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Guidelines and Policies for the

Conduct of Research

in the Intramural Research Program at NIH

National Institutes of Health
Office of the Director

Preface

For the last edition of "Guidelines and Policies for the Conduct of Research in the Intramural Research Program (IRP) at the NIH", I wrote a preface that described the emergence of the IRP from the COVID-19 pandemic and the renewal of opportunity and energy it afforded the biomedical enterprise. Little did we know what lay ahead! We have been beset by challenges to the veracity and integrity of science, reductions in our workforce and truncations of the careers of those just getting started. What better time to renew and reinvigorate our knowledge of, dedication to, and dissemination to the public of honesty and integrity in research! It has been said that no good crisis should be allowed to go to waste. We must leverage this apparent crisis as a rallying cry and as a mandate that we ensure that the public knows of all we do both to implement research and scientific integrity to the fullest and to improve and enhance surveillance, enforcement, and updating of their principles and practice.

In order for the NIH to sustain research excellence and to protect the integrity of science and the professional development of each member of the IRP, everyone in the IRP needs to understand the rules of the road for the conduct of intramural research. This edition of Guidelines on the Conduct of Research serves to provide each member of our community, whether they be investigators, trainees, staff researchers, visiting researchers, or support staff, with information they need to be productive, successful, and fulfilled by their contributions. This edition has notable additions to provide guidance on scientific record-keeping, the use of electronic research records, data sharing and use policies, mentoring, dual use research of concern, and posthumous authorship. We are all aware of the importance of publishing our research, but as science becomes more interdisciplinary and as authoring tools become more complex, authorship issues, too, become more complex and can be difficult to resolve. We are pleased that there is a newly updated section on NIH Information Technology with more about the use of artificial intelligence in research, writing, and publication of research papers at NIH.

It is essential 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 conduct and oversight in every aspect of science.

These guidelines were developed by the Scientific Directors in 2007 then revised in 2016, 2019, 2021, 2023, and 2025 by the intramural scientists serving on the Committee on Scientific Conduct and Ethics. This edition was approved on July 30, 2025, by the Scientific Directors.

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National Institutes of Health

9th Edition

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A check mark (**√**) indicates that the section summarizes a specific policy

Contents

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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. ▲

Gold Standard Science

On May 23, 2025, the US President issued an Executive Order (EO) entitled "Restoring Gold Standard Science"[1] which articulates nine standards that should apply to federally funded scientific research. According to the EO, science supported by the federal government should be:

(i) Reproducible;
(ii) Transparent;
(iii) Communicative of error and uncertainty;
(iv) Collaborative and interdisciplinary;
(v) Skeptical of its findings and assumptions;
(vi) Structured for falsifiability of hypotheses;
(vii) Subject to unbiased peer review;
(viii) Accepting of negative results as positive outcomes; and
(ix) Without conflicts of interest.[1]

Many of the chapters in the Guidelines and Policies for the Conduct of Research in the NIH IRP address these standards (see Table 1).

Table 1: Gold Standard Science

Standard	Chapter (s)
Reproducibility	Scientific Recordkeeping, Data Management, Scientific Rigor and Reproducibility, Publications
Transparency	Scientific Recordkeeping, Data Management, Scientific Rigor and Reproducibility, Authorship, Publications
Communicative of error and uncertainty	Scientific Recordkeeping, Scientific Rigor and Reproducibility
Collaborative and Interdisciplinary	Collaborations and Team Science; Ethical Leadership and Management
Falsifiability	Scientific Rigor and Reproducibility
Unbiased peer review	Peer Review; Publications
Acceptance of negative results	Data Management
Without conflict of interest	Conflict of Interest; Ethical Leadership and Management; Peer Review

Other NIH IRP rules and policies, such as policies concerning data sharing, conflict of interest, and publication clearance review, also help to support Gold Standard Science. ▲

[1] The Whitehouse, Restoring Gold Standard Science, May 23, 2025. Retrieved from: https://www.whitehouse.gov/presidential-actions/2025/05/restoring-gold-standard-science/

Academic Freedom

NIH researchers must be able to engage in open discussions and debates about competing scientific theories and be able to challenge existing scientific views. Academic freedom ensures that researchers have the ability to respectfully and openly express ideas, perspectives, and discordant views about scientific data and scholarly research without risk of official interference, professional disadvantage, or workplace retaliation. A framework for the intramural guidance on Academic Freedom is published in the Sourcebook.[2]

Manuscript review

IRP researchers must be able to freely communicate their scientific findings as part of their official duties. The previous manuscript "clearance" form has been updated to a manuscript "review" form[3], to be used prior to initiating submission of scientific publications and products, including perspectives and commentaries. ICs should use the review process to ensure adherence to policy and regulatory compliance (including but not limited to human subject protections, animal study procedures, dual-use or select-agent research regulations, and the NIH Public Access Policy), and not for the review of scientific content and/or findings. Importantly, the review form also mandates the inclusion of a disclaimer that makes it clear that the opinions expressed may not represent those of the NIH, as follows:

This research was supported [in part] by the Intramural Research Program of the National Institutes of Health (NIH). The contributions of the NIH author(s) are considered Works of the United States Government. The findings and conclusions presented in this paper are those of the author(s) and do not necessarily reflect the views of the NIH or the U.S. Department of Health and Human Services.

The form also contains an additional field for certifying when the scientific findings have legislative or policy implications. In those cases, scientists must first work with the NIH Office of Science Policy (OSP) and Office of Legislative Policy and Analysis (OLPA) to ascertain if or how to address them.

Media communications

The NIH media clearance process has also been revised to support academic freedom. Under the previous process, IRP researchers needed clearance from the Office of Communications and Public Liaison (OCPL) before talking to the media. Under the revised process, IRP researchers do not need OCPL clearance, but they must notify the OCPL before providing a statement to the media to allow for coordination with OCPL and make OCPL aware of the media interview. IRP researchers are also strongly encouraged to take advantage of OCPL resources, such as documents that provide guidance on how to interact with the media. Before IRP researchers respond to any media inquiries, they must complete the "Request for Comment" notification form and include 3-5 talking points when filling it out. Scientists who proactively want to engage with the media are encouraged to first consult with OCPL prior to any outreach. When IRP researchers are speaking about their findings and conclusions with a media outlet, they must share that any statements made may not necessarily reflect the views of the NIH or HHS. Scientists may not provide advice on NIH, HHS, or US government policy without prior approval (see Sourcebook for more details).

Scientists must follow existing policies (e.g., ethics, personal social media use, etc.) to communicate about their science in their personal capacity (i.e., not using official NIH titles or affiliations). While practicing

[2] Intramural Academic Freedom Guidance. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications/intramural-academic-freedom-guidance

[3] Manuscript Review Form. Retrieved from https://oir.nih.gov/system/files/media/file/2025-08/form-manuscript_review.pdf

academic freedom, IRP researchers must be cognizant of ethical considerations and real or perceived Conflict of Interests (COI)[4,5] in their communications. Researchers must declare any COIs for full disclosure and transparency and follow NIH Ethics policies and rules[6] regarding outside activities, COIs, receiving gifts, etc.

