Sixth Edition

2019

Guidelines and Policies for the

Conduct of Research

in the Intramural Research Program at NIH

National Institutes of Health
Office of the Director

Preface

It is an exciting time to be a member of the Intramural Research Program (IRP) at the National Institutes of Health. Research is increasingly multidisciplinary and relies on innovative technologies that are developing almost too quickly to count. Team science has largely replaced single-scientist research. Because of the technological advances, and team-science approaches, it is more important than ever to promote a culture of research integrity on intramural campuses. A culture of integrity is one in which every individual understands how to perform research ethically and does so. These guidelines were written to provide important information about how to perform ethical research and maintain a culture of research integrity in the IRP.

I would like to draw your attention to the section on our "Research Environment," and specifically to the chapter on *Harassment, Sexual Harassment, and Inappropriate Conduct*. We expect the research culture in the IRP be civil, and that all members of the community be treated fairly and with respect. The IRP trains more than 4000 research trainees and clinical fellows a year. Our fellows leave the NIH to join the larger scientific community–and we must position these trainees to be future leaders in research. It is our responsibility to instill in them a commitment to building a civil, inclusive research community that offers opportunity to all.

It is important that every investigator involved in research at NIH read, understand, and incorporate the *Guidelines and Policies* into everyday practice. The progress and excellence of NIH intramural research are dependent on our vigilance in maintaining the highest quality of conduct in every aspect of science.

These guidelines were developed by the Scientific Directors in 2007 then revised in 2016 and 2019 by the intramural scientists serving on the Committee on Scientific Conduct and Ethics. This edition was approved November 12, 2019 by the Scientific Directors.

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Introduction

Scientists in the Intramural Research Program of the National Institutes of Health (NIH) are responsible for conducting original research consonant with the goals of their individual Institutes and Centers. These *Guidelines and Policies* were developed to promote high ethical standards in the conduct and management of research by NIH intramural scientists. It is the responsibility of all supervisory personnel who oversee research groups, core facilities, and other entities, as well as successive levels of organizational leadership (especially Institute and Center Scientific Directors), to ensure that every NIH scientist is cognizant of these *Guidelines and Policies* and to resolve issues that may arise in their implementation.

Intramural scientists at NIH, as is true for all scientists, should be committed to the responsible use of scientific tools and methods to seek new knowledge. While the general principles of scientific methodologies are universal—formulation and testing of hypotheses, controlled observations or experiments, analysis and interpretation of data, and oral and written presentation of all of these components to scientific colleagues for discussion, replication and further conclusions—their specific applications may differ across scientific disciplines and the specific context. All research staff in the Intramural Research Program should maintain exemplary standards of intellectual honesty in formulating, conducting, presenting, and reviewing research, as befits the leadership role of the NIH. Both OIR and NIH leadership expect that all members of our thriving community will conduct themselves in a manner that is consistent with NIH Policy. It is important to note that failure to adhere to the principles and expectations set forth by NIH Policy may result in disciplinary action.

These *Guidelines and Policies* complement existing NIH regulations for the conduct of research such as those governing human subjects research, animal use, radiation, and chemical and other safety issues, as well as the standards of ethical conduct that apply to all NIH researchers and federal employees. ▲

Data Management and Archiving

Research data, including detailed experimental protocols, all primary data, and procedures for data acquisition, analysis, and presentation, are the essential components of scientific processes and progress. Scientific integrity is inseparable from meticulous attention to the acquisition and maintenance of these research data.

Data integrity is ultimately the responsibility of the Principal Investigator (PI). It is therefore incumbent upon the PI to establish robust best practices that ensure all data generated in the research group are appropriately reviewed.

√ The results of all research should be carefully recorded and retained in a form that will allow continuous access. Notebooks and documenting electronic information should be annotated and indexed to facilitate detailed analysis and review of data; i.e., a third party should be able to reconstruct the experiment based on the recorded information. To mitigate the risk of loss, electronic data should be backed up regularly, and stored at a location away from the original data. Similarly, it is prudent to scan hard-copy notebooks periodically and to keep electronic copies at a different site. All intramural research records remain the property of the NIH and must be maintained for at least 7 years after completion of the project (e.g., publication of the final results); records that support patent or invention rights must be maintained for 10 years after the patent expires or is abandoned; and records of historical significance should be identified and transferred to the National Archives to be maintained permanently.[1] More details regarding research retention schedules can be found at the NIH Office of Management website.[2]

√ All primary data, including those from observations and experiments not directly leading to publication, must be retained.[1] For example, all usable confocal microscopy imaging files should be retained in their original format, except for technically problematic data that had been discarded immediately. If acquired images or image sequences become prohibitively large, it may be acceptable to keep a subset of images as recorded, while compressing others if considered best practices for the field. The volume of imaging data continues to expand exponentially, creating challenges for their secure storage. Researchers should only use storage mechanisms that are approved by the NIH Intramural Research Program (IRP) and their Institute or Center (IC).

√ All primary research data in the IRP are subject to request under the Freedom of Information Act (FOIA).[3] Analyses should be available to supervisors and scientific collaborators for timely review, consistent with requirements of confidentiality. Investigators should be reminded that research data are legal documents for purposes such as establishing patent rights or defending the veracity of published

[1] Manual Chapter 1743; Managing Federal Records. Retrieved from https://policymanual.nih.gov/1743
[2] NIH Records Management. Retrieved from https://oma.nih.gov/dms/programs/rm/Pages/Home.aspx
[3] 5 USC § 552; Freedom of Information Act Statute. Retrieved from https://www.foia.gov/foia-statute.html

results and are subject to FOIA and to subpoena by Congressional committees and the courts. However, not all information requested through FOIA is subject to release. The NIH IRP supports increased efforts to ensure rigor, reproducibility, and transparency of research.[4] In general**,** notebooks, other research data including computer files and supporting materials, such as unique reagents, should be maintained and made available by the laboratory in which they were developed. Departing scientists may take copies of notebooks and other data for further work, with the approval of their supervisor. The policy and process for taking copies of NIH records is described in Manual Chapter 1743, "Managing Federal Records[1]," which includes the requirement that the requestor complete Form NIH-3000 at least 45 days prior to departure. PIs should consider documenting the intent to continue to work together with a Research Collaboration Agreement (RCA). Under special circumstances, such as when required for continuation of research, departing investigators may take unique reagents with them if adequate arrangements for their safekeeping and availability to others are documented by the appropriate Institute or Center official. The transfer of a reagent outside of NIH should be documented through a Material Transfer Agreement (MTA)[5].

√ Data management, including the decision to publish, is the responsibility of the PI. After publication, the research data and any unique materials that form the basis of that communication should be made available promptly and completely to all qualified scientists seeking further information. Exceptions may be necessary to maintain confidentiality of clinical data or if unique materials were obtained under agreements that preclude their dissemination. Recognizing that large genomic data sets and human data in general are especially valuable to the biomedical research community, the NIH has established the NIH Genomic Data Sharing (GDS) Policy and the Human Data Sharing (HDS) Policy to ensure that such data are appropriately accessible to qualified scientists.[6] ▲

[4] Enhancing Reproducibility Through Rigor and Transparency. Retrieved from https://grants.nih.gov/policy/reproducibility/index.htm
NIH CRADA policy. Retrieved from https://www.ott.nih.gov/policy/cradas
[5] CRADA & MTA FAQs. Retrieved from http://www.ott.nih.gov/crada-mta-faqs
[6] NIH Notice No. NOT-OD-14-124; NIH Genomic Data Sharing Policy. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html
Manual Chapter 3016; Intramural Research Program Human Data Sharing (HDS) Policy. Retrieved from https://policymanual.nih.gov/3016

Authorship

Authorship is the fulfillment of the responsibility to communicate research results to the scientific community for external evaluation. Authorship is also the primary mechanism for allocating credit for scientific advances and thus forms the basis for assessing a scientist's contributions to developing new knowledge. Authorship potentially conveys great benefit to co-authors, but it also involves personal responsibility for the data published.

Strictly speaking, authorship refers to the listing of names of study researchers in any communications, either oral or written, of experimental results and their interpretation. For each individual the privilege of authorship should be based on a significant contribution to the conceptualization, design, execution, or interpretation of the research, as well as to the drafting or substantively reviewing or revising the research article. Authorship also conveys responsibility for the study. Individuals who do not meet these criteria but who have assisted the research by their encouragement and advice or by providing space, financial support, reagents, occasional analyses, or patient material should be acknowledged in the text but not be authors. The Committee on Scientific Conduct and Ethics (CSCE) devised general guidelines to assist with determination of who deserves to be an author. These guidelines can be found in the NIH Sourcebook.[7]

Disputes over authorship inclusion and order are not uncommon, including in those cases where one or more contributor(s) has left the lab where the research was primarily performed. NIH developed processes for resolution of authorship disputes, using a four-tiered process involving discussion, mediation, the option for peer review of the publication and/or authorship, and if unsuccessful, a final decision by the IC Scientific Director or the Deputy Director for Intramural Research (DDIR). This process is outlined in detail in the NIH Sourcebook.[8]

It is expected that members of each research group and Laboratory or Branch will freely discuss and resolve questions of authorship, including the order of authors, before and during the course of a study. Further, each author has the responsibility to review and support their contributions to the manuscript and be willing to support the general conclusions of the study submitted (originally or in revision) for publication. The NIH recommends, and many journals now require, that the transmittal letter accompanying a manuscript submission identify the exact contribution of each author.

The corresponding author should be considered the primary author (but is not necessarily the first author), with the additional responsibilities of coordinating the completion and submission of the work, satisfying pertinent rules of submission, and coordinating responses of the group to inquiries or

[7] General Guidelines for Authorship Contributions. Retrieved from https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-authorship_contributions.pdf

[8] Processes for Authorship Dispute Resolution. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training/processes-authorship-dispute-resolution

challenges. The corresponding author is responsible for confirming that: 1) the contributions of all collaborators (intramural and extramural) are appropriately recognized, 2) each author has reviewed and authorized the submission of the manuscript in its original and revised forms, 3) the data in the manuscript have been reviewed if revised, and 4) the data in the manuscript and all analyses are reproducible.

