NIH Grants and the IRB

This guidance provides information for National Institutes of Health (NIH) grant applications and awards. When applying for an NIH grant, it is common that the application will ask about the involvement of human subjects and subsequent IRB review and approval. If the application moves on to consideration and award, the grant agency will likely have IRB-related questions that you need to answer.

The National Institutes of Health (NIH) funds a number of human subjects research projects. There are additional requirements and processes for IRB review when a study is funded by the NIH. This document provides guidance for the "just-in-time" (JIT) process and the requirement of a single Institutional Review Board (sIRB) for multi-site studies.

Please note that the IRB does not assist in writing grant applications to the NIH. Any questions regarding the application process should be directed to the NIH or the NC State Proposal Development Unit (PDU) (opens in a new window). More information about the grant process can be found on the NIH Website for Grants and Funding (opens in a new window). More information about NC State University's IRB's cooperative research policy (Word document) including information about reliance agreements and single IRB review can be found on the IRB's website.

The Just-In-Time Process

The NIH utilizes the "just-in-time" (JIT) process for certain programs and award mechanisms. JIT refers to the application timeframe in which applicants are required to submit updated time-sensitive information to the NIH only if an award is likely.
The JIT notice usually includes a request for content that was not included in the initial application, such as:

- current support information for all key personnel
- certification of IRB approval of the project's proposed use of human subjects
- evidence of compliance with the education in the protection of human research participants
- information related to Human Embryonic Stem cells (hESCs)
- and other program-specific requirements.

NIH issues auto-generated JIT request emails to all applicants who have an overall impact score below 30. It is important to note that this notification is not a Notice of Award nor should it be considered an indicator of possible funding.

- If your grant application receives a just-in-time notice, you still need to submit a completed IRB protocol and related documents for review to the NC State IRB.
- As soon as you receive the first auto-generated JIT email request and determine that your score is likely to be competitive for an award, you should begin the initial new protocol submission or amendment process with the IRB if you have not already done so.
- Researchers do not need to have a fully complete IRB application to be granted a Just-In-Time request; they do, however, need to complete the following steps:
    - Open a new IRB application in the eIRB system.
    - Write "[Just-In-Time Request]:" for all other grant proposals. The protocol title should match your grant title.

- For Just-In-Time requests, list the public or private entity you are seeking funding from.
- List the faculty point of contact for the protocol. This should be someone at NC State who is also listed on the grant application.
- For Just-In-Time requests, all designed procedures, or as many designed procedures as are presently available, should be provided and the IRB application should be completed to the best of the researcher's ability.
- Click the "Save" button above the narrative boxes you just pasted text into.
- Navigate to the routing and status tab of the eIRB application and click the "Submit to IRB office" button. The IRB office cannot process a Just-In-Time request without a submitted protocol.
- Complete the letter request form (opens in a new window) on the NC State IRB website for a Just-In-Time request letter. No requests submitted over email can be honored.
- Please note, a Just-In-Time request is staged research; you should first familiarize yourself with the NC State IRB guidance on phased and staged research protocols (Word document) before requesting a Just-In-Time request.
- Please email irb-coordinator-admin@ncsu.edu and cc the irb-director@ncsu.edu when messaging the office about JIT requests.

Use of the Single IRB (sIRB)

Applicability

The NIH policy on the use of a single institutional review board of record for multi-site research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research (studies reviewed via expedited procedures (opens in a new window) or full board procedures) funded by the NIH will use a single Institutional Review Board (sIRB). This review is to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. The NIH's sIRB policy is intended to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

The NIH sIRB policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol (protocols that address the same research questions, involve the same methodologies, and evaluate the same outcomes are considered to be the "same research protocol") involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. It does not apply to career development, research training or fellowship awards. Foreign sites participating in NIH-funded, multi-site studies are not expected to follow this policy. In addition to the NIH's sIRB policy, the cooperative research requirement at 45 CFR 46.114 (opens in a new window).

The cooperative research requirement from 45 CFR 46 requires a single IRB review but it's broader in scope than NIH's sIRB policy in that "cooperative research projects are those projects covered by this policy that involve more than one institution." This means that it does not have to have the same exact protocol at each place, but all protocols need to be reviewed by the reviewing IRB. The different protocols must be a part of the same research project.

