**Consent Addendum for Optional Data Sharing With a National Institute of Health (NIH) Data Repository Guidance and Frequently Asked Questions**

For more information:

[National Institute of Mental Health Data Archive (NDA)](https://nda.nih.gov/)

[NDA FAQs](https://nda.nih.gov/about/faq.html)

[What is the National Institutes of Health (NIH) Data Repository?](#Whatistherepository)

[How do I know if this consent addendum applies to me and my research study?](#Doesitapply)

[If I receive new NIH funding for my IRB-approved study, what should I do to add this consent addendum as a revision to my approved research application?](#RevisionRequest)

[Can I make changes to the consent addendum?](#CanIchangeit)

[Can I remove the reference to biospecimens in the “What is research data?” section or DNA sequencing in the “What is personally identifiable information?” section if they are not applicable to my study and could confuse my participants?](#CanIchangeWhatisresearchdata)

[Can I change any of the variables that will be collected for the NDA listed in the “What will happen to my research data?” section?](#CanIchangevariables)

[Is the participant data shared with the NDA identifiable?](#Isdataidentifiable)

[Can I ask my participants to share their research data with the NDA without also collecting their personally identifiable information (PII)?](#PseudoGUID)

[Can participants really remove their data from the NDA? Other NIH template language suggest that they cannot do this.](#Isdataremovable)

[If I am working with children, who should sign this consent addendum – the parent or the child?](#Workingwithchildren)

**What is the National Institutes of Health (NIH) Data Repository?**

In an effort to meet the goals of identifying the factors that influence the prevention, cause, diagnosis, and treatment of a variety of diseases and disorders, the NIH uses data repositories for long-term storage, cross-research referencing, and analysis of anonymized human subjects research data. This process gives researchers access to more data than they could collect on their own making it easier and faster for them to gather, evaluate, and share research information and results from multiple sources.

**How do I know if this consent addendum applies to me and my research study?**

If awarded a grant from NIH, a PI may be required to ask their participants to share their anonymized data with an NIH data repository. At this time, the following institutes may include this requirement:

* The Eunice Kennedy National Institute of Child Health and Human Development (NICHD)
* National Human Genome Research Institute (NHGRI)
* National Institute of Alcohol Abuse and Alcoholism (NIAAA)
* National Institute on Deafness and Other Communication Disorders (NIDCD)
* National Institute of Environmental Health Sciences (NIEHS)
* National Institute of Mental Health (NIMH)
* National Institute of Neurological Disorders and Stroke (NINDS)

**If I receive new NIH funding for my IRB-approved study, what should I do to add this consent addendum as a revision to my approved research application?**

To add this consent addendum, submit a [Revision Request Form](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#revisionform) to [IRB@brown.edu](mailto:IRB@brown.edu). Along with the Revision Request Form, you will need the consent addendum and an update to your IRB Application’s [Data Security Assessment](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/forms-and-templates#data) reflecting the collection of the new identifiable data in **Question #2**. Depending on your IRB-approved Data Security Assessment, Question #2 may be the only change necessary.

**Can I make changes to the consent addendum?**

Yes, but you may only make a change after consulting with the HRPP to ensure that the change does not affect the requirements of the NDA.

**Can I remove the reference to biospecimens in the “What is research data?” section or DNA sequencing in the “What is personally identifiable information?” section if they are not applicable to my study and could confuse my participants?**

Yes. These references are provided as examples. If including them as examples will not be helpful to your participants, you may remove them from the addendum. However, the respective sections must remain in the template, and you must include examples that are applicable and understandable to your participants.

**Can I change any of the variables that will be collected for the NDA listed in the “What will happen to my research data?” section?**

No. The variables listed in the consent addendum template are required by the NDA.

**Is the participant data shared with the NDA identifiable?**

No. All participant identifiers are removed by the NIH before the data is added to the NDA to protect the confidentiality of participants.

**Can I ask my participants to share their research data with the NDA without also collecting their personally identifiable information (PII)?**

Yes. You can ask you participants to share their data with the NDA without collecting their PII by creating a “pseudo-GUID” for them. Participants *are not required* to share any PII with you unless they want to have their research data linked across multiple studies.

Brown has written documentation from the NIH that a GUID created with PII and a pseudo-GUID created without any identifiers should be treated by researchers and are treated by the NIH exactly the same. This means that any code you create for use as a pseudo-GUID must follow the requirements of the NDA by:

* remaining linked to a single participant,
* maintaining that link for the life of your study,
* using that pseudo-GUID to share data about the participant with the NDA, and
* allowing the participant the ability to withdraw any unshared data from the NDA at any time.

**Can participants really remove their data from the NDA? Other NIH template language suggest that they cannot do this.**

Yes. The Policy for the NDA (in the “Removal of Participant’s Consent to Share” section) confirms that participants can withdraw their data at any time from the NDA. However, any data from the NDA that has already been shared with other researchers cannot be retracted, as Brown’s consent addendum states.

**If I am working with children, who should sign this consent addendum – the parent or the child?**

The consent addendum should be included as part of the parent [permission](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#permission) process, but whether you also include it in the [assent](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#assent) process depends on the age and [decisional capacity](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#decisional) of your child participants.

Brown has written documentation from the NIH that the NDA leaves the process of collecting and documenting parent permission and child assent, as applicable, for a child to share their research data and PII in order to create a GUID up to each IRB and research institution’s policies.