√ All manuscripts and abstracts coming from the IRP must be cleared in accordance with the policy[9] and instructions included in the Sourcebook.[10]

It is not unusual for a co-author to leave the NIH prior to the final submission of a manuscript. The senior and/or corresponding author must ensure that the departing co-author is fully included in the revision process and agrees to submission of the final version of the manuscript. If the senior author makes a good faith effort to contact the departed co-author but is unable to do so, they should consider consulting with a supervisor about removing the co-author and placing an acknowledgement of the contributions of the co-author in the manuscript. When the departing co-author is the senior and/or corresponding author of a manuscript that uses data collected in the Intramural Research Program (IRP), they must use the NIH IRP manuscript clearance process prior to an initial submission. In this case, the manuscript must clearly annotate that the work was performed in the NIH IRP, but that the departing author is no longer affiliated with NIH. The departing author must also obtain approval from their previous NIH supervisor prior to submitting a revision of a previously submitted manuscript. If the departing author is unwilling or unable to communicate with their prior supervisor, NIH has the authority to remove the departing author from the manuscript prior to submission or re-submission, and/or to contact the publisher requesting that the manuscript not be published or be corrected/retracted if already published, because the manuscript uses data collected in the IRP and was submitted without NIH approval. ▲

[9] Manual Chapter 1184; Preparation and Clearance of Scientific, Technical and Public Information Presented by NIH Employees or Produced for Distribution by NIH. Retrieved from https://policymanual.nih.gov/1184
[10] Publication and Abstract Clearance. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance

Publications

Publication of results is an integral and essential component of scientific research. Other than presentation at scientific meetings, publication in peer-reviewed scientific journals is the appropriate mechanism for the first public disclosure of new findings. Timely publication of new and significant results is important for the progress of science. Guidelines for submitting research publications can be found in the Sourcebook.[11] Although generally considered the end point of a research project, publication is also the beginning of a process in which the scientific community at large can assess, correct, and further develop any particular set of results.

√ All NIH publications must be reviewed by each IC Scientific Director or a delegated official to assure quality and compliance with applicable requirements[10] such as to identify dual-use concerns,[12] described in the Sourcebook. If the publication describes a possible patentable invention, contact the IC Technology Transfer Office prior to public release. The legal standard for inclusion of a researcher as an inventor on a patent is more strict than the policy for naming a researcher on a publication.

√ Each paper should contain sufficient information for the informed reader to assess its validity, including all the information that would be necessary for scientific peers to repeat the experiments.[9] The NIH position on reproducibility states that all essential data should be included in the published paper or be deposited in appropriate public databases or made available online. It is an obligation of NIH intramural scientists to make reasonable amounts of expandable materials (e.g., monoclonal antibodies) and analytical amounts of limited reagents that are essential for reproducibility of the published experiments available to qualified scientists. More information on policies and guidance for sharing NIH-funded research resources can be found on the Office of Extramural website.[13]

Fragmentary publication of the results of a scientific investigation, sometimes referred to as "salami slicing," or multiple publications based on the same or similar data are inappropriate. Each publication should make a distinct and substantial contribution to its field. As a corollary to this principle, tenure appointments and promotions should be based on the importance of the scientific accomplishments and not on the number of publications in which those accomplishments were reported. Equally, authors should avoid publishers who entrap researchers into submitting their work and then charge them publishing fees but do not undertake serious peer review. Publications in such venues are unlikely to be counted as legitimate. Authors should seek to publish in journals that are findable (indexed in authoritative resources, e.g., Medline, Embase, Web of Science, Scopus).

√ All NIH-funded investigators are required to post their final peer-reviewed manuscripts, upon

[11] Submitting Research Publications. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications
[12] Dual-Use Research. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research
[13] NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources. Retrieved from https://grants.nih.gov/policy/sharing.htm

acceptance for publication, to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) via the NIH Manuscript Submission System[14] (NIHMS).[15] Authors must select the option to release their manuscripts to the public immediately, or within 12 months after the official date of final publication, depending on the publisher's embargo agreement. NIH expects that only in limited cases will authors deem it necessary to select the longest delay period.

The NIH encourages researchers to use interim research products[16], such as preprint servers, to speed the dissemination and enhance the rigor of their work. Interim research products are complete public research products that are not final. A common form is the preprint, a complete public draft of a scientific document. Preprints are typically unreviewed manuscripts written in the style of peer-reviewed journal articles, but they can also include a preregistered protocol. The purpose of a preprint is to obtain feedback prior to submission for publication, and the typical mechanism for receiving feedback is through a blog-style posting on a platform that accepts interim research products, with some examples but not limited to BioRxiv.org[17], MedRxiv.org[18], ChemRxiv.org[19], and ASAPbio.org[20]. NIH researchers are not required to use preprint servers, and these products do not need to be submitted to PubMed Central[21], although they still fall under the NIH publication policies[22] and require IC clearance prior to submission. It should be noted that the preprint version of the manuscript will remain in the public space even after the peer-reviewed paper is published. Consequently, some researchers may decide that they do not want to use an interim research product for their work.

Preprint publications may be cited in BSC reports, NIH bio-sketches, and NIDB Annual Reports, and should include the Digital Object Identifier (DOI). An example of such a citation is shown below:

> Bar DZ, Atkatsh K, Tavarez U, Erdos MR, Gruenbaum Y, Collins FS. Biotinylation by antibody recognition- A novel method for proximity labeling. BioRxiv 069187 [**Preprint**]. August 11, 2016 [cited 2017 Jan 12]. Available from: https://**doi**.org/10.1101/069187.

Researchers should use a reputable repository that:

- ensures that the content is findable, accessible, interoperable and re-usable;
- supports open access;
- uses a Creative Commons license[23];
- is regulated by rigorous policies and processes to prevent plagiarism or other types of research misconduct, and conflicts of interest;
- has a link between the preprint and the final publication; and,

[14] NIH Manuscript Submission System. Retrieved from https://www.nihms.nih.gov/db/sub.cgi
[15] NIH Public Access Policy. Retrieved from https://publicaccess.nih.gov/policy.htm
[16] NIH Notice Number NOT-OD-17-050. Retrieved from https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html
[17] bioRxiv. Retrieved from https://www.biorxiv.org/
[18] medRxiv. Retrieved from https://www.medrxiv.org/
[19] ChemTxiv. Retrieved from https://chemrxiv.org/
[20] ASAPbio. Retrieved from https://asapbio.org/
[21] NIH Public Access Policy. Retrieved from https://publicaccess.nih.gov/
[22] Submitting Research Publications. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications
[23] Creative Commons licenses. Retrieved from https://creativecommons.org/licenses/

- ensures long-term preservation and access of the preprint.

The preprint should acknowledge the IRP as the source of funding, clearly state that the work is not peer-reviewed and declare any competing interests. NIH manuscript clearance[24] is required for submissions of interim research products. Manuscript clearance is expected for submission of public feedback on a repository site regarding a preprint, or for any other public blog posting that indicates your NIH affiliation[25], in accordance with ethics guidance[26] and IC-specific publication policies and procedures. Researchers are encouraged to consult with their supervisors prior to a public blog posting.
▲

[24] NIH Publication and Abstract Clearance policy. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-clearance
[25] NIH Manual Chapter 1184. Retrieved from https://policymanual.nih.gov/1184
[26] Official Duty Activities. Retrieved from https://ethics.od.nih.gov/topics/ODA/2-ODA-chart.pdf

Mentoring and the Responsibilities of Research Supervisors and Trainees

Research training is a complex process, the central aspect of which is a period of research carried out under the primary supervision of an experienced scientist. This supervised research experience is not merely the performance of tasks assigned by the supervisor, but rather it is a process wherein the trainee takes on an increasingly independent role in the selection, conceptualization, and execution of research projects. The trainee should be provided with training in the skills and knowledge necessary for their research projects and should expect to receive training in the full range of professional skills necessary for success along whatever career trajectory they choose to follow**.**

Importantly, it must be recognized that the trainee has unique, time-sensitive needs relevant to career progression and advancement. As such, guidance, advocacy, and sponsorship are essential components of training.

In general, a trainee will have a single primary research supervisor who usually fills the role of primary mentor as well. However, trainees are encouraged to identify additional individuals (e.g., scientific staff, more senior trainees) who function as mentors for specific aspects of training or career development. Also, supervisors should encourage trainees to take advantage of the numerous NIH campus resources including Institute and Center training offices and directors, the NIH Office of Intramural Training and Education (OITE), the NIH Library, and the Foundation for Advanced Education in the Sciences (FAES).

It is the responsibility of the primary supervisor to serve as a role model and provide a rich research environment in which the trainee has the opportunity to acquire both conceptual and technical skills in the research field of interest. In this setting, each trainee should have a clear research training plan (e.g., Individual Development Plan) with end goals and intermediate milestones. Progress should be assessed regularly. A "Welcome Letter" or "Lab Compact" is recommended as a useful tool for mentors or other supervisors to introduce trainees to the specific expectations and responsibilities of both trainees and mentors in their research groups. Several examples are available for supervisors in the NIH Sourcebook.[27]

The primary mentor should interact with the trainee personally on a regular basis (e.g., once a week) to review primary data and to give timely feedback on research designs, results, progress, and publications. Good communication is critical to a successful training experience. Supervisors must be sensitive to the fact that each trainee has preferred communication, learning, and work styles, as well as biases and norms shaped by their previous life experiences. A good mentor seeks to understand each trainee's unique qualities and adapts his/her training approach accordingly.

Specific aspects of the mentor–trainee relationship deserve emphasis. Mentors should impart to the new investigator appropriate standards of scientific conduct, including appropriate ethical conduct, both

[27] Introduction to "My Laboratory." Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training/instruction-responsible-conduct-research-postdoc-irta-crta-vf-research/introduction

by instruction and by example. Mentors should promote career development by encouraging their trainee to present at scientific meetings, by facilitating opportunities for collaboration and networking, and by encouraging attendance at scientific seminars and other scientific and professional activities at NIH. Mentors should provide trainees with timely, objective, and realistic appraisals of their performance along with advice regarding career directions, opportunities, and advancement. Trainees have responsibilities to their supervisors as well as to their research institutions. These include adherence to these *Guidelines and Policies* and other applicable rules, and to programmatic constraints related to the needs of the research team and Institute or Center. The same standards of professionalism and collegiality apply to trainees as to their supervisors and mentors. Trainees should play active roles in seeking the tools and experiences necessary to accomplish their goals.