Choosing a lead site

When completing the NIH grant application for multi-site research, the researcher must describe the sIRB arrangements including which institution will act as the lead site. In selecting a single IRB, applicants should consider:

- the history and experience of the IRB
- the IRB's capacity to serve as the IRB of record for the particular protocol.
- the IRB must be registered with OHRP and must have the expertise necessary to review the proposed research
- any of the participating sites may serve as the single IRB
- an independent IRB or another qualified IRB may be proposed, however, information about who will pay for this private review must be addressed in the budget for a single IRB review.

Sites should agree to a single IRB arrangement prior to the submission of an application or proposal. This means that if you want NC State to serve as the IRB of record, you must check with the NC State IRB office before putting this information in the grant application. Contact irb-coordinator-admin@ncsu.edu to ensure it is appropriate for the NC State IRB to serve as the single IRB of record. Additionally, you must check with the other sites to ensure they will rely on the review and approval of the selected reviewing IRB. The grant applicant should indicate the participating sites' willingness to rely on the selected single IRB in the single IRB plan. The IRB can provide an official letter to submit with the grant application, indicating a willingness to serve as the IRB of record or rely on the reviewing IRB. This should occur **BEFORE** grant application submission.

Note that the NIH does not require the single IRB to be accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP accreditation is intended to indicate that an organization follows rigorous standards for ethics, quality, and protections for human research and is often used by biomedical IRBs. The NC State IRB is not currently accredited by AAHRPP. If NC State is chosen to be the single IRB, it needs to be established that each site will rely on an IRB that is not AAHRPP accredited before an application is submitted to the NIH. The NC State IRB will likely pursue AAHRPP accreditation in a few years.

The NC State IRB is flexible regarding who will serve as the IRB of Record.

Describing the sIRB in the IRB Application

When submitting an application for the JIT request in the eIRB:

- Answer "Yes" to the question, "Will the investigators be collaborating with researchers at any institutions or organizations outside of NC State?"
    - You can then list each collaborating site, the Principal Investigator for each site and research staff if known. You will need to indicate which institution

will serve as the single IRB. This needs to match your application to the NIH.

- You do not need to complete a reliance agreement request form at this time.
- The agreements will not be executed during the JIT review.
- The IRB will provide a letter of support noting that they agree to follow the sIRB requirements and will act as the single IRB if applicable.

If you do receive the award from the NIH, you will need to submit an amendment to update your research documents and application with the final research procedures and make a formal request for the reliance agreements.

Directions and all required forms for the agreements can be found on the Cooperative Research page of the NC State University IRB website (opens in a new window). If you need assistance, please contact the NC State IRB office at 919-515-7515 or email irb-coordinator-admin@ncsu.edu.

2023 NIH Data Management and Sharing Policy

The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life and reduce illness and disability. Data sharing is essential to this mission. It facilitates and expedites the translation of research results into scientific and clinical knowledge, products and procedures to improve human health.

The NIH is issuing the final NIH Policy for Data Management and Sharing (DMS Policy) to promote the management and sharing of scientific data generated from NIH-funded or conducted research. This policy establishes the requirements for submitting Data Management and Sharing Plans with grant applications to be in compliance with NIH Institute, Center, or Office (Institutes, Centers, and Offices)-approved Plans. NIH's Data Management and Sharing Policy (DMSP) also emphasizes the importance of quality data management practices and establishes the expectation for maximizing the appropriate sharing of scientific data generated from NIH-funded or conducted research, with justified limitations or exceptions. This policy applies to research funded or conducted by NIH that results in the generation of scientific data. This guidance is related to how the NIH DMSP relates to research with human subjects and any NIH requirements that will need to be communicated at the grant stage and followed up with during the IRB approval process.

Scope

The DMSP applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants, contracts, Intramural Research Projects, or other funding agreements regardless of NIH funding level or funding mechanism. The DMSP does not apply to research and other activities that do not generate scientific data, including training, infrastructure development, and non-research activities.

Definitions

Scientific Data: The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data do not include laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects, such as laboratory specimens.

