Additional Comments from The Center for HIV Law & Policy, Positive Women's Network-USA, and The US People Living with HIV Caucus regarding NIH's Request for Information: Developing Consent Language for Future Use of Data and Biospecimens

As advocates and people living with HIV (PLHIV), we are writing to express our continued support for recommendations from NIH that recognize the vital importance of informed consent and clear communication on the potential risks posed to participants in biomedical and public health research, for every subsequent use beyond that for which the data was originally collected. We believe, for example, that use of personal medical data, including test results, that are collected by public or private health care providers in the course of an individual's health care can only be used for other purposes unrelated to the individual's health if the provider has secured the person's written informed consent.

The informed consent of biomedical and public health research participants is what forms the bedrock of legitimacy for all forms of research where the lives, biospecimens, and trust of people who are studied are at stake. NIH's request for information (RFI) represents an effort to ensure that public health and biomedical research remain legitimate, safe, ethical, and fully respect the bodily autonomy and dignity of patients and participants.

This RFI comes at a time when the COVID-19 pandemic has shed a light on persistent issues in our public health data infrastructure and data sharing practices. While governmental and private sector groups are responding to recent scrutiny about public health research technologies, we have not yet laid the groundwork for encouraging trust in public health research.

The COVID-19 pandemic may have ignited conversations on issues related to the bodily autonomy and informed consent of public health research participants, but our organizations and networks have raised the alarm about risks for years. More specifically, the use of the personal health information of people living with HIV for identifying clusters or networks of sexual contacts (molecular HIV surveillance or MHS) has blurred—even crossed—the line between routine tracking of HIV incidence and prevalence with research. Our issue is not with MHS, but with the failure to inform and secure the consent of those persons whose sensitive health data is being used for other purposes, regardless of the larger societal benefits. Consequently, we need brighter lines and clear guidelines that make plain the difference between surveillance and research.

Using data collected in the context of delivering direct care for other purposes without notice and the informed consent of the subject perpetuates medical mistrust and disrupts public health goals

In any guidance on informed consent for data and biospecimen use and sharing, it must be clear that the use of personal data collected in the course of health care services for purposes other than patient care *is research*, and subject to informed consent requirements.[1] An important example of this is the increasing use of individual HIV care data to identify sexual contact clusters in particular communities.

In 2017, the Center for Disease Control and Prevention (CDC) announced a new, five-year program that required state health departments to collect and share molecular HIV testing-related data in exchange for funding through a program called PS18-1802. The program announcement stated that this federal program would strengthen "high-impact HIV prevention" activities by "further allowing health departments to align resources to better match the geographic burden of HIV infections within their jurisdictions and improve data collection and use for public health action."[2] The PS18-1802 amounted to a massive expansion of the same surveillance method and technology used when 27 local jurisdictions shared HIV-testing related data with CDC between 2013 and 2017.[3] While trusted, traditional public health surveillance methods relied on partner notification and contact tracing, CDC assured applicants that this funding opportunity would enhance the monitoring capabilities to track how HIV spreads through a community.

All state health departments seeking prevention funding from CDC were asked to "systematically collect, analyze, interpret, and disseminate HIV data to characterize trends in HIV infection," making the implementation of public health action, including providing treatment and prevention services, more efficient. This HIV prevention and surveillance strategy has come to be known as molecular HIV surveillance (MHS), and ever since the announcement of the PS18-1802 program, PLHIV networks and organizations working in public health and legal advocacy have organized together to share their concerns in a variety of forums.[4]

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[1] D. German, M.K. Grabowski, C. Beryer, *Enhanced use of phylogenetic data to inform public health approaches to HIV among men who have sex with men*, 14 Sexual Heath 89-96 (2017).

[2] *See* "Funding Opportunity Announcement (FOA) PS18-1802: Integrated Human Immunodeficiency Virus (HIV) Surveillance and Prevention Programs for Health Departments" (https://www.cdc.gov/hiv/funding/announcements/ps18-1802/index.html).