Allegations of suppression of academic freedom should be made to the Deputy Director for Intramural Research; appeals will be taken to the Principal Deputy Director. Note that non-FTE NIH staff may not interact with the media as representatives of the NIH. ▲

[4] OIR Sourcebook | Ethical Conduct in the IRP. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct

[5] IRP Guidelines on the Conduct of Research. Retrieved from https://oir.nih.gov/system/files/media/file/2025-01/guidelines-conduct_research.pdf

[6] 2400-01 - Introduction to Government Ethics at the NIH. Retrieved from https://policymanual.nih.gov/2400-01#F2B1B70D

Scientific Record Keeping

Good Record Keeping Practices

There's a saying in the law that "if it wasn't written down, it didn't happen." This key idea also applies to scientific research. Good record keeping is essential to the validity, accountability, reproducibility, and integrity of scientific research. Research records document the entire research process, from formulating a question or hypothesis and applying for funding, to designing experiments and studies, developing research protocols, and generating, analyzing, and interpretating data. Research records are the property of the NIH and must be accessible at all times to the Principal Investigator, Lead Investigator or Project Leader (hereafter referred to as PI). All NIH records, including scientific data, must be kept in electronic/digital formats.[7]

Research records include, but are not limited to:

- Research data, including primary data, secondary data, and metadata
- Rules or procedures for collecting, labeling, annotating, storing, editing, cleaning, auditing, processing, excluding, and analyzing data
- Records of materials used in research
- Research protocols, such as protocols for conducting laboratory experiments or research with human or animal subjects
- Rules or procedures for calibrating scientific instruments
- Standard operating procedures for data collection, testing, animal care, patient care, and so on
- Research proposals and grant applications
- Computer software used in data processing, statistical analysis, and digital image manipulation
- Preliminary analyses of data
- Questionnaires
- Informed consent documents
- Audit reports
- Drafts of manuscripts and final publications
- Correspondence with journals
- Correspondence with research oversight committees and funding organizations

Data are a tangible record of an observation made by a human being (e.g., clinical findings or observations of animal behavior) or a machine (e.g., DNA sequence data; MRI or electron microscopy images). Primary (raw, original) data are directly related to the object of study; secondary (or derived) data are indirectly related to the object of study; and metadata are about or derived from the data. For example, for an MRI imaging study of traumatic brain injury, primary data could include MRI images and records of clinical laboratory tests and neurological examinations; secondary data could include spreadsheets, tables, figures, diagrams, and images derived from the data; and metadata

[7] NIH Intramural Electronic Lab Notebook Policy. https://oir.nih.gov/sourcebook/intramural-program-oversight/electronic-lab-notebooks/intramural-electronic-lab-notebook-policy

could include data about these data (such as height, width, pixels, kilobytes, and compression for the MRI images).

Data may be recorded on different media and in different formats, including:

- Electronic notebooks
- Electronic spreadsheets
- Word processing documents
- Machine outputs (such as the output of flow cytometer or DNA sequencer)
- Digital images
- Photographs
- Audio and video recordings
- Temporary paper notes*
- Medical records

* Researchers sometimes face situations in which bringing a laptop or other electronic device into an area is not practical or safe, or some data cannot be recorded efficiently using an electronic device. In these cases, non-digital data must be converted as quickly as possible into digital data to serve as the official record. Hand-written data must be transcribed and/or digitally scanned or photographed and uploaded.

Research materials are physical entities, objects, and substances (other than equipment or instruments) that are used to generate data. For example, in gel electrophoresis, the macromolecules and the gel are materials, and the data would be a digital image of the gel. It is important to keep good records of materials for the same reasons that it is important to keep good records of data. For example, in animal drug safety experiments, it is important to keep records of the species, strain and sex of the animal used, housing, the type of feed, the drug used, expiration data, lot number, and so on.

Research materials may include:

- Tissues, tissue sections on slides, liquid biopsies
- Cells and cell lines
- Blood, saliva, hair
- DNA, RNA, proteins
- Microbes
- Gels
- Chemical reagents
- Dyes, stains
- Pharmaceuticals
- Laboratory animals
- Zoological and botanical collections

There are at least five reasons why it is important to keep good records in scientific research.

First, good record keeping is necessary for data analysis, publication, collaboration, peer review, and other research activities. Research records can help you to communicate with members of your research team and collaborators, brainstorm for ideas, and draft or revise your research plans. When it is time to publish your research, you need to be able to find the data that support your conclusions and analyses. Editors and reviewers may also request additional data beyond what you submit. After publication, you may need to deposit your data in a data repository and share it with colleagues who want to repeat your experiments or examine your work more closely to fulfill journal and NIH requirements for data sharing.[8]

Second, good record keeping is important for reproducing results (see Chapter on Rigor and Reproducibility, below.[9])

Third, good record keeping can help defend you against false allegations of research misconduct. Misconduct allegations commonly arise when other scientists are unable to repeat published research. Often, the underlying reason for this failure is that the original research was not described in sufficient detail in the publication. While good research records cannot prevent you from ever facing allegations of misconduct, they can help you to refute them.

Fourth, good record keeping is mandated by federal law or NIH policy for some types of research, such as research involving hazardous radioactive or biological materials, recombinant DNA, products regulated by the Food and Drug Administration (FDA), laboratory animals, and human subjects. Researchers need to be aware of all applicable record keeping requirements that apply to their research and comply with them. Federal record keeping laws also apply to NIH research.

Records containing information that personally identifies human subjects must comply with NIH policies and federal regulations that protect privacy and confidentiality as well as information technology (IT) security requirements. Federal human research regulations mandate that institutional review boards (IRBs) must determine that confidentiality and privacy will be adequately protected before approving a human research protocol. The Privacy Act also establishes standards for protecting private information collected by the federal government. Investigators who conduct research involving human subjects should contact the NIH's IRB Office (IRBO) with questions about research record keeping storage and security requirements. See discussion of Clinical Research below.

Fifth, good record keeping is necessary to support intellectual property (IP) claims. If you are conducting research that may be patentable, you need records to support your patent application and defend your patent if it is challenged. Record keeping for patentable inventions is much more stringent than other types of record keeping. See additional discussion of IP below.

Responsibilities of the PI

While every member of the laboratory or research group has a responsibility to keep good research

[8] 2023 NIH Data Management and Sharing Policy. Retrieved from 2023 NIH Data Management and Sharing Policy | NIH Office of Intramural Research Also see the "Data Sharing" section under "Data Management" in these guidelines

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

records, data integrity is ultimately the responsibility of the PI. The PI may delegate some of these responsibilities to senior members of the laboratory or research group.

The PI is responsible for:

- Establishing best practices for research record keeping in the laboratory or research group, including practices related to collecting, labeling, annotating, storing, editing, cleaning, auditing, processing, excluding, analyzing data, and sharing data
- Ensuring that members of the laboratory or research group receive proper instruction in record keeping practices
- Ensuring that there is an "index" record of all retrievable data sources related to individuals and projects in the research group
- Convening regular meetings to review data, discuss record keeping practices, and deal with any problems or questions that arise
- Deciding when and how to share and publish data
- Responding to requests for data and materials

Elements of Good Record Keeping

Although record keeping practices vary across scientific disciplines, some principles apply to almost all forms of research. The overarching principle for scientific record keeping is that another person or research group should be able to reproduce or reconstruct your research from your records. If you are an NIH researcher and you leave the NIH before your work is complete, for example, then another researcher should be able to continue your work by consulting your records.