Data Management: The process of validating, organizing, protecting, maintaining, and processing scientific data to ensure the accessibility, reliability, and quality of the scientific data for its users.

Data Sharing: The act of making scientific data available for use by others (e.g., the larger research community, institutions, the broader public), for example, via an established repository.

Metadata: Data that provide additional information intended to make scientific data interpretable and reusable (e.g., date, independent sample and variable construction and description, methodology, data provenance, data transformations, any intermediate or descriptive observational variables).

Data Management and Sharing Plan (Plan): A plan describing the data management, preservation, and sharing of scientific data and accompanying metadata.

DMSP Requirements

- Submission of a Data Management and Sharing Plan outlining how scientific data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations. This is submitted to NIH at the grant application stage and will need to be submitted to the NC State IRB with the IRB protocol.

- Compliance with the awardee's plan as approved by the NIH Institutes, Centers, and Offices (Institutes, Centers, and Offices). This compliance will be addressed through the IRB review, approval, and post-approval monitoring processes established by the NC State IRB. Researchers will need to provide information from these processes to their NIH program officers as needed.

The NIH Institutes, Centers, and Offices may request additional or specific information to be included within the Plan in order to meet expectations for data management and data sharing in support of programmatic priorities or to expand the utility of the scientific data generated from the research.

Data Management and Sharing Plans Submitted to NIH

Researchers planning to generate scientific data are required to submit a Plan to the funding NIH Institutes, Centers, and Offices as part of the Budget Justification section of the application for extramural awards, as part of the technical evaluation for contracts, as determined by the Intramural Research Program for Intramural Research Projects consistent with the objectives of this Policy, or prior to release of funds for other funding agreements.

Plans should explain how scientific data generated by research projects will be managed and which of these scientific data and accompanying metadata will be shared. If plan revisions are necessary (e.g., new scientific direction, a different data repository, or a timeline revision), they should be updated by researchers and reviewed by the NIH Institutes, Centers, and Offices during regular reporting intervals or sooner. Plans from NIH-funded or conducted research may be made publicly available and should not include proprietary or private information.

Plan Elements*:* NIH has developed Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan (opens in a new window) that describes recommended elements to address in Plans.

Plan Assessment: The NIH Institutes, Centers, and Offices will assess the Plan, through the following processes:

- Extramural Awards: Plans will undergo programmatic assessment by the proposed NIH Institutes, Centers, and Offices. NIH encourages potential awardees to work with NIH staff to address any potential questions regarding Plan development prior to submission.
- Contracts: Plans will be included as part of the technical evaluation performed by NIH staff.
- Intramural Research Projects: Plans will be assessed in a manner determined to be appropriate by the Intramural Research Program.
- Other funding agreements: Plans will be assessed in the context of other funding agreement mechanisms (e.g., Other Transactions).

Managing and Sharing Scientific Data from Humans

NIH expects that in drafting Data Management and Sharing Plans, researchers will maximize the appropriate sharing of scientific data, acknowledging certain factors (i.e., legal, ethical, or technical) that may affect the extent to which scientific data are preserved and shared. Any potential limitations on subsequent data use should be communicated to individuals or entities (e.g., data repository managers) that will preserve and share the scientific data. The NIH Institutes, Centers, and Offices will assess whether Plans appropriately consider and describe these factors.

NIH prioritizes the responsible management and sharing of scientific data derived from human participants. Applicable federal, Tribal, state, and local laws, regulations, statutes, guidance, and institutional policies govern research involving human participants and the sharing and use of scientific data derived from human participants. Researchers proposing to generate scientific data derived from human participants should outline in their Data Management and Sharing Plans how privacy, rights, and confidentiality of human research participants will be protected (i.e., through de-identification, Certificates of Confidentiality, and other protective measures). The NC State IRB suggests working with the IRB office to discuss these plans at the NIH proposal stage.

NIH strongly encourages researchers to plan for how data management and sharing will be addressed in the informed consent process, including communicating with prospective participants how their scientific data are expected to be used and shared. Researchers should consider whether access to scientific data derived from humans, even if de-identified and lacking explicit limitations on subsequent use, should be controlled. The NC State IRB office can help with these determinations.