[3] Evans, D., and N. D. Benbow, *Ethical considerations for a public health response using molecular HIV surveillance data* (2017), p. 9 (https://www.cdc.gov/hiv/pdf/programresources/guidance/cluster-outbreak/cdc-hiv-Ethical-Considerations-Report.pdf).

[4] *See* Center for HIV Law & Policy, "Is Molecular HIV Surveillance Worth the Risk?" (https://www.hivlawandpolicy.org/sites/default/files/CHLP%20Molecular%20Surveillance%20Final_0.pdf) Positive Women's Network-USA, "Ending the Epidemic Requires Consent & Community Leadership," (https://www.pwn-usa.org/wp-content/uploads/2019/09/ETE-one-pager-v2.pdf,) Ohio Health Modernization Movement, "HIV Molecular Surveillance and Ohio" (https://youtu.be/UU2UNMY7xqg) and Edwin J. Bernard et al, "We Are People, Not Clusters!" *The American Journal of Bioethics* 20:10, 1-4 (https://www.tandfonline.com/doi/pdf/10.1080/15265161.2020.1809550?needAccess=true).

A significant issue we have raised is about the methods from which MHS data is collected and how it influences related public health analysis and research. This effort on behalf of NIH to make all relevant information available to biomedical and public health research participants and develop informed consent language is critically related to this issue.

Once an individual has been diagnosed with HIV their medical provider determines and prescribes a specialized treatment regimen based on an analysis of their unique viral profile. This exchange, between patient and medical provider, is one conducted for the purposes of delivering direct care for a patient, but now also involves the use of individualized medical data for public health analysis and research without any of the patient protections required for research. In fact, with the CDC's encouragement, "[current] practices … exempt nearly all uses of HIV surveillance data from consent requirements."[5] How can we hold on to the values of patient-centered care and informed consent for public health research when patients do not have the option to opt-out of sharing their viral sequence for molecular surveillance?[6] Similarly, how are state and local health departments communicating the implications of drug-resistance testing for patients living with HIV?[7]

Despite assurances from CDC that adjustments to the MHS program have been made following community feedback, concerns remain widespread and directly threaten many of the public health goals we share including ending the HIV epidemic and its syndemics. Most importantly, none of these adjustments include a requirement that individual patients receive notice of the planned use, the possible risks, and an opportunity to consent or to opt out of this research program.

Patients affected by HIV, who are confronted by barriers to healthcare, face discrimination in medical settings, and who are targeted for uniquely harsh criminal punishment have cause for alarm and believe their private health data is weaponized against them. There is fear among people living with stigmatized diseases and disabilities about being identified and treated as vectors of disease, rather than welcomed as human beings with dignity. The treatment of people living with HIV solely as vectors of disease is a part of how deeply HIV and STI stigma are embedded in society. The fact that their private medical data is used—without their knowledge or consent—to guide public health activities deepens medical mistrust in ways for which it is

[5] Stephen Molldrem and Anthony K. J. Smith, "Reassessing the Ethics of Molecular HIV Surveillance in the Era of Cluster Detection and Response: Toward HIV Data Justice," *The American Journal of Bioethics* 20:10 (2020), p. 15 (https://www.tandfonline.com/doi/pdf/10.1080/15265161.2020.1806373?needAccess=true).

[6] Ibid.

[7] After an initial round of community feedback following the announcement of PS18-1802, CDC revised their guidance to ensure the "ethical implementation" of their program. CDC urged all funded jurisdictions to complete "community engagement" by December 2019 to raise awareness about sharing HIV-related data between state and local health departments and "adapt" to concerns shared by PLHIV. Little evidence surfaced on whether and how state and local health departments were engaging people directly affected by MHS, let alone those whose fears ran deepest, or how agencies would invest and build their work on the informed consent of participants. The revised CDC guidance on the ethical implementation of MHS also directed states to assess the implications of HIV criminal laws on HIV prevention, but provided no incentives for agencies to do so, leaving what should be essential analysis entirely optional.

difficult to fully account. Further, some officials in public health have questioned the public health rationale of mapping the social and sexual networks of PLHIV as a productive use of scarce resources.[8] However, it is clear that building trust and mutual decision-making between healthcare providers and PLHIV lies at the foundation of any public health or biomedical research from which personal and private information is used.[9]

Trust in biomedical and public health research is only possible if participants are fully informed and their right to privacy and autonomy is protected prior to any subsequent use of their personal health data.