Research records should be:

- Legible
- Clear
- Complete
- Thorough
- Consistent
- Properly annotated to make them accessible
- Well-organized
- Indexed (in some cases)
- In English
- Dated
- Signed or assigned to a particular person
- Recorded so that new entries or corrections can be identified and validated
- Secure
- Backed-up

Records should describe or explain:

- Who conducted it (including the person making the record)
- What you did
- When you did it (clearly stating the date and time of day or whatever form of dating may be appropriate for the experiment)
- Why you did it
- What project the research was part of
- How you did it (including the methodology)
- What materials were used
- The findings
- The interpretation
- The next step(s)

Record Keeping Formats

Electronic Notebooks

An electronic notebook is a system used to create, store, retrieve and share electronic records. Instead of recording information on paper, the sketches, text, equations, images, graphs, and other data are recorded electronically. Electronic notebooks can record data inputted from a keyboard, or other program output, imaging equipment, microphone, and directly from scientific instruments. Electronic notebooks can range in capability and complexity from the simplest types that use ordinary software (such as word processing, spreadsheet, or graphics) on one's computer to annotate and keep track of data files, to more notebook-like systems or special commercial software for authentication.

Electronic notebooks facilitate data input, provide uniform formats for data recording, and allow collaborators to share data and add to the record. Commercial electronic notebook software varies in how much it resembles a paper notebook but usually includes all functions of a paper notebook. If personally identifiable and/or sensitive data are involved, appropriate Privacy Act and IT security standards must be met.

The security of electronic records, including access to a particular electronic notebook, its contents, and authentication of entries in a notebook, is a fundamental issue that must be addressed. Every electronic notebook should have a list of authorized users, one of whom should be the NIH PI, along with any other authorized supervisors. A group notebook may be set up for collaboration on a project. Mechanisms to ensure that data are not altered after entry are important. In commercial software this can be done automatically, and the signature can be digitally authenticated. If notebooks use common software that does not provide for automatic archiving, the notebook should be stored on a secure NIH server with daily backups for archival purposes.

Electronic Spreadsheets

Many researchers record data on spreadsheets. Although spreadsheets are convenient and user-friendly, they often do not include mechanisms for authenticating changes to the data. For example, if one goes

back and looks at a spreadsheet a day or two after entering data and finds a mistake, it may not be clear how to validate a correction to the spreadsheet. Researchers who work with spreadsheets should develop practices for promoting data integrity, such as: giving spreadsheets file names that clearly indicate the version date and the author; keeping track of spreadsheet versions; ensuring that spreadsheets that are shared with collaborators implement the same formats for recording data; storing spreadsheets on a server accessible only to team members; using the track changes function (if available) to indicate changes; and, periodically locking spreadsheets to preserve data.

Record Keeping for Intellectual Property Purposes

While it is often the case that intellectual property (IP) rights can be secured for research inventions documented using ordinary, good scientific record keeping practices, in cases of a legal challenge to an IP claim, a more stringent standard may be required as legal proof. In addition to the requirement for electronic notebooks mentioned above, the following requirements apply to record keeping for IP purposes:

- Each entry should be signed and dated.
- Entries should be periodically witnessed with a signature and date. The witness should have an understanding or familiarity with the inventor's work, but not be a co-inventor. The witness should be a person, who is available or can be easily reached for the next several years.
- Consecutive pages must be used.
- When acquiring photos, drawings, graphs, and related documents, such data should be clearly labelled, signed or assigned to a particular person, dated, witnessed and converted to an electronic format as quickly as possible (if not already in an electronic format).
- Electronic notebooks used for intellectual property purposes must have backup, dating, appropriate IT security, and authenticity and verification capabilities, such as the ability to timestamp entries and record signatures.

Record Keeping in Clinical Research

The principles of good record keeping that apply to all fields of science also apply in the clinical research setting, although their practical implementation varies, due to the requirements of patient care and FDA regulations. As noted earlier, confidentiality, privacy and IT security requirements in clinical research are much stronger than those in other types of research because clinical research involves the collection of private and sensitive information about human subjects. While the NIH is not subject to the Health Insurance Portability and Accountability Act (HIPAA) regulations, it complies with all applicable laws, rules and regulations governing the privacy and security of health information, including the Privacy Act of 1974.

Clinical Research Records

The following record keeping practices are important for protecting the privacy and confidentiality of

human research subjects in clinical or non-clinical research (e.g., natural history studies):

- Access to research records should be restricted to authorized personnel.
- Electronic records should be password protected, stored on NIH computers or servers, and encrypted if stored on laptops.
- Breaches of confidentiality should be reported to the IRB according to policies concerning the reporting of non-compliance and unanticipated problems.
- Whenever feasible and appropriate, data to be shared with other investigators or contributed to databases should be de-identified. The IRBO provides additional guidance for determining what constitutes individually identifying information.

Good Clinical Practice

√ Records generated by clinical studies regulated by the FDA must follow Good Clinical Practice standards and adhere to regulations found in 21 CFR parts 11, 50, and 312. Guidance on FDA requirements for investigator record-keeping and record retention specify that an investigator must retain records for two years following the date a marketing application is approved for a drug. Investigators must also follow the NIH Records Management Schedule.[10]

The regulatory binder or file organizes all essential documents that demonstrate that the investigator, sponsor, and monitor have complied with Good Clinical Practice standards and with all applicable regulatory requirements. This central binder also allows research team members to reference information and provides easy access to essential documents by the trial monitor, auditor, IRB, or regulatory authorities for review or audit purposes. It also offers research team members the opportunity to document the reasons for corrective changes in operating procedures that occurred because of unforeseen events that occur during a trial. This documentation may be helpful in a future audit. The PI is ultimately accountable for the maintenance of the regulatory binder.

Administration of all study drugs, including those that are self-administered, should be documented in the subject's medical record. The PI is also ultimately accountable for record-keeping related to the investigational drug or product, including documentation of drug stability and appropriate storage of drug, recording the distribution of drug, and maintaining accurate drug accountability records, such as receipts of drug shipments or invoices and drug accountability record forms. These responsibilities may be delegated to appropriate pharmacy staff. ▲

[10] NIH Records Management Schedule. Retrieved from https://oma.od.nih.gov/DMS/Pages/Records-Management-Schedule.aspx

Data Management

Storage of Research Records

Research records should be carefully recorded and retained in a form that will allow for continuous access. Records 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. In general**,** 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.

√ All intramural research records must be retained for 7 years after i) completion of the project (e.g., publication of the final results) or ii) they are no longer needed for scientific reference, whichever is longer; records that support IP rights must be maintained for 30 years after the patent is filed; however, non-historically significant research records that pertain to abandoned patents or patent applications are retained for 7 years after the termination of the research project/program or when no longer needed for scientific reference, whichever is longer; and, records of historical significance should be identified and transferred to the National Archives to be maintained permanently.[11] No NIH records may be destroyed unless consistent with the NIH policies governing record maintenance and retention and applicable regulations. More details regarding research retention schedules can be found at the NIH Office of Management website.[12]

All primary data, including those from observations and experiments not directly leading to publication, must be retained.[11] 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.