√ All NIH supervisors have a special responsibility to cast a wide net to assure recruitment and retention of a diverse and talented scientific community. The NIH is committed to the development of a biomedical research workforce that is representative of the diversity in American society and seeks to promote diversity in all of its training and research programs. This includes following NIH requirements for broadly advertised searches, strict prohibition against giving preference to relatives and friends when filling trainee or employee positions at the NIH,[28] and attention to assuring that all trainees and employees at the NIH are valued and included as respected members of the NIH community. At the Laboratory and Branch level, this includes keeping records, conducting research, and interacting with colleagues in English.[29] ▲

[28] Manual Chapter 2300-301-1; Nepotism. Retrieved from https://policymanual.nih.gov/2300-310-1#transmittal-sheet

[29] Policy on Use of English for Official Scientific Communication in NIH Laboratories and Branches. Retrieved from https://oir.nih.gov/sourcebook/personnel/recruitment-processes-policies-checklists/policy-use-english-official-scientific-communication-nih-laboratories

Collaborations and Team Science

Collaborative research and team science bring together investigators with distinct strengths to work together on defined problems or to address specific research goals. As research methods become more sophisticated team science is increasingly important, both within NIH intramural programs as well as in collaborations with extramural institutions. These arrangements are strongly encouraged and supported; the complex scientific questions that face us today often require interdisciplinary or multidisciplinary approaches.

Successful collaborations are characterized by a strong sense of direction, a willingness to commit time and effort, an efficient communication strategy for discussion among the group members, a system in place for reevaluation as the project progresses, and a clear definition of roles and responsibilities. It is advisable that the ground rules for collaborations, including eventual authorship issues, be discussed openly among all participants from the project's beginning. The NIH has developed a useful set of criteria to consider in establishing collaborations and a Field Guide for Team Science.[30]

Questions for Scientific Collaborators

Although each research project has unique features, certain core issues are common to most of them and can be addressed by having collaborators consider the following questions compiled by the NIH Office of the Ombudsman:

Overall Goals:

- What are the scientific issues, goals, and anticipated outcomes or products of the collaboration?
- When will the project be completed?

Who Will Do What?

- What are the expected contributions of each participant?
- Who will write any progress reports and final reports?
- How, and by whom, will personnel decisions be made? How and by whom will personnel be supervised?
- How and by whom will data be managed? How will access to data be managed?
- How will you handle long-term storage and access to data after the project is completed?

Authorship, Credit:

- What will be the criteria and the process for assigning authorship and credit?

[30] Collaboration and Team Science: A Field Guide. Retrieved from https://www.cancer.gov/about-nci/organization/crs/research-initiatives/team-science-field-guide

- How will credit be attributed to each collaborator's institution for public presentations, abstracts, and written articles?
- How and by whom will public presentations be made?
- How and by whom will media inquiries be handled?
- When and how will you handle intellectual property and patent applications?

Contingencies & Communications:

- What will be your mechanism for routine communications among members of the research team (to ensure that all appropriate members of the team are kept fully informed of relevant issues)?
- How will you decide about redirecting the research agenda as discoveries are made?
- How will you negotiate the development of new collaborations and spin-off projects, if any?
- Should one of the principals of the research team move to another institution or leave the project, how will you handle data, specimens, lab books, and authorship and credit?

Conflicts of Interest:

- How will you identify potential conflicts of interest among collaborators?
- Could a collaborator or any close family members or associates benefit financially from the research?
- Is a collaborator receiving money from someone who could benefit financially from the research?

Whenever collaborations with scientists outside of NIH involve the exchange of biological materials or research data, they are routinely formalized by written agreements developed by the Technology Transfer Office of your Institute.

Material Transfer Agreements (MTAs) are used for the simple transfer of proprietary research material with or without collaboration[5]. For example, an MTA is used if you request a reagent from, or give one to, a colleague outside the NIH, or provide blood samples to be analyzed as part of a multi-study collaboration. For transfers within the NIH, no MTA is required but the transfer should be documented, for example in an email, and retained for records. Data Transfer Agreements (DTAs) are used for the transfer of existing data collected from human subjects, clinical studies, or laboratory experiments for research purposes. Cooperative Research and Development Agreements (CRADAs) are used for agreements between one or more NIH laboratories and at least one non-federal group (private sector, university, not-for-profit, non-federal government). CRADAs provide a protected environment for long-term collaborations; they confer intellectual property rights to NIH inventions.[31] Researchers should comply with the terms of any research agreements governing release of data collected under

[31] NIH Office of Technology Transfer. Retrieved from https://www.ott.nih.gov/policy

the agreement.

The Office of Technology Transfer developed a set of FAQs to help investigators determine which instrument is most appropriate.[32]

Foreign Influences

Biomedical research is an international enterprise accelerated by international collaborations, training experiences in other than home countries, and the sharing of appropriately vetted information. Investigators are encouraged to carefully review the *Guide for NIH Intramural Principal Investigators to Navigate International Interactions and Avoid Inappropriate Foreign Influences on their Research*.[33] Special attention is required when deciding to:

1. invite a foreign scientist to work or train in an NIH laboratory;
2. accept an invitation to establish, oversee, or advise on research programs in foreign countries;
3. write letters of reference for foreign scientists or to provide material support for foreign research activities; and,
4. establish a collaboration with scientists from another country.

Most of our interactions with foreign scientists are beneficial to the NIH mission and lead to longterm collaborations and major scientific advances. It is important to enable continuing and future interactions among NIH scientific staff and foreign scientists where the NIH PI and NIH as an institution are satisfied that the circumstances of such interactions do not allow undue foreign influence on NIH-supported research. ▲

[32] CRADA & MTA FAQs. Retrieved from https://www.ott.nih.gov/faqs/crada-mta-faqs
[33] Guide for NIH Intramural Principal Investigators to Navigate International Interactions and Avoid Inappropriate Foreign Influences on Their Research. Retrieved from https://oir.nih.gov/sourcebook/personnel/recruitment-processes-policies/guide-nih-intramural-principal-investigators-navigate-international

Scientific Rigor and Reproducibility

Scientific Rigor is the robust and unbiased application of the scientific method to well-defined research questions. To facilitate robust results, valid data are obtained by utilizing independent approaches to address research questions and ensuring that experiments are sufficiently controlled and documented to be reproducible. Reproducibility or replication of experiments, observations, and results is an integral component of the scientific method and allows science to be "self-correcting." Combined, rigor and reproducibility are essential to the generation of knowledge and the elaboration of new principles.[34]

Rigor involves 4 areas of focus:

1. Careful assessment of prevailing knowledge in field of study to identify strengths and weaknesses in prior research and any gaps in knowledge.
2. How applications of the scientific methodology will ensure robust and unbiased experimental design, methodology, analysis, interpretation, and dissemination of information.
3. The careful consideration of biologic variables that can influence experimental design and scientific methodology; i.e., species, sex, age, weight, animal models, and environmental considerations.
4. Validation of reagents, chemicals, biologics, and tests used in the research.

Reproducibility involves the reproduction of results by independent researchers that serves to both validate the original findings and develop the next phases of scientific investigation. Sufficiently detailed information must be provided in the Materials and Methods sections of research studies to enable the replication of experiments by independent individuals or research groups. Technical replicates as well as biologic replicates are necessary to ensure rigorous observations. Data sharing in a timely fashion utilizing publicly accessible databases is essential to ensure rigor and reproducibility.

<u>Approaches to Improve Rigor and Reproducibility</u>

Many journals now include a checklist to ensure appropriate methodologies are detailed. A separate statistical section and an independent statistical review are utilized by many journals to ensure rigorous statistical analyses. While journals have set word limits for research manuscripts, there should be few limits on the length of the methods section so that sufficient details are presented to enable reproduction of research results. Online supplemental methods sections are another mechanism to ensure sufficient details are included. Investigators should report how often technical and biologic replicates are preformed and whether graphs are representative or averages of several experiments. Computation of appropriate sample size should be performed as part of the experimental design. Issues related to randomization procedures and inclusion and exclusion criteria should be explicitly detailed for experimental and clinical data. ▲

[34] Enhancing Reproducibility through Rigor and Transparency. Retrieved from https://grants.nih.gov/policy/reproducibility/index.htm

Research Misconduct

A positive research climate allows and encourages open debate about how data should be interpreted. Often there is more than one way to view the results of any given experiment and science is propelled forward by the discussion. To maintain a positive climate at NIH, differences of opinion should be expressed with civility and respect. Expressing disagreement or a differing interpretation of data is not equivalent to making an allegation of research misconduct.

Research misconduct becomes an issue when the integrity or veracity of the actual data can be questioned. The scientific community and general public rightly expect intellectual honesty in the formulation, conduct, reporting, and reviewing of scientific research. Investigators must act with integrity when editing, analyzing, and presenting data. Deceptive manipulation of data, be it misreporting of data, inappropriate exclusion of data outliers, or inappropriate enhancement of images, are examples of research misconduct. The manipulated data need not be published or presented at a conference to constitute research misconduct.

√ Research misconduct is defined as fabrication, falsification, or plagiarism (FFP) in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research data, materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit (including not citing one's own published work when warranted, which is self-plagiarism). Research misconduct does not include honest error or differences of opinion. The **research record** is the record of data or results, both physical and electronic, that embody the facts resulting from scientific inquiry; including but not limited to emails, research proposals, laboratory records, progress reports, abstracts, theses, presentations, internal reports, and journal articles.[35,36] Research records generated by NIH researchers are owned by NIH, may not be removed from the laboratory, and must be retained as an official NIH record.[1]

√ The NIH takes all **allegations of research misconduct** seriously. All NIH personnel are expected to report observed, apparent, or suspected research misconduct to the NIH Agency Intramural Research Integrity Officer (AIRIO).[35] The procedures followed at the NIH are designed to permit allegations of research misconduct to be processed promptly, confidentially, and fairly. This helps minimize any harm to the public that could result if misconduct is found, and it prevents damage to the career of those who are incorrectly implicated. Allegations of misconduct are handled through three stages: an initial **Assessment** made by the AIRIO that the matter warrants an Inquiry; an **Inquiry** during which a

[35] NIH Intramural Research Program Policies and Procedures for Research Misconduct Proceedings. Retrieved from https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/policy-nih_irp_research_misconduct_proceedings.pdf

[36] 42 CFR Parts 50 and 93; PHS Policies on Research Misconduct; Final Rule. Retrieved from https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

panel of scientists determine if there is substantive, credible evidence of FFP to warrant further examination; and an **Investigation** during which a panel of scientists makes a recommendation to the Deciding Official that the institution make a finding of research misconduct. The procedures to resolve an allegation of research misconduct may include the following: interviewing the person making the allegation (i.e., the Complainant), the subject of the allegation (i.e., the Respondent) and possibly other key staff from the lab; identifying and taking possession of NIH research records contained in laboratory notebooks and electronic files and closely examining them; conferring with subject matter experts including "forensic" data analysts; deliberation of the committee (Inquiry or Investigation); and writing a final report(s). The entire process may take several months to complete.