Data Repository Selection: NIH strongly encourages the use of established repositories to the extent possible for preserving and sharing scientific data. The Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research (opens in new

window) assists researchers in selecting a suitable data repository(ies) or cloud-computing platform.

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.

Genomic Data Sharing

The DMSP expects the submission of a Data Management and Sharing Plan that describes how the applicant will manage and share scientific data generated from NIH funds. To reduce the burden on applicants and staff, NIH now expects a single data sharing plan at time of funding application that satisfies both the Genomic Data Sharing (GDS) Policy and the DMS Policy. Therefore, on or after January 25, 2023, NIH will no longer be collecting separate GDS Plans.

Genomic data sharing considerations, such as, where and when genomic data will be shared, will be expected to be addressed in the Data Management and Sharing Plan.

In addition, compliance and enforcement for awards subject to the Genomic Data Sharing Policy will be handled in accordance with the compliance and enforcement terms in the DMSP.

Genomic Data Sharing: Institutional Certification

The Institutional Certification is provided by the submitting investigator and the NC State Institutional Official (IO). This certification assures NIH that submission of large-scale human genomic data to an NIH-designated data repository is consistent with the NIH Genomic Data Sharing Policy, the NIH Data Management and Sharing Policy, the informed consent of the original study participants, and/or the preferences of the original study population. The certification also states whether, after IRB review, research use limitation is deemed necessary. Find more information about NIH's Institutional Certification (opens in a new window) on their site.

- The Institutional Certification will be requested as part of the Just-in-Time (JIT) (opens in a new window) process and is required for award. The Institutional Certification, or in some cases, a provisional Institutional Certification, must be submitted and accepted before the award can be issued.
- Applicants are asked to anticipate genomic data sharing in their Data Management and Sharing (DMS) Plan (opens in a new window), which is submitted at the time of application. The DMS Plan should reflect the anticipated assurances and any limitations outlined in the Institutional Certification.
    - If the Institutional Certification reflects more updated information, applicants should update their DMS Plans and contact their Program Officers.

- Applicants' Data Management and Sharing Plans (opens in a new window) should reflect the assurances and any limitations anticipated in the Institutional Certification.

The IRB works with the investigator to determine if the Institutional Certification accurately reflects the terms of the participants' informed consent as well as the adequacy of the consent process for the generation and sharing of data for secondary research use, and that it is consistent with the NIH GDS Policy and Data Management and Sharing Policy.

By signing an Institutional Certification, an institution and its IRB, privacy board, or similar body assure NIH that:

- The study submission is consistent with relevant (e.g., local, state, federal, Tribal, and/or institutional) laws and policies;
- The certification states the data use limitations (opens in a new window), if any, on secondary research performed with the data;
- The participants' identities will not be disclosed to NIH-designated data repositories; and
- An IRB or equivalent body has reviewed the proposal and assures NIH that:
    - The data collection protocol appropriately protects the research participants;
    - The submission and sharing of the data are consistent with the informed consent of the study's participants; and
    - The risks associated with genomic data sharing have been considered

Responsible Management and Sharing of American Indian/Alaska Native Participant Data

NIH is committed to increasing its focus on the health of American Indians and Alaska Natives (AI/AN) through enhancing capacity for research in Native communities, promoting opportunities for the next generation of AI/AN researchers, and disseminating transparent and culturally responsive information about NIH and biomedical and behavioral research.

The NC State IRB suggests contacting their office at the grant application stage regarding participants who are also American Indian or Alaskan Native. The IRB office can help you design your research in a way that addresses these concerns from the get go. Additionally, the NC State IRB may require "local context review" (Word document) for all non-exempt research involving participants who are also American Indian or Alaskan Native. This review can be completed by Tribal Review

Proactively engage AI/AN Tribes in planning for data management and sharing.

- Establishing partnerships with AI/AN Tribes prior to initiating a research project is an important step toward building trust, facilitating mutually beneficial and equitable partnerships, and developing a culturally appropriate Plan.