To mitigate the risk of destruction or loss, electronic data and records should be backed up regularly and stored in a widely accessible format (e.g., PDF) at a location away from the original data. It is prudent to scan pre-existing (as of June 2024) hard-copy notebooks and to keep electronic copies at a different site.

Archives of primary data and other important records should be stored in a manner that prevents subsequent alterations; copies of these files may be used for further research or reanalysis. NIH has remote sites that accept archival material.

> Researchers should only use storage mechanisms that are approved by the NIH Intramural Research Program (IRP) and their Institute or Center (IC).

Electronic records must be securely stored on government issued NIH devices, such as desktop or laptop

[11] Manual Chapter 1743; Managing Federal Records. Retrieved from https://policymanual.nih.gov/1743
[12] NIH Records Management. Retrieved from https://oma.nih.gov/dms/programs/rm/Pages/Home.aspx

computers, external hard drives, USBs drives, data servers, or data generating equipment (such as MRI machines, DNA sequencers, or flow cytometers). Electronic records should be protected by passwords, NIH firewalls, and, in some cases, encryption. Years ago, electronic data were kept on reel-to-reel magnetic tapes, then floppy discs, followed by CDs. Since electronic media continue to evolve in response to advances in technology, it is important to make sure that the medium used is reliable and that files can be read later and transferred to new media. Storing data on servers can help researchers accommodate changes in electronic media.

A record of data locations must be maintained. That can be accomplished by entering the information in a database (which also needs to be maintained and backed up properly). Some new versions of modeling packages self-index the files that are created. There are commercial database systems where the backup may be done automatically.

Ownership of Research Records and Materials

All research records and materials are the property of the NIH. Research records may be copied (without personal identifiers) at the discretion of the supervisor. Departing scientists may take copies of 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,[11] which includes the requirement that the requestor complete Form NIH-3000[13] at least 45 days prior to departure. PIs should consider and are encouraged to document the intent to continue to work together with a Research Collaboration Agreement. Research materials must remain at the NIH. However, 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.[14]

Data Sharing

Intramural investigators are subject to the 2023 NIH Data Management and Sharing (DMS) Policy.[8] Scientific data and any unique materials (such as reagents, biospecimens, or transgenic animals) that form the basis of research should be shared to the fullest extent possible consistent with laws, regulations, and NIH policies[8]. Data and materials should be shared no later than the time of publication or when a research project or clinical protocol ends prior to publication. High-quality data that are not part of a publication, such as negative results, should also be shared.

All intramural researchers who generate scientific data as part of a ZIA project number must comply with the DMS Policy. Under this policy, intramural investigators must 1) prospectively plan for the managing and sharing of scientific data; 2) submit into the NIH Database (NIDB) a DMS plan using the NIH OIR Intramural Data Management and Sharing Plan Template; and 3) comply with the approved plan. Plans associated with a clinical protocol should additionally be submitted as part of the initial IC Scientific Review process. Data Management and Sharing Plans should outline how scientific data and any accompanying metadata will be

[13] NIH Form 3000. Retrieved from https://oma.od.nih.gov/Lists/DMSFormsList/Attachments/682/NIH-3000.pdf
[14] CRADA & MTA FAQs. Retrieved from http://www.ott.nih.gov/crada-mta-faqs

managed and shared, taking into account any potential restrictions or limitations.[8] DMS plans will be reviewed by the Scientific Director (or their designees), and investigators must indicate how they have complied with their approved DMS plans as part of the annual review, starting in 2025.

Data sharing may be limited by ethical, legal, or technical factors in some situations. Justifiable reasons for limiting the sharing of data include to maintain confidentiality or privacy in research with human subjects; to comply with federal, state, or Tribal law; or to abide by agreements imposed by human subjects restrictions, funders, or collaborating organizations.[15] However, researchers should strive to maximize the sharing of scientific data and materials. For example, confidentiality may be maintained by removing personal identifiers from human subjects data, using Data Use Agreements to share data, or both. Consent documents must inform research subjects about plans to share data with other researchers and allow subjects to consent to broad sharing of data. During negotiations with private companies or other outside organizations, NIH investigators and institutional officials can advocate for the broad sharing of data and materials in the agreement.

NIH encourages the use of established repositories for sharing scientific data. For some types of data, NIH or IC policy may mandate the use of a particular repository.

In addition, some scientific journals now require researchers to make data available to the public by depositing to a repository supported by the journal. When a data repository is not specified, researchers are encouraged to select a data repository that is appropriate for the data generated from the research project. Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse. NIH maintains a list of NIH-supported repositories including GenBank (a genomic data repository)[16] and dbGaP (a repository for human genotypic and phenotypic data),[17] . If a discipline or data type specific repository is not available, researchers should consider other options, including generalist repositories, supplementary material to articles submitted to PubMed Central for small datasets (up to 2 GB in size), or cloud-based data repositories for large datasets.

NIH-funded investigators are also subject to the NIH Genomic Data Sharing (GDS) Policy (ref D), in which NIH expects investigators to share human as well as non-human genomic data. Many of the GDS Policy requirements are incorporated into the DMS Policy, though the GDS policy has additional specific requirements. ▲

[15] NIH Scientific Data Sharing FAQs. Retrieved from https://sharing.nih.gov/faqs#/data-management-and-sharing-policy.htm?anchor=56549

[18] General Guidelines for Authorship Contributions. Retrieved from https://oir.nih.gov/system/files/media/file/2024-07/guidelines-authorship_contributions.pdf

[18] General Guidelines for Authorship Contributions. Retrieved from https://oir.nih.gov/system/files/media/file/2024-07/guidelines-authorship_contributions.pdf

Authorship

Authorship on manuscripts or presentations serves two critical purposes in research: 1) to give credit for scientific discoveries and innovations and 2) to ensure accountability. While authorship can benefit individuals by helping them achieve recognition and advance their careers, it also implies responsibilities for the data and analyses, including sharing underlying materials, methods, and datasets with the scientific community.

NIH policy supports the fair and responsible assignment of authorship to publications or presentations. Authorship should be based on the following:

1. Making a significant contribution to the conceptualization, design, execution, or interpretation of the research.

   AND

2. Drafting, revising, or carefully reading and confirming the research manuscript or presentation.

   AND

3. Taking responsibility for the research, particularly your contribution to it.

Individuals who meet the first and third criteria listed above must be allowed to read the manuscript or presentation so that they can meet all three criteria. Individuals who do not meet all three criteria should be acknowledged in the text, not in the author list. Individuals may be acknowledged for performing activities, such as providing encouragement, critical feedback, space, financial support, reagents, systems support, routine analyses, or patient material. The Committee on Scientific Conduct and Ethics (CSCE) has supplied general guidelines in the NIH Sourcebook that assist researchers in deciding who deserves authorship.[18]

Authorship roles

There are several authorship roles, each with different responsibilities. The research community has generally accepted practices for assigning these roles and not exact formulae. The first author usually contributes most significantly to the research, either to the conceptualization, design, or the primary experimental work of the study, and often writes the first manuscript draft. The last (or senior) author contributes significantly to the study's conceptualization, design, and interpretation and usually supervises or leads the research group.