Although misconduct proceedings are **confidential**, a finding of misconduct may result in NIH taking administrative actions to remediate the harm, consistent with applicable personnel rules and regulations, which may entail notifying certain parties with a "need to know" the sensitive information. A finding of research misconduct may result in the disclosure of the misconduct by NIH to research collaborators, professional journals, professional societies, news media, and the public. Administrative actions taken may include requiring a correction or retraction of pending or published papers, removal of personnel from a project, suspension, salary reduction, reduction in rank, or termination of employment.

√ The AIRIO will also take action to prevent **retaliation** against any complainant who brings forward an allegation in good faith.[35]

Although not research misconduct, poor scientific practices can impact the integrity and productivity of a research program. These practices are called Questionable Research Practices (QRPs) or **Detrimental Research Practices** (DRPs; a term coined by the 2017 NAS Report, *Fostering Integrity in Research*).[37] Examples of troubling DRPs include:

- Honorary or ghost authorship
- Poor stewardship of the research record
- Neglectful or exploitative supervision in research
- Misleading statistical analyses that fall short of falsification

A critical part of training and mentoring is promoting explicit discussion of best practices in the laboratory. To that end, discussion of research ethics, including the required annual case studies found in the Responsible Conduct of Research (RCR) Training Program, should be held regularly by NIH Institutes and Centers.[38] All personnel should understand the responsibilities and expectations relevant to recording and maintaining data in their laboratories, including the requirement to maintain research records for a minimum of seven years after completion of the project. PIs and supervisors should make a

[37] Fostering Integrity in Research. Retrieved from https://www.nap.edu/catalog/21896/fostering-integrity-in-research

[38] Annual Review of Ethics (Case Studies). Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training/annual-review-ethics-case-studies

point to review experimental data frequently. Presentation of figures in group meetings should be accompanied by primary data for verification whenever possible. Perhaps most importantly, PIs must model ethical research practices and ensure that undue pressure to succeed does not create a climate that tolerates DRPs. ▲

Harassment, Sexual Harassment, and Inappropriate Conduct

√ Science depends on creativity, and research has shown that diversity in the workplace increases creativity. Consequently, an inclusive workplace is good for research. In recognition of the importance of fostering and maintaining the most inclusive environment, the NIH leadership in October 2018, initiated a campaign aimed at increasing awareness and elimination of harassment, including sexual harassment, in the research community. This issue is addressed in detail by NIH Policy Manual Chapter 1311 which opens with:

> *"The contributions of each and every member of the National Institutes of Health's community are vital to successfully improving people's health and reducing the burden of disease. An environment where people feel welcome, respected, and valued is necessary for all individuals to contribute to their fullest potential. In alignment with this, the NIH is committed to creating and maintaining a work environment that is free of harassment and other inappropriate conduct. Harassment, bullying, intimidation, threats, or other disruptive behaviors are unacceptable and will be handled with administrative and/or legal action, as appropriate. Actions that run counter to our mission and goals will be met with consequences, no matter who the offender."*

√ The NIH will not tolerate inappropriate conduct or harassment, including sexual harassment. Timely and appropriate action will be taken against any individual found to be in violation of the policy outlined in this document.[39] The Civil Program, within the Workforce Relations Division in the Office of Human Resources, is responsible for conducting administrative inquiries into reports of harassment. Victims of or witnesses to harassment have multiple mechanisms for reporting.[40]

1. One can contact Civil directly by calling the Civil main line (301-402-4845), by reporting online, or by calling the NIH Anti-Harassment Hotline (833-224-3829). Hotline or on-line reporting can be done anonymously.

2. Confidential disclosures can be made to the NIH Office of the Ombudsman[41] or the Employee Assistance Program.[42] Trainees may also report to the Office of Intramural Training and Education (OITE).[43] These offices provide a confidential setting to discuss and clarify your options.

[39] Manual Chapter 1311; Preventing and Addressing Harassment and Inappropriate Conduct. Retrieved from https://policymanual.nih.gov/1311
[40] The NIH Civil Program. Retrieved from https://hr.nih.gov/working-nih/civil/
[41] Office of the Ombudsman. Retrieved from https://ombudsman.nih.gov
[42] Employee Assistance Program (EAP). Retrieved from https://www.ors.od.nih.gov/sr/dohs/HealthAndWellness/EAP/Pages/index.aspx
[43] Office of Intramural Training and Education. Retrieved from https://www.training.nih.gov/

3. It should be noted that all managers at NIH are required to contact Civil if they witness harassment or receive a report of harassment. Civil is available to help a manager understand how best to proceed.

Important links to guidelines and resources dealing with how to report harassment, procedures and offices for remediation, and individual responsibilities can be found at the following:

- The NIH Director: Changing the culture of science to end sexual harassment[44]
- NIH Manual Chapter 1311: Preventing and Addressing Harassment and Inappropriate Conduct[39]
  - Toolkit for Employees[45]
  - Toolkit for Supervisors[46]
  - Toolkit for Trainees and Fellows[47]
  - Toolkit for Contractors[48]
  - Additional Q&As for all staff can be found by visiting the NIH Civil website[49]

To learn more about ways to report a concern, please visit the "How I can Report Harassment or Inappropriate Conduct?" webpage at NIH Civil website.[50]

Disclosure of Personal Relationships Between Supervisor/Supervisee

Learning to become an excellent researcher involves tutelage of junior scientists by more senior mentors. By definition, this process establishes a power differential between the junior researcher and the mentor, who will be evaluating the work and eventually providing references for future employers. Consequently, it is important that relationships are transparent and that there is disclosure of a romantic relationship between supervisor/supervisee in cases where the supervisor has an actual, perceived, or potential for perceived, influence over the professional relationship or workplace.

[44] Changing the Culture of Science to End Sexual Harassment. Retrieved from https://www.nih.gov/about-nih/who-we-are/nih-director/statements/changing-culture-science-end-sexual-harassment
[45] Toolkit for Employees. Retrieved from https://ohr.od.nih.gov/intrahr/Documents/civil/ManualChapter1311ToolkitforEmployees_508.pdf
[46] Toolkit for Managers & Supervisors. Retrieved from https://ohr.od.nih.gov/intrahr/Documents/civil/ManualChapter1311ToolkitforSupervisors_508.pdf
[47] Toolkit for Trainees. Retrieved from https://ohr.od.nih.gov/intrahr/Documents/civil/ManualChapter1311ToolkitforTraineesandFellows_508.pdf
[48] Toolkit for Contractors. Retrieved from https://ohr.od.nih.gov/intrahr/Documents/civil/ManualChapter1311ToolkitforContractors_508.pdf
[49] NIH Anti-Harassment Policy and Guidance. Retrieved from https://hr.nih.gov/working-nih/civil/nih-anti-harassment-policy-and-guidance
[50] "How Can I Report Harassment or Inappropriate Conduct?" Retrieved from https://hr.nih.gov/working-nih/civil/how-can-i-report-harassment-or-inappropriate-conduct

√ The NIH Personal Relationship Policy Statement addresses problems that arise when there is a power differential between persons within a personal relationship. As stated in the NIH Policy Statement: Personal Relationships in the Workplace:[51]

> *Personal relationships (including romantic and/or sexual) between individuals in inherently unequal positions, where one party has real or perceived authority over the other in their professional roles, may be inappropriate in the workplace and are strongly discouraged. If such a relationship exists or develops, it must be disclosed. This applies to all individuals in the NIH community, including employees, contractors, students, trainees, and fellows and includes anyone who holds a position of authority or perceived authority over another individual from a scientific or administrative perspective.*

Persons who are involved in such relationships are required to disclose the relationship to their IC. The agency can then 1) reassign the work of one party to eliminate the supervisor/supervisee relationship, 2) have the supervisor recuse themselves from all official matters that affect the subordinate, 3) inquire as to whether inappropriate actions have occurred, or 4) take other appropriate action to eliminate the potential risk of the relationship.

It should be noted that relationships between senior staff and trainees are not appropriate. If you are involved in a personal relationship and are unsure whether you need to disclose, you can get help by contacting your IC's Executive Officer, by contacting the NIH Office of the Ombudsman,[41] or by reviewing:

- **√** NIH Policy Statement: Personal Relationships in the Workplace[51]
    - Toolkit for NIH staff, including trainees/fellows and contractors[45,47,48]
    - Toolkit for Managers and Supervisors[46] ▲

[51] NIH Policy Statement: Personal Relationships in the Workplace. Retrieved from https://hr.nih.gov/working-nih/civil/nih-policy-statement-personal-relationships-workplace

Peer Review and Privileged Information

Peer review is expert critique of either a written scientific work, such as an article prepared or submitted for publication, a grant proposal, or a clinical research protocol, or of an investigator's research program, as in a site visit. Peer review requires that the reviewer be expert in the subject under review and it is an essential component of the conduct of science. Decisions on the funding of research proposals and on the publication of study results must be based on thorough, fair, and objective evaluations by recognized experts. Therefore, although it is often difficult and time-consuming, scientists have an obligation to participate in the peer review process. In doing so, they make an important contribution to science.

