourage consultation with the appropriate contacts to determine and take into consideration the applicable regulations, policies, and laws relevant to studies involving these populations, including assent for participants under 18, prior to storage and sharing of data and biospecimens.
    - *Also consider plans for recontact at age of majority and plan for biospecimen and/or data destruction if efforts to recontact are not successful. Language in the parental permission form should address this.*

- Some cultural/donor/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/regulations/policies governing research that may impact the storage and sharing of data and biospecimens. We strongly encourage 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. We recommend that those responsible for study conduct and oversight 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.
    - *Consider adding language about genomic data sharing with NIH, for example:*
        - *"We may share your coded samples, DNA research information, health information, and results from research with other central tissue or data banks,*

such as those sponsored by the National Institutes of Health (NIH), so that researchers from around the world can use them to study many conditions. These central banks may store samples and results from research done using the Columbia University Biobank-NYP samples and health information. The central banks may share these samples or information with other qualified and approved researchers to do more studies. We will not give central banks your name or any other information that could directly identify you. There are many safeguards in place at these banks to protect your privacy."

- *If the future use of data and biospecimens will be limited, this information should be specified in the consent language.*
- *As technology advances for coding and deidentifying data and biospecimens, consider the implications for privacy and confidentiality and adjust language as appropriate.*
- *Consider the challenge of maintaining contact information and implementing periodic outreach to remind participants to provide changes to the biobank.*
- *It is important for the protocol and consent documents to be consistent with respect to storage and future use.*
- *Instructions for revoking or otherwise revising decisions should be explicit and flexible in terms of offering multiple modalities.*
- *The protocol and consent form should describe:*
    - *what will happen to data and samples if the biobank ceases to operate under the current leadership;*
    - *who can use the data and samples;*
    - *that consent/permission is being provided only for use of deidentified or coded samples for which the recipients will not have access to the key to the code, i.e., that this is not 'broad consent' for any and all future use of identifiable data or samples;*
    - *that recipients will need to sign an agreement stating terms of use (e.g., will not try to re-identify, will notify biobank if identity is inadvertently discovered, will not contact donors if identity is discovered);*
    - *when participants will be contacted for future use, e.g., if identifiable use of data or samples is proposed;*
    - *if there are limits to use of data or samples.*
- *The consent form should include:*
    - *a statement that the donor will not have any input or control over the types of studies for which the deidentified or coded (no key) data or samples are used;*
    - *a statement as to the possibility that data from research that uses the material may be uploaded without identifiers to repositories for other researchers to use.*

IV. Sample Language Components:

Component 1: Introduction - Description

Considerations for those responsible for study conduct and oversight: The Introduction-Description component is meant to provide prospective research participants with an introduction to, and description of the storage and sharing of data and biospecimens in the study.

- If participants may be re-contacted to collect new or replacement data or biospecimens, include language to address re-contacting.

- Those responsible for study conduct and oversight will need to consider the appropriate timeframe for data and biospecimen storage based on their study and anticipated uses. For some, the appropriate timeframe may be indefinite, while others may have a clear, limited timeframe.

Instructions for those responsible for study conduct and oversight: See sample language below for the Introduction-Description component. If using this sample language, include the first three paragraphs then choose either Option #1 or Option #2. Replace embedded instructions identified in **[bold, bracketed text]** with specific information pertaining to the study and remove **[Option #1 and #2 text]**.

Sample Language:

This study is collecting data and biospecimens from and/or about 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 aspects of health. These studies may be done by researchers at other institutions, including commercial entities. Our goal is to make more research possible to learn about health and disease.

Your data and biospecimens will be stored **[indicate the name of the institution where they will be stored, including any biobanks to be utilized] until/unless they are shared**. *We plan to keep your data and biospecimens for* **[indicate time frame or "indefinitely," or until "used completely," etc.]**.

Access to the data and biospecimens is controlled by **[indicate which entity has control].** *Your data and biospecimens may be shared without direct identifiers such as your name with investigators around the world. To use your data and biospecimens, researchers must get approval [from whom/what] and they must agree not to try to identify you.*

[Option #1: If the data/biospecimens are coded and can be linked back to the participant]

We will protect the confidentiality of your information to the extent possible. Your name and other identifying information will not be on any data and biospecimens you provide. The data and biospecimens will have a code that links to your identifying information. The code key will be kept at [indicate which entity has control] in a locked location separate from your information. The code key can only be accessed by people who have permission from [indicate which entity has control].

[Option #2: If the data and biospecimens are completely delinked from identifiers and cannot be linked back to the participant]

Your name and identifying information will not be on any data and biospecimens you provide. Investigators cannot link your identifying information to the data and biospecimens.

Component 2: Voluntary Participation

Considerations: The Voluntary Participation component informs prospective research participants about the voluntary nature of data and biospecimen storage and sharing.

- In general, participants should be given the option to agree to, or opt out of, having their data and biospecimens stored and shared for future research. Providing options for participants to agree to, or opt out of, having their data and biospecimens stored and shared is particularly important in studies that offer the prospect of direct benefit to the participant. Mandating agreement to storage and sharing may be considered coercive if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway in order to join a possibly beneficial clinical trial. If the research protocol offers no prospect of direct benefit, then it may be reasonable for storage and sharing not to be optional.

- If the protocol is a repository protocol with the sole intent of collecting data and/or biospecimens for future use, no opt out mechanism is necessary.

Instructions: Choose either Option #1 or Option #2. Remove **[Option#1 and #2 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, but your data and biospecimens might still be used if they have already been shared. If you say "no," you can still fully participate in this study. Please initial and date next to your choice:

_____YES, *use my data and biospecimens in other research studies ____Date*

_____NO, do NOT use *my data and biospecimens in other research studies ___Date*

[Option #2: When sharing of data and biospecimens will not be optional (e.g., for studies 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 may still use your data and biospecimens that have already been shared. If you do not want your data and biospecimens used for other projects, you should not participate in this study.

Component 3: Discontinuation/Withdrawal

Considerations: The Discontinuation/Withdrawal component describes what will happen if the participant changes their mind about storage and sharing.

Instructions: Adjust language as necessary.

Sample Language:

You can change your mind about sharing your data and biospecimens at any time. If you change your mind, please contact the study team to let us know. We will not share your data and biospecimens going forward. We will do our best to retrieve all your data and biospecimens that have already been shared, but it may not be possible. For example, if some research with your data and biospecimens has already been done, the information from that research may still be used. We will not know which data and biospecimens are yours if the identifying information

was removed. Also, if the data and biospecimens have been shared already with other researchers, it might not be possible to get them back.

Component 4: Risks & Benefits

General Considerations: The Risks & Benefits component describes the reasonably foreseeable risks/discomforts related to storage and sharing of data and biospecimens, and any benefits related to storage and sharing of data and biospecimens that prospective participants may receive.

Considerations - Risks: If identifying information (e.g., key to the code) will remain with the data and biospecimens during storage and sharing, include language that addresses the additional measures designed to safeguard participants' privacy (e.g., access controls).

- Ensure that the safeguards listed are consistent with language addressing the storage and sharing of data and biospecimens in the introduction.

- 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.
- *Include a statement that a breach could occur despite best efforts but the risk is very low due to the precautions that are in place. [The IRB should confirm that plans in the protocol are sufficiently robust to safeguard the data.]*

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

Sample Language:

[**Risks**] *When we share your data and biospecimens, there is a small risk that people may get access to it who are not supposed to. We will protect your data and biospecimens as much as possible during storage and when they are shared. However, there is a small chance your identity could be discovered.*

[**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 helps others in the future.*

Component 5: 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.