[18] General Guidelines for Authorship Contributions. Retrieved from https://oir.nih.gov/system/files/media/file/2024-07/guidelines-authorship_contributions.pdf

The corresponding author coordinates the completion and submission of the work; satisfies pertinent rules of submission; assembles the group's responses to inquiries and challenges; makes data publicly available per NIH and journal policies; and fulfills requests for data, methods, or materials such as reagents or biospecimens.[8] The corresponding author is also responsible for confirming: 1) recognition of the contributions of all collaborators (intramural and extramural), 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 within the parameters of the study design and methods. The corresponding author is usually, but not always, the first or last author. Sometimes the nature of the research makes more than one corresponding author advisable. For example, suppose the research used materials or distinct conceptual and experimental contributions from collaborating laboratories. In that case, having a corresponding author from each laboratory may help handle requests for materials and expertise. Also, if the research involves a collaboration between researchers from different countries, it may be advisable to have a corresponding author from each country to deal with possible variations in laws and regulations.

√ **Reminder:** All manuscripts and abstracts that include authors from the IRP must be reviewed per the policy and instructions in the Sourcebook.[19]

Joint first or last (senior) authors[20]

Sometimes researchers may want to recognize contributions by naming more than one person as joint first or last authors. Manuscripts or presentations often indicate that joint authors "contributed equally" to the research. The designation "contributed equally" should accurately reflect the actual contributions of the authors and should not be used primarily to settle authorship disputes.

Researchers named as equal contributors should follow the authorship order in the manuscript when they report their publications on their CVs, tenure review packages, or grant applications. They should indicate that they contributed equally to these documents to ensure they (and their colleagues) receive proper recognition. Researchers should not switch the order of the names as the reordered authorship would not then accurately reflect the established scientific record and may be considered misrepresentation. For example, if Dr. Alpha and Dr. Beta both contributed equally to a research project, but Dr. Beta's name is listed first on the manuscript, Dr. Alpha should indicate this on their CV as follows:

> Beta L*, **Alpha I***, Gamma J, Delta B, Epsilon C, and Zeta H. Protein XYZ promotes respiratory inflammation and childhood asthma through the ABC pathway. BioEFG 2021; 1:14-20. *These authors contributed equally to this work.

[19] Publication and Abstract Review. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications/publication-abstract-review

[20] The NIH Committee on Scientific Conduct and Ethics acknowledges the contributions of Dr. Emily Summerbell for this section

Post-humous authorship

Sometimes individuals who have substantially contributed to a research project die before it is completed or published. When this happens, they may not meet all the three criteria for authorship listed above. Nevertheless, these individuals deserve some form of recognition appropriate for their work. To ensure that individuals who have died receive appropriate recognition, the following recommendations should be followed:

a. If the individual dies before they can review the first draft of the manuscript, they should not be listed as an author but may be mentioned in the acknowledgements.
b. If the individual has had a chance to review the submitted draft of the manuscript and has approved it, but has not read the subsequent version, including the final published version, they may be listed as an author if the remaining authors have good reasons to believe that they would approve the final version if they were alive. A note explaining the situation should be included in the manuscript, including, possibly an obituary in the manuscript or supplemental material. Decease individuals should be identified as such with Obelius, including a date of death.
c. If the individual was listed as the corresponding author during the submission process, the other authors should make arrangements to take over these responsibilities.

Author departures from NIH

It is not unusual for a co-author to leave the NIH before 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 the final version of the submitted manuscript. If the most of the departing author's work was done while at the NIH, then the NIH should be listed as their affiliation on the manuscript and a note indicating their new affiliation may be included. If the senior author cannot contact the departing author after having made a reasonable effort, they may remove them as a co-author and acknowledge their contributions to the research 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 are responsible for ensuring approval of the manuscript through the NIH IRP manuscript review process before submitting it to a journal. In this case, the manuscript must annotate that the departing author performed the work in the NIH IRP but is no longer affiliated with NIH. The departing author must also obtain approval from their previous NIH supervisor before submitting a major revision of a previously submitted manuscript. If a departing author is unwilling or unable to communicate with NIH, NIH has the authority to remove the departing author from the manuscript before submission or re-submission. The NIH may also contact the publisher about the manuscript being submitted without NIH approval using data collected in the IRP and request the manuscript not be published or be corrected/retracted if already published.

Authorship transparency within research teams

The senior (or lead) investigator is responsible for assigning authorship to research contributors fairly according to authorship policies. It is expected that members of each research group will freely discuss and resolve questions of authorship, including the order of authors, before and during the course of a study. Further, each author is responsible for reviewing and supporting their contributions to the manuscript and being 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.

Authorship conflicts

Disputes over authorship naming, order, and responsibilities are not uncommon. The NIH has various resources for helping researchers to discuss authorship issues and resolve authorship disputes, including but not limited to the NIH Office of the Ombudsman/Center for Cooperative Resolution (CCR), the IC Scientific Director, and (for trainees) the IC Training Director and the NIH Office of Intramural Training and Education. The NIH has a formal process for resolving authorship disputes described in the NIH Sourcebook[21].

Author eligibility

The criteria for authorship do not refer to specific roles or positions. Therefore, any individual who meets all three criteria listed above could be named as an author, including, in some cases, human research participants or non-scientists who help with research projects, also known as citizen- scientists. Researchers should consult with the NIH Office of Human Subjects Research Protections and their IC Clinical Director before naming human participants as authors to address ethical and regulatory issues, such as confidentiality/privacy and consent. Citizen-scientists who are named as authors should understand and accept authorship responsibilities. Sometimes, it may be proper to name individual citizen-scientists as authors. Still, in many cases, it may suffice to acknowledge the contributions of a group of citizen-scientists. Artificial intelligence tools do not meet the authorship criteria and therefore are not eligible to be named as authors. See the chapter on Ethical Concerns Related to Information Technology. ▲

[21] Processes for Authorship Dispute Resolution. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/authorship-guidelines-resources/nih-irp-authorship-conflict-resolution-process

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.[22] 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[19] such as to identify dual-use concerns,[23] 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 stricter 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.[19] 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 Sourcebook.[8]

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. Authors should avoid journals (or publishers), sometimes referred to as "predatory journals" that promise rapid review and publication but charge high publication fees (which may not be well disclosed upfront) and do not perform rigorous peer review (or any review at all). Publications in such venues are unlikely to be counted as legitimate and may taint the author's publication record. Authors should seek to publish in journals that are ethically managed, well-regarded in their field, and findable (indexed in authoritative resources, e.g., Medline, Embase, Web of Science, Scopus).

[22] Submitting Research Publications. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications
[23] Dual-Use Research. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research

√ All NIH-funded authors are required to comply with the 2024 NIH Public Access Policy[24]. They must ensure that their peer-reviewed manuscript is submitted to the National Library of Medicine's (NLM) PubMed Central (PMC) for public availability at the time of publication, without embargo. This can be done either by an author submitting the Author Accepted Manuscript upon acceptance to PMC via the NIH Manuscript Submission System[25] (NIHMS); or by the publisher submitting the Final Published Article to PubMed Central, without embargo, on behalf of the author. Some publishers submit to PMC for free, authors can check the list here. Some publishers offer to submit the Final Published Article to PMC as part of an open access package that can be purchased for a fee. To document their rights and responsibilities, NIH authors must submit the Manuscript Cover Sheet at the time of submission to the journal.