The review should be fair and unbiased and should uphold scientific quality consistent with appropriate publication policies. It should be based solely on scientific evaluation of the material under review within the context of published information and should not be influenced by information unavailable publicly, or by non-scientific information such as authors' affiliations. The reviewer should avoid any real or perceived conflict of interest that might arise because of a direct competitive, collaborative, or other close relationship with one or more of the authors of the material under review. Such a conflict of interest would usually require a decision not to participate in the review process and to return (or not access) material unread. Potential conflicts should always be declared to the person managing the review, such as the editor of a journal or the scientific review officer of a grant review panel. Reviewers should refuse work with known predatory publishers. Reviewers must not review their own manuscripts and fake reviewer accounts should not be used. The transparency of the peer-review system must be maintained through all stages. Some specific review activities may require review and approval by a supervisor and/or deputy ethics counselor in an IC.[52]

An underlying principle for performing peer review is that reviewers should not benefit unfairly from the submitted information. All material under review is confidential information. Material from the review should not be used by the reviewer to guide their own research program. It should not be shared with anyone unless necessary to the review process, in which case the names of those with whom the information was shared should be made known to those managing the review process. Material under review should not be copied and retained or used in any manner by the reviewer unless specifically permitted by the journal or reviewing organization and by the author. ▲

[52] Official Duty Activities. Retrieved from https://ethics.od.nih.gov/topics/ODA/2-ODA-Chart.pdf

Scientific Integrity at the NIH

The National Institutes of Health (NIH) seeks fundamental knowledge about the nature and behavior of living systems through research that it funds and conducts. The mission of the NIH is to apply that knowledge toward enhancing health, lengthening life, and reducing the burdens of illness and disability. The NIH accomplishes this mission in two ways: 1) by being the nation's largest single funder of biomedical research at universities and institutions throughout the U.S. and abroad through its Extramural Research Program; and 2) by conducting applied and basic biomedical research within the laboratories and clinics of its Intramural Research Program.

√ At NIH, scientific integrity refers to maintaining the quality and objectivity of the research activities that the National Institutes of Health funds and conducts, such that they are sound and worthy of the public's confidence.[53]

Upholding high standards of scientific integrity means maintaining the quality and objectivity of the research conducted and funded by the NIH. A commitment to sound, objective science strengthens public trust in policies informed by scientific data. In addition to federal and departmental requirements, the NIH has numerous policies in place to ensure the scientific integrity of its Intramural and Extramural Research Programs. The NIH also participates in a wide range of federal policy-making in the areas of clinical research, biotechnology, and biosecurity. Science seeks verifiable truth. The NIH policies are designed to ensure transparent processes that will lead to objective, credible, and readily available scientific findings. These policies also protect against fraud, waste, and abuse by identifying and addressing fabrication, falsification, and plagiarism thus providing effective stewardship of public funds.

Inquiries about the NIH Scientific Integrity policy may be addressed to the Office of Science Policy.[54] ▲

[53] NIH Policies and Procedures for Promoting Scientific Integrity. Retrieved from https://www.nih.gov/sites/default/files/about-nih/nih-director/testimonies/nih-policies-procedures-promoting-scientific-integrity-2012.pdf

[54] NIH Office of Science Policy. Retrieved from https://osp.od.nih.gov/

Conflicts of Interest

A conflict of interest (COI) is a situation in which a person has a financial, professional, personal, or other interest that may compromise judgment related to the performance of his or her ethical, legal, or professional duties. COIs are an important ethical concern because they can interfere with the objectivity and integrity of science and undermine the public's trust in research. COIs can occur in many different areas of science, including research design and implementation, publication, peer review, service on advisory panels, recruitment of human subjects, and research oversight (e.g., service on institutional review boards or animal care committees). The three main strategies for dealing with COIs are: 1) disclosing the conflict to the affected parties, 2) avoiding the conflict, and 3) taking measures to manage the conflict and reduce its impact. When there is a potential COI, full disclosure and complete transparency is always the best policy. Most scientific journals and grant review organizations have rules concerning the disclosure of COIs, which NIH scientists should follow.

The NIH Ethics Program has specific rules concerning COIs, outside activities (such as consulting and speaking), gifts, honorary awards, and investments, and these issues are an integral component of the federal government's annual reporting and online ethics training.[55] Intramural researchers should know these rules and, when in doubt, refer any questions to the Deputy Ethics Counselor of their Institute or Center.

√ Scientists should disclose all relevant financial interests when required by the NIH Ethics Office, including those of the scientist's immediate family, to: 1) the scientist's Institute or Center during the planning, conducting, and reporting of research studies; 2) funding agencies before participating in peer review of applications for research support; 3) conference organizers before presentation of results; 4) journal editors when submitting or refereeing any material for publication; and 5) anyone receiving oral or written communications about the scientist's research. Financial interests include, but are not limited to, ownership of stock or equity, patents, consulting arrangements, honoraria, service on advisory boards, or management appointments having fiduciary responsibilities.[56]

Another type of conflict that can occur in research is a conflict of commitment. Conflicts of commitment may arise when researchers devote excessive time to activities that have no direct bearing on their official employment duties. Outside activities (with or without compensation) are not permitted during work hours. Outside activities can take away time from official duties and, in general, all such outside activities require prior review from the Institute or Center (IC) ethics office. Examples could include excessive commitments of time for work on behalf of committees of scientific societies or journals or participating in outside clinical practice.

Similarly, over commitment—even though well-intended—can become an ethical problem. For example, when researchers take on too many trainees, or oversee too many clinical trials, they may

[55] NIH Ethics Program. Retrieved from https://ethics.od.nih.gov/default.htm
[56] Manual Chapter 2400; Ethics. Retrieved from https://policymanual.nih.gov/2400-01

be unable to give a best effort to all of them. Signs of over commitment include when advisors cannot find sufficient time to meet with their fellows or to review and critique first drafts of manuscripts within a few days or a week, or when PIs are unable to personally supervise the running of their clinical trials. Failure to personally oversee clinical research that uses FDA-regulated products is one of the most common findings cited in audit reports and FDA warning letters.

Human Subjects

√ The NIH Human Research Protection Program has standard operating procedures for dealing with COIs in research with human subjects.[57,58] ▲

[57] 18 USC §§ 203,205, and 207-209; 5 CFR Parts 2634-2641, 5 CFR Parts 5501-5502
[58] HRPP Standard Operating Procedure/Policy Approval & Implementation. Retrieved from https://irbo.nih.gov/confluence/display/IRBO/HRPP+Policies+and+Procedures

Social Responsibility, Media Inquiries, and Dual-Use Research

According to the NIH mission statement, one of the goals of NIH is "to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."[59]

Scientific research conducted by NIH intramural investigators often provides information and knowledge that can be used to inform the subsequent diagnosis, treatment, or prevention of diseases and advance human health and well-being. However, research may sometimes have unintended adverse social impacts. For example, publishing a study on sexually transmitted diseases and drug abuse in an identifiable community may lead to discrimination and bias against members of that community. Research that provides data on the risks of a vaccine might discourage members of the public from having their children vaccinated. Publicly sharing the sequence of a universal virulence factor might enable others to make a deadly bioweapon from an otherwise harmless organism.

NIH intramural investigators therefore have a responsibility to anticipate the possible social and environmental consequences of their research and to take steps to minimize their potential for harm. Scientists who are studying identifiable communities or populations, for example, should be aware of the potential impact of their research on those communities and, when appropriate, work with community leaders to ensure that their research addresses important community needs. In some cases, it may be necessary to delay publication of research to allow for additional review and comment by NIH committees, journal editorial boards, or communities impacted by the research. When research may be readily misused by others to threaten public health and safety, agriculture, the environment, or national security, scientists should consider whether it should be published in full, in redacted form, or possibly not at all.

Media Inquiries

News media inquiries also raise issues concerning social responsibility for NIH scientists, since communications with the news media are an opportunity to educate the public about important advances in biomedical research.[60] However, journalists and members of the public may sometimes misinterpret or misunderstand the results of research. Also, communications with the news media can have a significant impact on the public's opinion of NIH research. Intramural investigators should contact their institute's communications office prior to responding to inquiries from the news media. Investigators who are being interviewed by the news media should communicate their main points in a manner that is both accurate and understandable to the public.

[59] NIH Mission and Goals. Retrieved from https://www.nih.gov/about-nih/what-we-do/mission-goals
[60] Guidelines on the Provisions of Information to the News Media. Retrieved from https://www.hhs.gov/sites/default/files/media_policy.pdf

Dual Use

√ The United States Government policy defines dual use research of concern as: "research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security."[61] The NIH Intramural Research Program requires that each publication be evaluated for dual use; and, if questions are raised, a central committee works with the author to ensure that information contained within the manuscript does not support nefarious use.[62] Annual Dual Use Research of Concern (DURC) reviews must be completed in the NIH PI Dashboard (requires authorization for access).[63] These reviews must be certified by the PI of record on the recombinant materials or pathogen registration document. ▲

[61] United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. Retrieved from http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
[62] Dual-Use Research. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research
[63] NIH PI Dashboard. Retrieved from https://oms.ors.nih.gov

Animal Care and Use

The use of laboratory animals is an essential component of biomedical research, and humane and effective use of animals is a necessary and important element of such research activities. Animal research, for the purposes of these *Guidelines and Policies*, is defined as *in vivo* research performed on laboratory animals in order to develop knowledge that contributes to the improvement of health and well-being of humans as well as other animals.

The NIH Office of Animal Care and Use (OACU) provides oversight of animal research in the NIH Intramural Research Program (IRP) and provides a full range of resources related to policy, training, guidelines, and regulations.[64] The animal care and use program of each NIH Institute and Center is directed by an institute-appointed Animal Program Director who is a senior veterinarian possessing extensive research in animal medicine and care expertise. An Animal Care and Use Committee (ACUC) is appointed by the Institute Scientific Director to provide oversight of an institute's animal care and use program. The ACUC consists of institute scientists, nonscientists, safety specialists, and non-IC affiliated individuals. All components of the intramural NIH Animal Care and Use program are accredited by AAALAC International; meet the Public Health Service Policy and standards for the care and use of laboratory animals; and comply with the US Animal Welfare Regulations.[65]

Before conducting research involving animal subjects, researchers must develop a detailed Animal Study Proposal (ASP) that is approved by an ACUC. The ACUC has responsibility for ensuring that the proposed research follows all pertinent regulations governing the ethical use of animals in research. This includes ensuring that personnel are properly qualified to conduct the study and trained in the specific animal procedures used in the study.

√ When developing an Animal Study Protocol, investigators should adhere to the following principles:[66]

> Reduce the number of animals requested to a minimum but adequate number required to achieve the experimental goals. Where applicable, this number should be dictated by the amount of data required to achieve significant statistical power to support the study's conclusions.
>
> Refine the experimental methods to minimize the pain and stress experienced by the animal subjects.
>
> Replace study animals with animals of a lower phylogenetic ranking or non-animal models whenever possible: e.g., insects, cell lines, computational models.