Informed consent from research participants built on an open dialogue between professionals delivering direct care and their patients is a crucial building block for the legitimacy of public health research. That is no less the case when the subjects of public health research face deep-rooted stigma in every aspect of their lives—stigma that is fed by hostile and invasive public health interventions, criminalization, harmful media representation, and a reluctance on behalf of medical staff to have simple conversations with the patients they're sworn to protect.[10]

Informed consent is essential, but is not the only threshold from which we may judge whether biomedical or public health research fully accounts for all the risks that participants must consider. Faith in public health surveillance, analysis, and research can only be built on *trust*, and for there to be sufficient trust between patients and their medical providers, patients must be shielded by robust protections that are not currently in place. Among experts in bioethics, epidemiology, virology, and public health, one of the most-raised concerns about the implementation of MHS has been a full evaluation of risks posed to their subjects.[11] Unfortunately, public health professionals have prioritized the use and misuse of medical data from PLHIV rather than seek consultation from the communities affected or investing in sufficient protections for patients.[12]

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[8] The Center for HIV Law & Policy, "Webinar: Is HIV Molecular Surveillance Worth the Risk?" (https://www.hivlawandpolicy.org/news/webinar-hiv-molecular-surveillance-worth-risk)(referencing statements of Andrew Gans, HIV, STD and Hepatitis Section Manager of the New Mexico Department of Health.

[9] Hargraves, I., A. LeBlanc, N. D. Shah, and V. M. Montori, "Shared Decision Making: The Need For Patient-Clinician Conversation, Not Just Information," *Health Affairs (Project Hope)* 35(4): 627–629 (https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2015.1354).

[10] *See* GLAAD and the Southern AIDS Coalition, "2021 State of HIV Stigma: A Study" (https://www.glaad.org/sites/default/files/HIV-StigmaStudy_2021_081621%20%281%29.pdf); *Axios*, "LGBTQ patients report bad experiences with health care providers" (https://www.axios.com/lgbtq-health-care-doctors-bad-experiences-118ce16a-5094-4aa1-bd01-d58bfd0630e0.html); *and The New York Times*, "Gay and Transgender Patients to Doctors: We'll Tell. Just Ask." (https://www.nytimes.com/2017/05/29/health/lgbt-patients-doctors.html).

[11] Mutenherwa, F., D. R. Wassenaar, and T. de Oliveira, "Experts' perspectives on key ethical issues associated with HIV phylogenetics as applied in HIV transmission dynamics research," *Journal of Empirical Research on Human Research Ethics* 14(1): 61–77 (https://journals.sagepub.com/doi/pdf/10.1177/1556264618809608).

[12] *See* Bryn Nelson, "Questioning the Benefits of Molecular Surveillance," *Poz* (https://www.poz.com/article/questioning-benefits-molecular-surveillance).

The use of HIV-testing related data without notice and consent is of particular concern because of the continuing and significant criminalization of people living with HIV, coupled with the 2018 NASTAD study finding that state and local health department policies on sharing information with law enforcement can vary widely, leaving discretion to individual departments.[13] That is an unacceptable reality of the current implementation of MHS. Without uniform and concrete protections that shield law and immigration enforcement from accessing private medical information, it is impossible to conceive of any ethical or safe subsequent use of this kind of identifiable medical data in the absence of informed consent. This issue must be addressed by federal agencies who can and should incentivize states to create firewalls between public health information and law and immigration enforcement, preventing the dangerous weaponization of HIV-testing related data.