The NIH encourages researchers to use interim research products[26], 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[27], MedRxiv.org[28], ChemRxiv.org[29], and ASAPbio.org[30]. NIH researchers are not required to use preprint servers, and these products do not need to be submitted to PubMed Central[31], although they still fall under the NIH publication policies[32] and require IC review 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. Researchers should be careful about publishing manuscripts with direct clinical or public health implications because preprints are not peer reviewed, and information that turns out to be mistaken or misleading (following peer review) could be shared with the public.

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.

[24] 2024 NIH Public Access Policy. Retrieved from https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html
[25] NIH Manuscript Submission System. Retrieved from https://www.nihms.nih.gov/db/sub.cgi
[26] NIH Notice Number NOT-OD-17-050. Retrieved from https://grants.nih.gov/grants/guide/notice-files/not-od-17-050.html
[27] bioRxiv. Retrieved from https://www.biorxiv.org/
[28] medRxiv. Retrieved from https://www.medrxiv.org/
[29] ChemRxiv. Retrieved from https://chemrxiv.org/
[30] ASAPbio. Retrieved from https://asapbio.org/
[31] NIH Public Access Policy. Retrieved from https://publicaccess.nih.gov/
[32] Submitting Research Publications. Retrieved from https://oir.nih.gov/sourcebook/submitting-research-publications

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[33];
- 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,
- 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 review[19] is required for submissions of interim research products. Manuscript review 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[34], in accordance with ethics guidance[35] and IC-specific publication policies and procedures. Researchers are encouraged to consult with their supervisors prior to a public blog posting. ▲

[33] Creative Commons licenses. Retrieved from https://creativecommons.org/licenses/
[34] NIH Manual Chapter 1184. Retrieved from https://policymanual.nih.gov/1184
[35] Official Duty Activities. Retrieved from https://ethics.od.nih.gov/official

Mentoring and the Responsibilities of Research Supervisors, Mentors, 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 pursue**.** The level of independence and intensity of the research training should be matched to the educational level and preparation of each trainee and should be sufficiently flexible to accommodate their unique needs.

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. The Office of Intramural Training & Education (OITE; www.training.nih.gov) is an NIH-wide resource for all trainees, and for supervisors and mentors of trainees, and should be consulted with on all substantive mentoring concerns. OITE disseminates NIH-wide policies regarding intramural training and works closely with training offices in the ICs, and other trans-NIH offices, to support supervisors in providing a positive training experience for all fellows.

At the present time, NIH fellows are represented by a union, NIH Fellows United under the umbrella of the United Auto Workers (UAW). OIR/OITE policies established to support fellows in having a positive training experience are compliant with standards established in the negotiated collective bargaining agreement (CBA) with the union, and OITE plays a critical role in supporting managers and mentors in complying with the CBA. It is imperative that supervisors and mentors engage with the OITE regularly to understand how unionization impacts research training and the mentor-mentee relationship. It is our hope that careful attention to policy guidance and how unionization may alter the dynamic relationship between mentors and mentees will support positive mentoring relationships.

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 (or in some cases, assigned directly to) additional individuals (e.g., scientific staff, more senior trainees) who function as mentors for day-to-day tasks or more specific aspects of training or career development. Supervisors should be aware of well-being, educational/career counseling, and professional development resources offered through OITE and encourage participation in appropriate events. Supervisors should also encourage trainees to take advantage of other numerous NIH campus resources, including Institute and Center training offices and directors, the Library, and the Foundation for Advanced Education in the Sciences (FAES). NIH policy, and the NIH Fellows United CBA, sets a minimum requirement of 10% protected time to allow trainees to participate in relevant professional development activities; this time is considered a part of the fellow's research experience and should be encouraged by all supervisors and mentors.

It is the responsibility of the primary supervisor to serve as a role model and provide a rich research

environment in which the trainee can acquire both conceptual and technical skills in the research field of interest. In this setting, each trainee should understand the goals of the research group, have a clear understanding of the expectations, and a research training plan (e.g., Individual Development Plan) with end goals and intermediate milestones. Progress should be assessed regularly and with the goal of promoting learning, not shaming or degrading fellows. A "Welcome Letter" or "Lab Compact" is recommended as a useful tool for supervisors to introduce trainees to the specific expectations and responsibilities of both trainees and mentors, including the supervisor themself, in their research groups. Several examples are available on the OITE Intranet for supervisors and mentors. While there is some flexibility in how to use these resources, all supervisors must comply with basic requirements to provide written expectations at the outset of the fellowship and feedback annually; OITE provides forms to meet these requirements. In addition to the required processes, trainees may elect to complete an Individual Development Plan (IDP) through OITE and discuss it with their PI. If asked for their input on the plan, PIs should engage in thoughtful discussion of the plan with their fellows.

The primary mentor as well as the supervisor (if not the same person), 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 and mentors alike 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, whether or not they are the official supervisor, seeks to understand each trainee's unique qualities and adapts their training approach accordingly.

Specific aspects of the mentor–trainee relationship deserve emphasis. Supervisors and mentors should impart to the new investigator appropriate standards of scientific conduct, including appropriate ethical conduct, both by instruction and by example. Supervisors and 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. Supervisors and mentors should provide trainees with timely, objective, and realistic appraisals of their performance along with advice regarding career directions, opportunities, and advancement. In addition, supervisors and mentors should pay careful attention to preparing senior fellows to mentor other fellows when appropriate and should avoid assuming that all senior fellows are prepared to mentor more junior members of the research group. In addition, supervisors should make sure that fellows preparing to become mentors participate in well-being, leadership, and mentor training offered by OITE in advance of supervising others. Other important considerations are a commitment to holding regular meetings as a triad and checking in with both the mentor and mentee throughout the experience.

Trainees have responsibilities to their supervisors and mentors, 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.

Healthy mentoring and supervisory relationships are built on the establishment of healthy boundaries and the maintenance of a professional and courteous relationship. Supervisors should seek guidance whenever there are signs that the relationship is strained given the challenges of resolving issues in hierarchical environments. Supervisors can seek support from a variety of places, both within and outside of their IC, including OITE and the NIH Ombuds. Supervisors should also encourage trainees to seek support and guidance on maintaining healthy supervisory relationships, including from OITE and IC training office staff.

All NIH supervisors engaged in recruitment of trainees or employees are responsible for casting a wide net to foster development of a talented scientific workforce. The NIH is committed to supporting a biomedical research workforce that is representative of American society and seeks to promote excellence in 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,[36] and attention to assuring that all trainees and employees at the NIH are valued and respected as members of the NIH community. At the Laboratory and Branch level, this includes keeping records, conducting research, and interacting with colleagues in English.[37] ▲

[36] Manual Chapter 2300-301-1; Nepotism. Retrieved from https://policymanual.nih.gov/2300-310-1#transmittal- sheet
[37] 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.[38]

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?
- How will credit be attributed to each collaborator's institution for public

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

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.[8] 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 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.[39] Researchers should comply with the terms of any research agreements governing release of data collected under the agreement.