[64] NIH Office of Animal Care and Use. Retrieved from https://oacu.oir.nih.gov/
[65] NIH Manual Chapters and Other Relevant NIH Policies on Animal Care and Use are Summarized. Retrieved from https://oacu.oir.nih.gov/nih-policies
[66] PHS Policy on Humane Care and Use of Laboratory Animals. Retrieved from https://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf

In addition, NIH expects that all animal studies consider sex as a biological variable, or an adequate explanation be provided addressing why this is not possible.[67]

All staff participating in animal research must initially complete the course "Using Animals in Intramural Research: Guidelines for Animal Users."[68] Refresher training is required every three years. Other training may be required for studies using certain animal species and employing particular experimental techniques. Principal investigators receive further training from the course "Using Animals in Intramural Research: Guidelines for Principal Investigators." [69]

Scientists should be mindful that views on animal research vary considerably. As such, it is absolutely critical that all research involving animals be conducted in accordance with the highest ethical standards as reduced to practice through the established guidelines and regulations (available, for reference, through the OACU). Furthermore, scientists should take responsibility for how their animal research is portrayed in the public domain, keeping in mind that communicating this high standard of practice and care is important for securing the public's continued trust and support for these important activities. ▲

[67] NIH NOT-OD-15-102; Consideration of Sex as a Biological Variable in NIH-funded Research. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html
[68] Training Resources. Retrieved from https://oacu.oir.nih.gov/training-resources
[69] NIH Office of Animal Care and Use Training. Retrieved from https://oacutraining.od.nih.gov/public_menu.aspx

Human Biospecimen Tracking and Storage

√ Biological specimens (or "biospecimens") from study participants must be stored, tracked, shared, and disposed of according to the highest ethical and scientific standards to maintain the public's trust, to preserve and protect the specimens and the substantial investment these resources represent, and to facilitate research by maximizing use of the specimens.[70] All human biospecimens acquired by scientists in the NIH IRP should be handled and stored following the best practices available. Human biospecimens include blood and other body fluids, tissues, nucleic acids, and other direct derivatives from human tissues including human embryonic and induced pluripotent stem cells, and other immortalized human cell lines.[71]

NIH has developed detailed *Guidelines for Human Biospecimen Storage, Tracking, Sharing and Disposal*[72] as is required by Congress, in Section 104 of the National Institutes of Health Reform Act of 2006 (Pub. L. 109-482), enacted on January 15, 2007.[73]

The Guidelines cover all aspects of human biospecimen storage and tracking and address legal and ethical considerations; collection and storage; inventory database systems and tracking; quality management practices, including standard operating procedures; shipping and sharing; and custodianship. The Guidelines reinforce the requirements that human biospecimens used by NIH researchers must be:

- Collected in accordance with an IRB approved informed consent that is properly signed by the subject, or under an approved waiver of informed consent granted by an independent ethical review body, in accordance with 45 CFR Part 46, Protection of Human Subjects, as applicable and appropriate;

- Used under prospective and continuing IRB review and approval or an exemption from IRB review from the NIH Office of the IRBO, as applicable and appropriate;

- Stored and used in accordance with the Privacy Act, as applicable and appropriate;

- Handled in accordance with the U.S. Occupational Safety and Health Administration's

[70] Manual Chapter 1189; Policy for the Management of and Access to Scientific Collections. Retrieved from https://policymanual.nih.gov/1189
[71] 45 CFR 46; Protection of Human Subjects. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
[72] Guidelines for Human Biospecimen Storage, Tracking, Sharing, and Disposal within the NIH Intramural Research Program. Retrieved from https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-biospecimen.pdf
[73] Biennial Report of the Director. Retrieved from https://report.nih.gov/biennialreport10-11/appendices/NIH_Appendix_A.html

Bloodborne Pathogens Standard and best practices to protect the integrity of biospecimens and protect the workers;

• Packed and shipped conforming to all applicable regulations and standards, including the U.S. Department of Transportation and International Air Transport Association standards; and stored with an individual computer-generated label or electronic tracking device with a unique identifier, which enables the investigator to link to a basic set of information on specimen acquisition or the protocol and informed consent (or waiver) under which the specimen was collected, as well as the NIH Clinical Center Clinical Research Information System patient identification number, as appropriate, and which is able to withstand all potential storage conditions. ▲

Health & Safety

√ The promotion of health and safety policies, practices, and procedures is the responsibility of each member of the NIH community. Each person in the laboratory has a vital role to play by ensuring that research is conducted in a manner that keeps personnel in the laboratory safe, protects that community from research-associated hazards, and maintains the public trust of scientific research.[74]

Employees are expected to perform their work in a safe manner and to ensure that they do not place themselves, coworkers, study participants, visitors, or support personnel at risk of injury or illness due to unsafe conditions.

All employees are responsible for attending required safety training, wearing appropriate personal protective equipment (PPE), and following safety procedures established by the NIH, their IC, and their specific laboratory.[75]

√ Supervisors (e.g., principal investigators, laboratory directors, laboratory managers, etc.) must provide a workplace free of known hazards for their laboratory staff and visitors. Supervisors should conduct a risk assessment of all laboratory activities to identify potential hazards and implement control strategies for those hazards. They must ensure that their staff are aware of these hazards and are properly trained to minimize or eliminate the hazards.[74]

The NIH, through the Office of Research Services, has many resources available to assist the research community in conducting their research in a safe and responsible manner. These resources include:

- The Division of Occupational Health and Safety (DOHS) provides expert guidance and technical support for the NIH research community. Each institute is assigned a safety specialist who serves as a safety resource for researchers, laboratory managers, supervisors, and IC senior management.[76]

- Additionally, the DOHS Occupational Medical Service (OMS) supports the research community with all occupational safety and health concerns. The NIH OMS provides support for medical emergencies, pre-placement evaluations, surveillance programs (e.g., the Animal Exposure Program), support for work-related travel, and basic care for work-related injuries

[74] Manual Chapter 1340; NIH Occupational Safety and Health Management Program. Retrieved from https://policymanual.nih.gov/1340#06CAE9F2
[75] NIH Office of Management; Training Requirements & Available Courses. Retrieved from https://www.safetytraining.nih.gov/
[76] Division of Occupational Health and Safety. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/Pages/safety_health_specialists.aspx

and illnesses. All injuries and illnesses must be reported to the OMS.[77]

• The Division of the Fire Marshal (DFM) proactively addresses the fire protection and life safety needs of the NIH community by mitigating risk through collaborative services such as design reviews, pre-occupancy inspections, fire safety consultative services, and a wide-range of other fire safety services.[78]

• The Division of Radiation Safety (DRS) specializes in radiation safety, regulatory compliance, and risk management for biomedical and clinical research efforts that directly support the NIH mission. They provide comprehensive services and innovative solutions to protect individuals, populations, and the environment from ionizing radiation.[79]

Other resources for help maintaining a safe and healthy research environment include:

• The NIH Occupational Safety and Health Committee (OSHC). The OSHC provides safety policy recommendations to the Director of the NIH in matters pertaining to occupational health, accident control, and fire prevention.[80]

• Individual IC safety and health committees. Each IC has a safety and health committee that addresses specific safety needs of the IC. The IC safety and health committees turn the broader framework of NIH policy into practices and policies that work for their specific IC.

• Safe Techniques Advance Research Science (S.T.A.R.S.) Training Program. This program is for NIH summer students, aged 21 and under. The S.T.A.R.S. program provides students with the knowledge of a broad range of safety topics applicable to a biomedical research facility in a hands-on "Learn by Doing" laboratory environment. It fosters critical thinking and problem-solving skills vital to potential hazard recognition and accident prevention through mock learning scenarios and challenges. Students learn how important it is to stop, think, and apply safe laboratory practices.[81]

Maintaining a safe and healthy research environment is an important responsibility that is shared by all NIH personnel. This includes regularly reviewing all stored materials, keeping an inventory of all biological materials, and appropriately disposing of materials no longer in use. It requires the support of everyone to ensure that research at the NIH is conducted in a manner that protects all NIH personnel and the community around us. It is consistent, well-planned, conducted by trained personnel, and is

[77] DOHS Occupational Medical Service. Retrieved from https://www.ors.od.nih.gov/sr/dohs/HealthAndWellness/OccupationalMedical/Pages/oms_main.aspx
[78] Division of the Fire Marshal. Retrieved from https://www.ors.od.nih.gov/ser/dfm/Pages/default.aspx
[79] Division of Radiation Safety. Retrieved from https://drs.ors.od.nih.gov/Pages/default.aspx
[80] Occupational Safety and Health Committee. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/Pages/Occupational-Safety-and-Health-Committee.aspx
[81] Student Laboratory Safety Training. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/Training/Pages/student_labtraining.aspx

done using proper equipment that minimizes variables and compensates for the unexpected. Safe science is good science. ▲

Fetal Tissue Research

Human fetal tissue (HFT) has intrinsic cellular properties that make it invaluable for innovative, translational research, but its use also has profound ethical implications. NIH intramural investigators and contractors should be mindful that research involving HFT requires significant additional oversight, and must be conducted in accordance with applicable federal, state, and local laws, regulations, and policies.[82]

√ Researchers may acquire, use and store HFT for intramural research projects. Acquisition, from either a commercial source or from an academic institution, clinic, or hospital, requires prior approval.[82] Researchers are also required to report annually on their acquisition, use or storage of HFT.[72] Use of HFT is reported annually on the publicly facing Research, Condition, and Disease Categories (RCDC) by intramural project number.[83] Intramural researchers with HFT projects are at times required to answer data calls on various aspects of their use of HFT. Research on transplantation of HFT for therapeutic purposes is permitted but requires additional intramural regulatory oversight because of the statutory provision(s) addressing such research. Please contact the Office of Intramural Research if you are considering research in which HFT or cells would be transplanted as part of clinical research.

√ All experiments using HFT must be reviewed and approved either by the Office of Human Subject Research Protections, via a determination of "Not Human Subjects Research" for de-identified tissue, or when tissues have associated identifiable information via a protocol approved by the IRB.[71,84] In association with human subjects review, the investigator will execute an Attestation document that must be filed with the IC (with a copy retained in the investigator's records). A copy of the Attestation must accompany all requests for purchase of HFT from commercial sources. All commercial suppliers of research material must provide documentation that they comply with the applicable Federal law and policies.

