Frequently Asked Questions related to

Human-Derived Data & NIH's Data Management & Sharing Policy

Q: Are there any resources available to develop consent form language related to data sharing?
A. The JHU IRBs have consent templates available on their respective websites that include language related to data sharing. Notably sharing via open access is not a part of standard consent template language and must be explicitly included in any consent forms for studies that plan to share via open access.

JHU Consent Templates:

- JHM IRB Combined Informed Consent/HIPAA Authorization Template (December 2018, Version 16)
- BSPH Consent Forms: https://publichealth.jhu.edu/offices-and-services/institutional-review-board-irb/forms/revised-common-rule-forms
- Homewood IRB Written Consent Form Template: https://homewoodirb.jhu.edu/files/2019/04/FINAL_Informed-Consent_Template_04.30.19.docx

In addition, NIH has developed a guidance related to informed consent to assist researchers in addressing the requirements of NIH's Data Management & Sharing Policy. See: Informed Consent Resource for Secondary Research with Data and Biospecimens. Please consider your specific data sharing plan and make any appropriate edits to the template language.

Q: Are there any specific requirements for data management and sharing plans for human-derived data?
A. Yes. The NIH Policy requires that the plan specify whether external access to scientific data derived from humans will be controlled and if so, how. Data sharing and management plans must also describe any applicable factors affecting subsequent access, distribution, or reuse of scientific data including any **informed consent or privacy/confidentiality limiters.** Examples of limiters may be limiters imposed by the research consent, HIPAA requirements or any agreements with third parties about future use of the data.

Q: Will I be required to upload a copy of my data and management & sharing plan in my JHU IRB application?
A. Yes. For any new applications with NIH funding applied for on/after January 25, 2023, study teams must upload a copy of the Data Management & Sharing Plan submitted with the IRB application. For previously-approved studies that secure new funding applied for on/after January 25, 2023 that is subject to the Data Management & Sharing requirements, you must submit a change in research (or Amendment for the BSPH IRB) to provide a copy of the Data Management & Sharing Plan included with the grant application.

Q: Are the IRBs required to complete an institutional certification related to my data sharing plans?
A. No. Unlike the policy for genomic data sharing, which is still in effect, a process for institutional review and certification by the IRB is not required for sharing of non-genomic data.

Q: What will the IRB consider related to my data management and sharing plan?

A. The JHU IRBs will look for consistency between the proposed data sharing plan and other study documents submitted for IRB review such as:

- eIRB application (eIRB, eHIRB, PHIRST)
- Protocol
- Risk Tiers Calculator
- Informed Consent Form

The IRBs are also responsible for ensuring the plan for sharing aligns with any applicable laws related to use and sharing of human-derived data (e.g. HIPAA, FERPA) and that risks to participants are appropriately minimized through the plan as proposed.

Q: What are my options if I want to use data collected under an older consent form or where there was no consent at all?

A. If the original study consent did not specify the proposed plans for sharing, the IRB may determine it is necessary to re-consent participants to enable the sharing. If re-consent is not practicable, the IRB may determine a waiver of consent is appropriate. In order to waive consent the sharing must pose no more than minimal risks to participants. Generally where no consent was obtained for the proposed sharing, the information that may be shared will be limited and appropriate controls for the sharing will be required to ensure potential risks to participants are minimized. In cases where the original consent prohibited the sharing, data may not be shared.

Q: Is dbGaP a controlled access repository?

A: The dbGaP repository is a controlled access repository. Genomic Summary results may be made available via unrestricted access but explicit consent is required for this type of sharing.

Q: Are there minimum number of years a data set should be shared and be accessible?

A: NIH does not establish a specific length of time that data must be shared and accessible but the policy does include this information to assist researchers in developing a data management and sharing plan:

Data Preservation and Sharing Timelines: Shared scientific data should be made accessible as soon as possible, and no later than the time of an associated publication, or the end of performance period, whichever comes first. Researchers are encouraged to consider relevant requirements and expectations (e.g., data repository policies, award record retention requirements, journal policies) as guidance for the minimum time frame that scientific data should be made available, which researchers may extend. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html

Q: Do data retention requirements affect length of making data available?

A: NIH policy does contemplate that at a minimum "award record retention requirements" should be considered as guidance for the minimum time frame when data should be made available and shared.

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For example, if the retention requirements are 3 years following completion of the activity, it may be reasonable to presume data should be accessible for sharing during this time period. It is important that researchers consider all applicable record retention requirements when developing a plan. JHU IRB guidance on record retention is accessible here:
https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/record_retention.html;
https://publichealth.jhu.edu/sites/default/files/2022-05/data-retention-guidelines-9122019.pdf
https://homewoodirb.jhu.edu/files/2018/10/PP-10.26.18_clean.pdf