The de-identification of medical data is not reliable protection

CDC has also suggested that there's "little privacy risk" from the harms associated with mapping social and sexual networks based on analyses of HIV-testing related data because the data that's reported across jurisdictions is "de-identified."[14] However, there are a series of studies showing that data de-identification does not sufficiently protect the privacy and security of medical data. In 2010, Mark A. Rothstein published an article in the *American Journal of Bioethics*, uncovering how easy it was to reconstruct identifiers from de-identified data:

> Despite using various measures to de-identify health records, it is possible to re-identify them in a surprisingly large number of cases by using computerized network databases containing voter registration records, hospital discharge records, commercially available databases, and other sources (Malin and Sweeney 2004; Sweeney 2002). Indeed, it is likely that between 63% (Golle 2006) and 87% (Sweeney 2000) of the population of the United States could be uniquely identified by using only gender, ZIP code, and date of birth.[15]

In 2018 researchers were able to re-identify anonymized patient records from hospital data using names from local news stories and articles.[16] At a time when law enforcement department resources and funding continues to swell to unsettling levels, it is reasonable to suppose they have the tools they would need to build the simple databases necessary to re-identify de-identified medical data. In fact, the dangerous mission creep of law enforcement into areas of public health is already underway, which could be acutely seen when 52 West New York

[13] *See* NASTAD, "HIV Data Privacy and Confidentiality Legal & Ethical Considerations for Health Department Data Sharing" (https://www.nastad.org/sites/default/files/Uploads/2018/nastad-hiv-data-privacy-06062018.pdf).
[14] Kempner, "CDC Explains and Defends Molecular Surveillance System."
[15] Mark A. Rothstein, "Is Deidentification Sufficient to Protect Health Privacy in Research?" *American Journal of Bioethics* Vol. 10: 9, (2010) pp. 3-11 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3032399/pdf/nihms-264889.pdf).
[16] Ji Su Yoo, Alex, ra Thaler, Latanya Sweeney, and Jinyan Zang, "Risks to Patient Privacy: A Re-identification of Patients in Maine and Vermont Statewide Hospital Data," *Technology Science* 2018100901(https://techscience.org/a/2018100901/).

sheriff's department members were deputized as COVID-19 contact tracers.[17] The Health Information Technology Advisory Committee's (HITAC) Public Health Data Systems Task Force was charged by the Office of the National Coordinator for Health Information Technology to review our public health data systems and share recommendations to address related issues. Their recent report contained a recommendation that "ONC should collaborate with CDC to support policies that facilitate data sharing without data use for discriminatory purposes and ensure the appropriate level of access is provided to each level ... of public health authority.[18] However, this recommendation fails to fully address the risks posed to participants with stigmatized and criminalized health conditions.

NIH's goal to share relevant information with the research participants from whom they obtain identifiable and intimate information must also sufficiently communicate all potential risks to patients prior to securing consent for further use of their data. NIH's effort to create the best consent practices for biomedical and public health research must also:

- Clearly communicate the meaning and purposes of public health research such as MHS, and individuals have the right to opt out of subsequent use of their identifiable health data. Share with participants that law and immigration enforcement can obtain private medical records without a court order and in some jurisdictions, state health department staff may even cooperate in criminal prosecutions against them.
- Disclose to patients that since 1997 researchers have repeatedly shown that de-identified patient records can be combined with other data sources, potentially re-identifying their de-identified data, which raises the risk that their information can be used against them in the event of a data security breach.

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[17] Andy Young, "WNY Rushes To Meet Contact Tracer Requirement After Confusion," Spectrum News (https://spectrumlocalnews.com/nys/buffalo/news/2020/05/18/wny-rushes-to-meet-contact-tracer-requirement-after-confusion)
[18] Final Report of the Health Information Technology Advisory Committee's (HITAC) Public Health Data Systems Task Force, p. 17 (https://www.healthit.gov/sites/default/files/page/2021-08/2021-07-14_PHDS_TF_2021_HITAC%20Recommendations%20Report_Signed_508_0.pdf).