When HFT is received as part of collaborations with organizations outside of the NIH, either a Material Transfer Agreement or Collaborative Agreement must be executed, which contains specific language assuring that the materials were obtained in compliance with the applicable federal law and policies or alternatively provided information on comparable restrictions in force in their country if coming from outside the United States.

Derivation of human Embryonic Stem Cells (hESCs) from human embryos in the intramural program is prohibited by the annual appropriations restriction on funding of human embryo

[82] Special Research Considerations. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations
[83] Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC). Retrieved from https://report.nih.gov/funding/categorical-spending#/
[84] NIH NOT-OD-15-143; NIH Policy on Informed Consent for Human Fetal Tissue Research. Retrieved from https://grants.nih.gov/grants/guide/notice-files/not-od-16-033.html

research. Researchers may acquire existing, approved hESCs from a commercial source or through an MTA, following intramural guidelines and processes. [85] ▲

[85] Human Embryonic Stem Cell (hESCs) Use in the Intramural Research Program. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/human-stem-cell-use/human-embryonic-stem-cell-hescs-use-intramural-research-program

Human Subjects Research

√ Research involving human subjects conducted by NIH intramural researchers is governed by various federal regulations, ethical standards, and policies that protect the rights and welfare of individuals who participate in research and promote the public's trust in the research enterprise. These include federal regulations, most notably 45 CFR 46, the DHHS Protection of Human Subjects (Subpart A, the "Common Rule" and Subparts B-E)[71] and Food and Drug Administration (FDA) regulations (where applicable); the ethical principles found in the Belmont Report; NIH policies; and HRPP Standard Operating Procedures/Policies (SOPs) developed by the Office of Human Subjects Research Protections (OHSRP). OHSRP administers the NIH Human Research Protection Program (HRPP), with support from NIH Institutes and Centers, NIH officials, NIH Institutional Review Boards (IRBs), researchers, and staff of the Intramural Research Program (IRP) who conduct and support research. The NIH HRPP is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The OHSRP, in support of the Deputy Director for Intramural Research, develops and maintains the NIH HRPP SOPs.[86] The NIH HRPP SOPs can be found on the Office of Institutional Review Board Operations (IRBO) website.

√ No research involving human subjects, including their identifiable data or specimens, may commence until after the investigator has obtained IRB review and approval or a determination that the proposed activity is exempt from IRB review.[87]

Human Subjects Research refers to activities in which an investigator, for research purposes:

i. Obtains information [*about* the individual] or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens [*from living individuals*].[71]

For information on whether a specific activity might constitute human subjects research or not, refer to guidance available on the Office of IRBO website.[88]

All intramural investigators conducting human subjects research that will not be directly overseen by an NIH Institutional Review Board (IRB) are expected to consult with the Office of IRBO.

√ All IRP investigators who conduct human subjects research are required to complete CITI human subjects research protections training in order to assure that they understand what is required when

[86] HRPP Policy and Procedures. Retrieved from https://irbo.nih.gov/confluence/display/IRBO/Policies+and+SOPs
[87] HRPP SOP 7; Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBS). Retrieved from https://irbo.nih.gov/confluence/display/IRBO/HRPP+Policies+and+Procedures
[88] Decision Tree: Is the Activity Research Involving Human Subjects?. Retrieved from https://irbo.nih.gov/confluence/display/IRBO/Templates+Forms+and+Guidelines#TemplatesFormsandGuidelines-Guidance

they conduct this type of research.[89] Additionally, investigators, who conduct non-exempt human subjects research, must also complete CITI Good Clinical Practice (US FDA Focus) training.

The NIH HRPP requires that each protocol approved by an NIH IRB have a single PI who is responsible for its design and conduct.[90] PIs also have special responsibilities to provide leadership and oversight over the conduct of their research protocol(s) and the research team. Upon IRB approval, the PI may delegate specific aspects of the conduct of the research to other members of the research team in writing, but the PI retains overall responsibility.

Collection, Storage, and Sharing of Data

√ Investigators must ensure the integrity and confidentiality of data collected in the course of clinical research and protect the privacy of human subjects. Attention should be paid to:

- Appropriate safeguards to protect the confidentiality of subject data; for example, by removing personally identifiable information (PII) from data, specimens, and records; utilizing secure electronic systems and locations; and limiting who may have access to the specimens or data.
- Appropriate storage and retention of research records, data, and specimens, in accordance with NIH policy and FDA regulations, as applicable.[1]
- A Plan for Data Sharing, approved by the IC Scientific Director or designee, as required by the Intramural data sharing policies, including:
  - Human Data Sharing (HDS) Policy (July 31, 2015);[13] and
  - Genomic Data Sharing (GDS) Policy: The GDS policy applies to all NIH IRP research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data. These data must be submitted to a repository (e.g., dbGaP). Individual ICs may have additional interpretations and requirements.[13]

More information about Intramural data sharing policies can be found in the Sourcebook.[91]

[89] HRPP Policy Number 201; Education Program. Retrieved from https://irbo.nih.gov/confluence/display/IRBO/Policies+and+SOPs
[90] HRPP SOP 19; Investigator Responsibilities. Retrieved from https://irbo.nih.gov/confluence/display/IRBO/Policies+and+SOPs
[91] Intramural Data Sharing. Retrieved from https://oir.nih.gov/sourcebook/intramural-program-oversight/intramural-data-sharing

Registration and Results Reporting of Clinical Trials

√ The Clinical Center Office of Protocol Services registers all IRB-approved NIH human clinical trials[92] at ClinicalTrials.gov when NIH is identified as the responsible party. Clinical trials must also comply with the Food and Drug Administration Amendments Act (FDAAA)[93] and NIH policy requirements for reporting of results.[94] The PI must ensure that trial results and informed consent documents are submitted within the required time frames. The PI may consult the IC Clinical Director for additional information. ▲

[92] 42 CFR 11; Clinical Trials Registration and Results Information Submission. Retrieved from https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

[93] FDA Amendments Act (FDAAA) Section 801: "Basic Results" Provisions. Retrieved from https://www.govinfo.gov/content/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf#page=82

[94] 42 CFR 11 402(j); Clinical Trials Registration and Results Information Submission. Retrieved from https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol1/xml/CFR-2017-title42-vol1-part11.xml

Research Material Management and Research with High-Consequence Pathogens: Institutional Biosafety

√ The NIH Institutional Biosafety Committee (IBC) oversees intramural use of microbiological agents, their vectors, and associated recombinant and synthetic molecular technology. These are powerful research tools but can pose significant risk to the research personnel who use them as well as to the environment during their use, storage, and disposal; therefore, researchers using these tools share the responsibility for their ethical use with the NIH IBC.[74]

It is a requirement at NIH that Principal Investigators register with the NIH IBC any recombinant DNA experiments covered under the NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules.[95] Work involving potentially infectious human, plant, or animal materials, and human pathogens, human and non-human primate blood, tissues, and body fluids, including primary human cell cultures, must also be registered with the IBC.

√ All potentially hazardous biological materials must be inventoried prior to long-term storage in any freezer, refrigerator, cold room, or other location. This requirement applies to all NIH federally owned or leased facilities and all NIH contractor or subcontractor facilities. Inventory data should be recorded at the time of registration. Accurate inventories should be maintained in each laboratory and reviewed at least annually during the registration review process. ICs must develop policies that assure that unneeded or unwanted materials are not abandoned by research personnel. Annual inventory updates are required.[96]

The DOHS implements various programs and policies that address conducting high-risk infectious disease research. Among other activities, the DOHS is responsible for implementing the NIH Biological Surety Program, the NIH Select Agent Program (see below), and the NIH Quarantine Permit Service Office (QPSO). All questions related to requirements of these programs can be directed to the DOHS at 301-496-2960.[97]

Select Agent Program

√ Select Agents are biological agents and toxins that the Federal Select Agent Program (SAP) (HHS and USDA) has determined to pose a severe threat to both human and animal health, to plant health, or to animal and plant products known as select agents/toxins.[98] Any microorganism or toxin capable of harming living organisms or the environment, regardless of its origin (naturally occurring, engineered, or synthesized) can be classified as a select agent. Anyone planning to work with select agents/toxins must

[95] NIH Guidelines. Retrieved from https://osp.od.nih.gov/biotechnology/nih-guidelines/
[96] Manual Chapter 3035; Working Safely with Potentially Hazardous Biological Materials. Retrieved from https://policymanual.nih.gov/3035
[97] Biological Safety. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/bio_chem_safety.aspx
[98] NIH must comply with the regulations and requirements of 42 CFR 73, 7 CFR 331 and 9 CFR 121.

enroll in the SAP and receive approval prior to the possession, use, and transfer of select agents/toxins. If unescorted access is required to areas containing select agents or areas associated with the biocontainment of select agents, individuals must contact the SAP. Additional information can be found at the Federal Select Agent Program on the Center for Disease Control website[99] and the DOHS Select Agent Program website.[100]

Biological Surety Program

√ The NIH Biological Surety Program (BSP) was established to ensure that work pertaining to high risk infectious disease research is performed in the safest and most responsible manner possible by a trained, responsible, and reliable workforce. The Biological Surety Program applies to all intramural NIH personnel, Federal and non-federal, and visitors assigned to work in BSP spaces. BSP spaces are defined as all NIH ABSL-4, BSL-4, ABSL-3, and BSL-3 facilities, including areas of critical infrastructure, and information systems that support these laboratories.[101]

Quarantine Permit Service Office (QSPO)

√ Individuals wishing to import any biological material (infectious or non-infectious) from outside the United States to the NIH must contact the QPSO.[102] Upon review of submitted forms, QPSO determines whether the intended importation requires the issuance of a CDC import permit and label or an NIH Letter for Non-Infectious Importation. QPSO provides the required documentation to the applicant. Individuals wishing to export any biological material (infectious or non-infectious) from the NIH to a destination outside of the United States must submit a "Declaration for Exportation of Biological Materials" (NIH 2388) to QPSO and secure the necessary approvals prior to shipment.[103] ▲

[99] Federal Select Agent Program. Retrieved from https://www.selectagents.gov/
[100] Select Agent Program. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/select_agents.aspx
[101] Manual Chapter 3037; NIH Biological Surety Program. Retrieved from https://policymanual.nih.gov/3037
[102] Biological Materials Shipping. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/shipping_biological_material.aspx
[103] Manual Chapter 1340-1; Permits for the Import, Transfer, or Export of Biological Materials. Retrieved from https://policymanual.nih.gov/manage/chapter/view/1340-1

Ethical Concerns Related to NIH Information Technology

As a science, research, and information-based organization, the NIH relies on computers, networks, and a variety of other information technology (IT) systems to fulfill its mission. Information technology touches every aspect of research and discovery, including the acquisition of data, the processing of data, the archiving of data, and the dissemination of our research to the public. Accordingly, the NIH works continuously to improve our information security posture, and proactively manage risk while supporting and safeguarding the NIH community, culture, and mission. From an ethics perspective there are four major IT topics that members of the NIH community should be aware of: IT security, accessibility, compliance, and privacy. These are discussed below.[104]

IT Security

√ Our first line of **defense** of our IT infrastructure is our researchers. The rigorous measures needed to **protect research data** often seems to be in marked contrast to the open, collaborative nature of science. Information security is a balancing act, weighing openness and transparency against the risk that always accompanies the choices we make, our behaviors, and the care we take with our security. Regular IT Security and Privacy Awareness Training is taken seriously at the NIH and is required of all staff.[105]

Internal Risks. Be aware that security breaches that occur within the institution are often accidental or the result of complacency, but they also may be malicious, with intent to harm.