The Office of Technology Transfer developed a set of FAQs to help investigators determine

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

which instrument is most appropriate.[14]

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 *Avoiding Undue Foreign Influence on IRP Research*.[40] 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 long-term 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. ▲

[40] Avoiding Undue Foreign Influence on IRP Research. Retrieved from https://oir.nih.gov/sourcebook/personnel/policies-recruitment-processes/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.[41]

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. ▲

[41] 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. Plagiarism does not include authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project.

Research misconduct does not include honest error or differences of opinion. The research record is the record of data or results, 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.[42,43] 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. [4]

Text recycling[44] is the reuse of material in a new document, without quotations, and where at least one author of the new document is also an author of the prior document. Although this practice used to be referred to as self-plagiarism, text recycling is not plagiarism or self-plagiarism. Recent publications show that text recycling may be done ethically and appropriately, as long as there is full disclosure, and

[42] NIH Intramural Research Program Policies and Procedures for Research Misconduct Proceedings. Retrieved from https://oir.nih.gov/system/files/media/file/2021-08/policy-nih_irp_research_misconduct_proceedings.pdf

[43] 42 CFR Part 93; PHS Policies on Research Misconduct; Final Rule. Retrieved from https://www.federalregister.gov/documents/2024/09/17/2024-20814/public-health-service-policies-on-research-misconct.

[44] https://textrecycling.org/what-is-text-recycling/

the authors are careful to not recycle text in ways that might mislead the reader.

√ 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).[42] 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 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 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.[42]

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*).[45] 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

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

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.[46] 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 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. ▲

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

Harassment, Sexual Harassment, and Inappropriate Conduct

√ The process of scientific research is a creative and rigorous endeavor, requiring critical analyses by many people with varying expertise in the gathering and interpretation of data. The free exchange of ideas and critiques is vital to the development of robust results and sound conclusions. Multiple studies[47,48,49,50,51,52,53] have repeatedly indicated that both creativity and productivity increase when people with different viewpoints and different life experiences are involved in an effort. Furthermore, a mind-set that is open to new experiences also increases creativity[54]. As we aspire to be an outstanding research institution, it is crucial that we acknowledge the benefits of these differences among our work colleagues and are committed to fostering a community in which all members are welcomed to participate and feel safe to respectfully express their viewpoints. Harassment in any form is detrimental to workplace productivity[55]. To support the most productive work environments, it is crucial to combat harassment in the workplace.

Laws and policy governing behavior at NIH

To make sure that only respectful behavior is allowed at NIH, we are governed by federal law, HHS policy, and NIH policy to ensure that our interactions with others are ethical, legal, and without fear of harassment or retaliation.

These laws include:

1) **Title VII of the Civil Rights Act of 1964[56], the Civil Rights Act of 1991[57], and the Supreme Court decision Bostock v. Clayton County, 590 U.S. 644 (2020)[58]**, which prohibits discrimination based on several protected classes, and covers the full spectrum of employment decisions, including recruitment, selections, terminations, and other decisions concerning terms and conditions of employment and provides for the recovery of compensatory damages in the Federal sector cases of intentional employment discrimination. In

[47] Cognitive Diversity for Creativity and Inclusive Growth. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/39600033
[48] Rebel Ideas: The Power of Diverse Thinking . Retrieved from https://www.matthewsyed.co.uk/book/rebel-ideas-the-power-of-diverse-thinking/
[49] The Case for Cultural Diversity in the Intelligence Community. Retrieved from https://www.tandfonline.com/doi/abs/10.1080/08850600150501317
[50] Teams Solve Problems Faster When They're More Cognitively Diverse. Retrieved from https://hbr.org/2017/03/teams-solve-problems-faster-when-theyre-more-cognitively-diverse
[51] Joint Impact of Interdependence and Group Diversity on Innovation. Retrieved from https://journals.sagepub.com/doi/abs/10.1016/s0149-2063_03_00033-3
[52] The Development and Validation of a Cognitive Diversity Scale for Chinese Academic Research Teams. Retrieved from https://www.frontiersin.org/journals/psychology/articles/10.3389/fpsyg.2021.687179/full
[53] Why Diverse Teams Are Smarter. Retrieved from https://hbr.org/2016/11/why-diverse-teams-are-smarter
[54] Not Quite Equal Odds: Openness to Experience Moderates the Relation Between Quantity and Quality of Ideas in Divergent Production. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/30886597
[55] Sustainable Work Performance: The Roles of Workplace Violence and Occupational Stress. Retrieved from https://pmc.ncbi.nlm.nih.gov/articles/PMC7037902/
[56] Title VII of the Civil Rights Act of 1964. Retrieved from https://www.justice.gov/sites/default/files/crt/legacy/2010/12/15/Title_VII_Statute.pdf
[57] Civil Rights Act of 1991. Retrieved from https://www.eeoc.gov/civil-rights-act-1991-original-text
[58] Bostock V. Clayton County, Georgia Certiorari to The United States Court of Appeals for the Eleventh Circuit. Retrieved from https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf

the case of sexual harassment, employers are prohibited from harassing employees based on their sex; this includes unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates a hostile work environment.

2) **Equal Pay Act of 1963**[59]**, which** protects men and women from sex-based wage discrimination in the payment of wages or benefits, who perform substantially equal work in the same establishment.

3) **Age Discrimination in Employment Act of 1967**[60], which prohibits age-based discrimination, including harassment, of employees 40 or older.

4) **The Americans with Disabilities Act**[61] and the **Rehabilitation Act of 1973**[62], which protects employees and job applicants from employment discrimination and retaliation based on disability.

5) **Other laws**[63] enforced by the Office of the Special Council and the Merit Systems Protection Board that protect Federal employees for certain prohibited personnel practices.

6) **The HHS Equal Employment Opportunity and Anti-Harassment Policy**[64] established to create and maintain a workplace that is free of discrimination, reprisal, and harassment, and that embodies our core values in our day-to-day programs, practices, and services.

7) **The NIH Anti-harassment Policy** [65] which prohibits 1) egregious and/or a pattern of disrespectful or inappropriate conduct, 2) any conflict of a sexual nature, 3) bullying, 4) harassment/hostile work environment, 5) property damage, or 6) physical assault/violence **AND** requires that management report such incidents to Civil (situations 1-4) or NIH Division of police (situations 5-6) upon learning of the behavior. These issues are addressed in detail by NIH Policy Manual Chapter 1311[66], 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*

[59] Equal Pay Act of 1963. Retrieved from https://www.eeoc.gov/statutes/equal-pay-act-1963
[60] Age Discrimination in Employment. Retrieved from https://uscode.house.gov/view.xhtml?path=/prelim@title29/chapter14&edition=prelim
[61] Americans with Disabilities Act of 1990, As Amended. Retrieved from https://www.ada.gov/law-and-regs/ada/
[62] Section 504, Rehabilitation Act of 1973. Retrieved from https://www.dol.gov/agencies/oasam/centers-offices/civil-rights-center/statutes/section-504-rehabilitation-act-of-1973
[63] Protections Against Discrimination and Other Prohibited Practices. Retrieved from https://www.ftc.gov/policy-notices/no-fear-act/protections-against-discrimination#:~:text=Title%20VII%20of%20the%20Civil%20Rights%20Act%2C%20as%20amended%2C%20protects,religion%2C%20sex%20and%20national%20origin
[64] The HHS Equal Employment Opportunity and Anti-Harassment Policy. Retrieved from https://www.hhs.gov/about/agencies/asa/eeo/index.html
[65] Civil Policy and Guidance. Retrieved from https://hr.nih.gov/working-nih/civil/nih-anti-harassment-policy-and-guidance
[66] 1311 - Preventing and Addressing Harassment and Inappropriate Conduct. Retrieved from https://policymanual.nih.gov/1311

and goals will be met with consequences, no matter who the offender."