Consent for Data and Biospecimen Sharing for Future Use: Points to Consider and Sample Language

I. Introduction:

As a steward of the nation's biomedical research enterprise, NIH is dedicated to ensuring that when data and biospecimens are shared, that it is done ethically and securely, and with respect for the privacy, autonomy, and well-being of research participants and the communities to which they belong. As part of this commitment, NIH is working with stakeholders to identify best practices for developing and implementing effective consent practices to inform prospective research participants about potential risks and benefits of data and biospecimen sharing for future research. The following resource outlines suggested points to consider when addressing data and biospecimen storage and sharing in consent language and provides supplemental sample language that could be modified as needed when constructing informed consent forms. Of note, the sample language provided below is intended to serve as a helpful resource and is not a substitute for addressing federal, state, local, or tribal requirements that may apply to informed consent. 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 meant to supplement informed consent forms for research studies that include the storage and sharing of data and biospecimens. This resource is neither a linear nor comprehensive consent template. Additionally, the sample language does not address all possible scenarios for which informed consent may be needed for data and biospecimen storage and sharing. The sample language will need to be tailored to institutional and study specific requirements. It is the responsibility of investigators and institutional review boards (IRBs) to determine the appropriate use of the sample language including which components, if any, are relevant to a specific study's informed consent and the most appropriate section to incorporate the sample language within when doing so (e.g., the risks of storage and sharing may be included in the study's informed consent "risk" section or in another appropriate section). Not all of the components will be appropriate for every informed consent form. Investigators should carefully select language appropriate for the study, and IRBs should ensure that the proposed language meets all applicable regulatory and policy requirements, including federal, state, local, and tribal requirements.

Documented informed consent is necessary for research involving the use of identifiable health data. However, u***se of this sample language is completely voluntary.*** This language is being provided as a resource for the research community and there are no requirements that any portion of the language be used in an informed consent form for an NIH-supported or -conducted study as long as the essential elements of informed consent are met.

This resource consistently refers to "data and biospecimens" as a means to capture all identifiable information and biospecimens that research participants may contribute as part of a research study. "Data and biospecimens" includes information collected from, or about a research participant during the course of a primary study or health care service (e.g., surveys, medical images, electronic health records, wearable device information) as well as human material (e.g., blood, tissue, urine, extracted DNA).

Some sample language includes embedded instructions to fill in specific information pertaining to the research study. These embedded instructions are identified in **[bold, bracketed text]** and will need to be replaced after study-specific language is inserted or removed entirely based on the instructions provided.

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 or criminal legal processes,[19] such as children, prisoners, individuals with impaired decision-making capacity, ~~or~~ economically or educationally disadvantaged persons, or persons from over-policed communities, 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.
- 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.
- 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 de-identifying data and biospecimens, consider the implications for privacy and confidentiality and adjust language as appropriate.

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

[19] D. German, M.K. Grabowski, C. Beryer, Enhanced use of phylogenetic data to inform public health approaches to HIV among men who have sex with men, 14 Sexual Heath at 92 (2017).

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:

We are ~~*This study is*~~ *collecting data and biospecimens from you that can be used for a research study. We also 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. However, you have the right to opt out of the use of your data for additional studies. If you consent to additional use of your personal data and biospecimens, you have the right to be informed of each additional research use in advance, and to opt out off further sharing of your data.*

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

Your data and biospecimens may be shared with investigators around the world. However, access to the data and biospecimens is controlled by **[indicate which entity has control].** *To use your data and biospecimens, researchers must get approval 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 in a locked location separate from your information. The code key can only be accessed by people who have permission. You have a right to know who will have access to your personal information, and the purposes for which it will be used.

[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 current or 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 or is a member of a community or group that is at higher risk of coercion or social risk but feels compelled to agree anyway in order to join a possibly beneficial clinical trial. Even ifthe research protocol offers no prospect of direct benefit, it is still reasonable for storage and sharing t to be optional if unanticipated sharing of identifiable data poses any risk of adverse consequences to the participant.
- 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~~ use your personal data or to 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 next to your choice:

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

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

_____ *NO, do NOT use my data and biospecimens in any research studies*

[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 without your knowledge, you should not participate in this study.

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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.

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 or government agencies 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. This includes government and law enforcement agencies that demand access to identifiable health data in the possession of public health providers and researchers.*

[**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.