- Accidental breaches may occur as a result of inappropriately directed emails that include sensitive documents or personally identifiable information. How often do you get bounce-back emails that ask, "Did you mean to send this to me?"
- Complacency stems from taking a "this rule doesn't apply to me and won't affect what I do" attitude. How often do you forget about data security and send sensitive information inappropriately to your own personal email or download it to a USB drive?
- We seldom think about the potential for malicious threats from our scientists and trainees. We may know coworkers who seem permanently dissatisfied, want to take shortcuts, or look for information not related to their job online, regularly surfing the Internet and perhaps even downloading inappropriate information.

[104] IT Governance & Policy; IT Policy, Standards and Guidance. Retrieved from https://ocio.nih.gov/ITGovPolicy/Pages/spec_policy.aspx

[105] Manual Chapter 2813; NIH Information Security and Privacy Awareness Training Policy. Retrieved from https://policymanual.nih.gov/2813. The training may be accessed at https://irtsectraining.nih.gov/

Know When and How to Get Help

- When? Get help immediately if you encounter problems with system access, cannot connect using VPN, lose a laptop or mobile device, get caught in a phishing scheme, or accidentally disclose sensitive information. Report lost or stolen equipment within one hour.
- How? Contact the NIH IT Service Desk http://itservicedesk.nih.gov/.

Select Tips

- Use a strong password or pass-phrase containing a sequence of upper and lower-case letters and characters that is easy to remember and type.
- Use two-factor authentication when available.
- Be conscious of any sensitive information or data to which you have access. If you do need to distribute sensitive information, make use of government-approved encryption procedures.
- When using portable equipment, be extra-careful. Oftentimes, this type of equipment vanishes from cars, homes, airports, and public transportation.
- When using social media, be careful not to blur your professional and private lives. Remember that once you post something, it is virtually impossible to remove it.

IT Accessibility

√ Because all Americans are entitled to the same access to government-generated resources, such as NIH web pages, announcements, web movies, pictures, and directives, it is our shared responsibility to ensure that NIH-generated IT resources are accessible to people with disabilities (such as vision and hearing impairment)**.**[106]

IT Compliance

√ The Department of Health and Human Services (HHS) permits limited personal use of HHS IT resources (including government-furnished equipment such as mobile devices), which involves no more than minimal additional expense to the government, as long as the personal use[107] is minimally disruptive to personnel productivity; does not interfere with the mission or operations of HHS; and does not violate the *HHS Policy for Information Systems Security and Privacy*[108] or the *Rules of Behavior for Use of HHS Information Resources*.[109] It is important to remember that the privilege of using NIH computers, tablets,

[106] IT Governance & Policy; Section 508: Accessibility at NIH. Retrieved from https://ocio.nih.gov/ITGovPolicy/NIH508/Pages/default.aspx
[107] HHS Policy for Personal Use of Information Technology Resources. Retrieved from https://intranet.hhs.gov/sites/default/files/s3fs-public/s3fs-public/pol-pers-use-it-rsrc.pdf
[108] Policy for Information Technology (IT) Security and Privacy Incident Reporting and Response. Retrieved from https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/policy-it-security-and-privacy-incident-reporting-and-response/index.html
[109] Rules of Behavior for Use of HHS Information Resources. Retrieved from https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/rules-of-behavior-for-use-of-hhs-information-resources/index.html

phones, networks, and other IT resources comes with the mandatory acceptance of a set of general rules of behavior designed to safeguard these resources and assure for their ethical use.[110]

IT Privacy

√ There are several facets to IT privacy. First, we need to protect information acquired in the course of our work and whose disclosure could harm others: personally identifiable information (PII), sensitive information (SI), and protected health information (PHI). Secondarily, we must be aware that we have no guarantee of privacy in our own communications such as e-mails when we use government-owned equipment (computers, tablets, telephones). We must keep all this in mind when posting any documents on the Web; on a social network for example. We also have to be aware of where we store documents; our own computer, a local server, or on the Cloud.[111] ▲

[110] NIH Information Technology General Rules of Behavior. Retrieved from https://irtsectraining.nih.gov/CSA/0301010_BehaviorRules.aspx

[111] Manual Chapter 1745; NIH Information Technology (IT) Privacy Program. Retrieved from https://policymanual.nih.gov/1745

Whistleblowing and Whistleblower Protections

As a community of scientists, we share a responsibility to disclose wrongdoing that impacts the integrity of NIH research, public health and safety, our government's honesty, accountability, and efficiency. Federal law protects "whistleblowers" (those who make a good faith allegation of a wrongdoing) from retaliation.

Reporting Concerns

HHS employees and agents (contractors, visiting scientists) can report a violation of any law, rule, or regulation; mismanagement; a gross waste of federal funds; or a substantial and specific danger to public health or safety through the following reporting web forms:

- HHS Office of Inspector General hotline[112]
- U.S. Office of Special Counsel hotline[113]

Allegations involving NIH programs and activities, including misuse of NIH grant or contractor funds, grantee or contractor conflicts of interest, and other misconduct or misuse of NIH resources by NIH employees or others doing business with NIH, can be reported via:

- Division of Program Integrity, Office of Management Assessment, Submit Allegations[114]

Intramural employees may also report concerns related to the NIH research environment using the following reporting web forms:

- Intramural Animal Welfare Concerns[115]
- Intramural Human Research Subject Protections[71]
- Intramural Unsafe or Unhealthful Conditions[116]
- Intramural Research Misconduct concerns[117]
- Intramural Harassment or Civility concerns[118]
- Intramural EEO discrimination concerns[119]

[112] HHS Office of Inspector General; Submit a Hotline Complaint. Retrieved from https://oig.hhs.gov/fraud/report-fraud/index.asp
[113] U.S. Office of Special Counsel Complaint & Disclosure Form. Retrieved from https://osc.gov/Documents/Resources/Forms/OSC%20Form-14.pdf?csf=1&e=HZ1hra
[114] Division of Program Integrity. Retrieved from https://oma.od.nih.gov/DPI/Pages/Home.aspx
[115] Anonymous Reporting of Animal Welfare Concerns. Retrieved from https://oacu.oir.nih.gov/nih-policies/reporting-animal-welfare-concerns/anonymous-reporting-animal-welfare-concerns
[116] Unsafe or Unhealthful Conditions Reporting. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/incidents_accidents/Pages/Report-of-Unsafe-Condition.aspx
[117] Anonymous Reporting of Research Misconduct Concerns. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/research-misconduct/anonymous-reporting-research-misconduct-concerns
[118] Civil Intake Form. Retrieved from https://hr.nih.gov/working-nih/civil/intake-form
[119] EEO Efile. Retrieved from https://nihefile.icomplaints.com/efile-nih-prod/login/

Reporting Retaliation

√ The Whistleblower Protection Act prohibits retaliation. This means it is unlawful for NIH to take or threaten to take a personnel action against an employee because he or she made a protected disclosure of wrongdoing. A protected disclosure is defined as a disclosure of information that the individual reasonably believes evidences a violation of law, rule, or regulation; gross mismanagement; gross waste of funds; and abuse of authority; or a substantial and specific danger to public health or safety. Personnel actions that are covered by this can include poor performance review, demotion, suspension, termination, or revocation or downgrade of a security clearance.[120]

In addition, the law prohibits retaliation for:

- filing an appeal, complaint, or grievance;
- helping someone else file or testifying on that person's behalf;
- cooperating with or disclosing information to OSC or an Inspector General; or
- refusing to obey an unlawful order.

If you believe whistleblower retaliation has occurred, you may get more information from the HHS Office of Inspector General (OIG) website,[121] including:

- Information on the Whistleblower Ombudsman, with helpful FAQs
- Information on how to report whistleblower retaliation
- Information on who is eligible for whistleblower protections
- Information on what complaints are investigated by the OIG (including whistleblower disclosures).

Do not assume that telling someone within NIH that you feel retaliated against (making an informal complaint) substitutes for claiming retaliation under the Whistleblower Protection Act through a formal process. ▲

[120] 5 U.S.C. 2302(b)(8)-(9), Pub.L. 101-12; Whistleblower Protection Act of 1989. Retrieved from https://www.govinfo.gov/content/pkg/STATUTE-103/pdf/STATUTE-103-Pg16.pdf

[121] Office of Inspector General. Retrieved from https://oig.hhs.gov/about-oig/about-us/index.asp

Concluding Statement

These *Guidelines and Policies* remind NIH scientists of the applicable rules, policies, and ethical standards to be incorporated into and maintained in the scientific culture of the Intramural Research Program. They provide a framework for the fair, open, and responsible conduct of research without inhibiting scientific freedom or creativity.

Advice on any of the topics covered in this document can be obtained from the offices cited. You can also consult with members of the NIH Committee on Scientific Conduct and Ethics,[122] with your Scientific Director, or with your Training Director. Support is also available from the NIH Office of the Ombudsman.[41] ▲

[122] Committee on Scientific Conduct and Ethics (CSCE). Retrieved from https://oir.nih.gov/sourcebook/committees-advisory-ddir/committee-scientific-conduct-ethics-csce