- Researchers should not only develop and proactively discuss the Plan with Tribal partners when preparing an application for funding but also engage Tribal partners when updating Plans throughout the research process.
- Engagement with AI/AN Tribes prior to initiating research equips researchers with a greater understanding of any Tribal laws, regulations, policies, or preferences prior to developing a Plan under the DMS Policy.
- The DMS Policy also allows researchers the opportunity to disclose any applicable NIH policy expectations prior to project initiation and involve AI/AN Tribes as research partners throughout all stages of the project.
- Note that in some cases, researchers may include in their budget requests costs for Tribal Nations that partner with researchers to develop a Plan and Tribal Nations may be reimbursed by the award recipient for their role in data management and sharing consistent with NIH rules for pre-award (pre-agreement) costs. These data management and sharing costs may be proposed by researchers in their budgets, and researchers should notify AI/AN Tribes that such reimbursement is dependent on the actual award. AI/AN Tribes or organizations receiving an award may also be eligible to have pre-award costs covered based on the NIH rules.

Establish mutual understandings of goals for data management and sharing.

- While the goals of a research project may be well documented, it is also important for researchers to understand the motivations and expectations of research participants/communities who engage in research and form equitable partnerships around a shared understanding of research goals, including those for data management and sharing. For instance, Tribal Nations may have expectations regarding how their data will be used and shared.
- Research agreements should describe planned data management and sharing practices, including when data sharing limitations are appropriate, to ensure mutual agreement about data management and sharing that aligns with AI/AN Tribes' preferences.
- Researchers should convey relevant data management and sharing agreements in the Plan (i.e., who made the agreement; applicable Tribal laws, regulations, and policies, etc.) and obtain Tribal letters of support, Tribal resolutions, and/or other forms of written documentation when required and if possible.
    - Agreeing to present research findings to communities, particularly before research results are broadly disseminated, can be one strategy for researchers to sustain relationships with AI/AN Tribes and increase trust.
    - It is also helpful to proactively discuss any Tribal pre approval processes that AI/AN Tribes may use to review manuscripts or the dissemination of research findings.

Incorporate AI/AN data management/sharing practices and preferences in Plans.

- Prior to submitting a Plan to NIH, researchers and AI/AN Tribal partners should consider whether data generated will be stewarded by Tribal Nations, researchers, or a trusted third party.

- The DMSP encourages the use of an established data repository to the extent possible but does not specify use of a particular data repository or which entity manages the data repository selected.
- NIH is committed to supporting Tribal data science resources, including data repositories, through efforts such as NIH-supported data centers, the Centers of Biomedical Research Excellence research infrastructure, and the NIH Office of Data Science Strategy's data science training.

Consider additional protections and appropriate limitations to future data sharing.

- AI/AN Tribes have legal rights to determine the conditions by which their data are shared when data are collected within their jurisdiction, including requiring Tribal approvals or participating in research review requests.
- Researchers and AI/AN partners are encouraged to jointly consider data sharing expectations, and any appropriate limitations on data sharing for secondary research.
- The DMS Policy recognizes that other factors (e.g., ethical, legal, and technical) may shape permissibility of data sharing, and these factors should be described in the Plans. Examples of factors to be considered include applicable Tribal laws, regulations, policies, and agreements governing participant research and resulting data; and distinct, culturally embedded, or spiritual values that inform Tribal preferences regarding the extent to which data are shared.
- Tribal laws, regulations, policies, and preferences, for example, may apply to de-identified data not protected under U.S. Federal regulations. Data sharing may also be limited in instances in which AI/AN Tribes wish to manage and share their own data, and no appropriate repository exists or is accessible.

Incorporate data management and sharing plans in the informed consent process.

- The DMS Policy strongly encourages researchers to communicate data sharing and future use limitations to research participants in the informed consent process. This includes accessible descriptions of conditions and oversight processes and safeguards on secondary research (e.g., whether all secondary research or secondary research beyond a pre-specified scope will be reviewed by an oversight body), plans related to return of secondary research results (e.g., whether results of secondary analyses will be returned to individuals and/or Tribes), and/or stipulations of the data repository used (e.g., whether certain secondary research domains or questions are acceptable and how long data can be made available for secondary analyses).
    - Though NIH encourages this, the NC State IRB office unit level standards require these disclosures.

- Researchers should ensure that when partnering with an AI/AN Tribe to conduct research within Tribal jurisdiction that the informed consent is accessible, responsive, and consistent with the preferences of the Tribal Nation and the preferences of the anticipated research participants.

- For example, individual AI/AN Tribes may have IRB policies that specifically prohibit broad consent practices. The DMS Policy does not have specific expectations about the consent process, such as broad consent, and emphasizes honoring appropriate sharing limitations in the informed consent process.

Safeguarding against future risk.

- The DMS Policy indicates that, in developing Plans, researchers should describe how participants' privacy, rights, and confidentiality will be protected.
- Unique populations, including AI/AN Tribes, are at greater risk of privacy vulnerabilities and/or stigmatization if participant protections are not appropriately planned for and implemented (e.g., easier data re-identification, or stigmatization resulting from misuse).
- To mitigate the potential for group harm to AI/AN Tribes, both individual and community data protections (e.g., de-identification of Tribal affiliation or other group identifiers and controlled access review) should be considered.
- In explaining participant protections in Plans, researchers partnering with AI/AN Tribes are recommended to include in Plans considerations of Tribal sovereignty by describing their compliance with expectations from any relevant Tribal law, regulation, policy, and/or preferences.
- Tribal IRBs and/or other relevant AI/AN research oversight entities may specify for researchers the data sharing preferences of relevant AI/AN Tribes. Compliance with the Plan is determined by the funding NIH Institutes, Centers, and Offices and may be reviewed during regular reporting periods, e.g., at the time of annual Research Performance Progress Reports (RPPRs).
- Breaches in compliance may result in enforcement actions consistent with the established NIH policies of the funding Institutes, Centers, and Offices and NIH, which could include additional special terms and conditions or termination of the award and may affect future funding decisions.

NIH's DMSP and the NC State University IRB

Researchers should work closely with the IRB during the development and implementation of the Data Management and Sharing Plan. The IRB can assist the researcher in developing consent language that is consistent with the Data Management and Sharing Plan and to manage any likely restrictions on data sharing. Please contact the IRB coordinator at irb-coordinator-pre@ncsu.edu for assistance in developing your Data Management and Sharing Plan.

The NIH Data Management and Sharing Plan ***does not*** replace the NC State IRB Office data access and security plan (Word document) if your study includes highly sensitive (red) or ultra sensitive (purple) data. Please review NC State OIT's site (opens in a new window) for data classification and contact the IRB office for confirmation of data classification. If your study includes data considered "red" or "purple," please contact the help desk (help@ncsu.edu) to aid in your completion of the data access and security plan (Word document).

Before submitting to the IRB or to NIH

- Contact the IRB office to discuss requirements for informed consent and your proposed NIH Data Management and Sharing Plan. This assures congruence with and completion of NIH's requirements for data sharing.
- Contact NC State OIT or your Departmental IT to discuss data security.

In your IRB Protocol

- Upload your NIH Data Management and Sharing Plan that was approved by NIH. This will be a part of your IBR review process.
    - You can reference this plan in the data sharing section of the IRB application. You do not need to summarize the plan.
- If the data are considered "red" or "purple" by NC State's OIT standards or if an NC State IRB member has determined the data are "red" or "purple," upload the completed data access and security plan (Word document). Note, this access and security plan is NC State specific and it should operationalize your stated Data Management and Sharing Plan (DMSP) that you submit to the NIH.
- Ensure that all data sharing information is clearly communicated within the consent form or broad consent addendum.
- Ensure that your IRB application discusses data sharing that is in line with your NIH Data Management and Sharing Plan.

After Initial IRB Approval

- Contact the IRB if there are any questions related to allowable data sharing, de-identification of data or adherence to the approved plan.
- Submit an amendment to the approved IRB protocol if changes need to be made to the NIH Data Management and Sharing Plan or the NC State IRB data access and security plan.
- Once a year, the IRB office will require you to provide an update on the NIH sponsored project. This will either allow closure of the study or provide the IRB the necessary information for proper oversight as required by the NIH Data Management and Sharing Policy. This annual review will result in documentation you can give to appropriate stakeholders such as your NIH program officer or NC State Sponsored Programs Staff.
- The Genomic Institutional Certification will be handled through initial submission or an Amendment process related to a specific study. The researcher should upload a signed Institutional Certification that the IRB office will review, facilitate signature from the IO, and approve the Institutional Certification.