8) For further guidance please see Manual Chapter 1311 - Preventing and Addressing Harassment and Inappropriate Conduct[66] .

Resources

As the NIH does 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 federal law, HHS policy, or the NIH Anti-harassment policy.

The Civil Program[67], within the Workforce Relations Division in the Office of Human Resources, is responsible for conducting administrative inquiries into reports of harassment. If you feel that you have been a victim of harassment or that your rights as detailed in the laws and/or NIH policy have been violated, you can:

1. Contact Civil directly by calling the Civil main line (301-402-4845), report online at civilworkplace.gov or call the NIH Anti-Harassment Hotline (833-224-3829). Hotline or on-line reporting can be done anonymously.

2. Confidentially discuss the situation with the NIH Office of the Ombudsman[68] or the Employee Assistance Program to understand your options.[69]

3. As a trainee, report to the Office of Intramural Training and Education (OITE).[70] (This is the preferred referral for trainees).

It should be noted that all supervisors at NIH are mandated to report to Civil if they witness or hear of any incident, whether under their supervision or that of another, that violates laws governing discrimination/harassment/retaliation. 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:

[67] The NIH Civil Program. Retrieved from https://hr.nih.gov/working-nih/civil/
[68] Office of the Ombudsman. Retrieved from https://ombuds.nih.gov/
[69] Employee Assistance Program (EAP). Retrieved from https://www.ors.od.nih.gov/sr/dohs/HealthAndWellness/EAP/Pages/index.aspx
[70] Office of Intramural Training and Education. Retrieved from https://www.training.nih.gov/

- NIH Manual Chapter 1311: Preventing and Addressing Harassment and Inappropriate Conduct[66]
- Civil Tool-kits: Preventing and Addressing Harassment and Inappropriate Conduct[71]
    - Toolkit for Employees[72]
    - Toolkit for Supervisors[73]
    - Toolkit for Trainees and Fellows[74]
    - Toolkit for Contractors[75]
    - Additional Q&As for all staff can be found by visiting the NIH Civil website[76]

To learn more about ways to report a concern, please visit the NIH Civil website[77].

Disclosure of Personal Relationships Between Supervisor/Supervisee[78]

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. ▲

[71] Civil Tool-kits: Preventing and Addressing Harassment and Inappropriate Conduct. Retrieved from https://hr.nih.gov/working-nih/civil/tool-kits
[72] Toolkit for Employees. Retrieved from https://nih.sharepoint.com/sites/NIH-IntraHR/Shared%20Documents/civil/ManualChapter1311ToolkitforEmployees_508.pdf
[73] Toolkit for Managers & Supervisors. Retrieved from https://nih.sharepoint.com/sites/NIH-IntraHR/Shared%20Documents/civil/ManualChapter1311ToolkitforSupervisors_508.pdf
[74] Toolkit for Trainees. Retrieved from https://nih.sharepoint.com/sites/NIH-IntraHR/Shared%20Documents/civil/ManualChapter1311ToolkitforTraineesandFellows_508.pdf
[75] Toolkit for Contractors. Retrieved from https://nih.sharepoint.com/sites/NIH-IntraHR/Shared%20Documents/civil/ManualChapter1311ToolkitforContractors_508.pdf
[76] NIH Anti-Harassment Policy and Guidance. Retrieved from https://hr.nih.gov/working-nih/civil/policy-and-guidance
[77] "How Can I Report a Concern?" Retrieved from https://hr.nih.gov/working-nih/civil/notify-nih
[78] 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.[79]

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. ▲

[79] Official Duty Activities. Retrieved from https://ethics.od.nih.gov/official

Scientific Integrity at the NIH

The National Institutes of Health (NIH) strives to produce basic and applied knowledge of biology and medicine by conducting and supporting rigorous, reproducible, and objective scientific research that can be used to diagnose, prevent, or treat diseases; enhance the quality and length of human life; and reduce the burden of illness and disability. The NIH accomplishes its mission by funding biomedical and behavioral research at universities, medical centers and other academic institutions through its Extramural Research Program (ERP); and 2) by conducting basic, clinical and translational biomedical research within the laboratories, clinics and core facilities of its Intramural Research Program (IRP).

Upholding the highest standards of scientific integrity is essential to the mission of the NIH. HHS defines scientific integrity as adhering to "professional practices, ethical behavior, and the principles of honesty and objectivity when conducting, managing, using the results of, and communicating about science and scientific activities. Transparency and protection from inappropriate influence are hallmarks of scientific integrity."[80] Scientific integrity is important for ensuring that NIH's research is rigorous, reproducible, and objective, and for fostering the public's support of the NIH's Extramural and Intramural Research and confidence in policies informed by NIH-generated data. In addition to federal-wide and intra-departmental requirements, the NIH has numerous policies in place to ensure the scientific integrity and to assure the public of the credibility of the scientific findings achieved through its Intramural and Extramural Research Programs. The NIH also participates in a wide range of federal policymaking in the areas of clinical research, biotechnology, and biosecurity. For inquiries about scientific integrity at the NIH IRP or ERP or to reported suspected violations, contact the NIH Office of Science Policy.[81] ▲

[80] The Scientific Integrity Policy of the U.S. Department of Health and Human Services. Retrieved from https://www.hhs.gov/sites/default/files/hhs-scientific-integrity-policy.pdf

[81] 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.[82] 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.[83]

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

[82] NIH Ethics Program. Retrieved from https://ethics.od.nih.gov/

[83] Manual Chapter 2400; Ethics. Retrieved from https://policymanual.nih.gov/chapter/browse/byfunctionalseries/4

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 guidance for researchers who are part of a covered research protocol for dealing with COIs in research with human subjects.[84,85] ▲

[84] 18 USC §§ 203,205, and 207-209; 5 CFR Parts 2634-2641, 5 CFR Parts 5501-5502

[85] Conflict of Interest Review. Retrieved from https://irbo.nih.gov/ancillary-review/conflict-of-interest-review/

Social Responsibility, Media Inquiries, and Dual-Use Research

Scientific research conducted by NIH intramural investigators is designed to generate knowledge that is likely to have beneficial applications in medicine, public health, biotechnology, and health policy. However, research may sometimes have unintended adverse impacts on individuals, communities, populations, and society. 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, and publicly sharing genomic sequence data for a deadly bacterial toxin for which there is currently no known antitoxin could enable someone to develop a bioweapon that deploys this toxin.

NIH intramural investigators therefore have a responsibility to anticipate the possible social consequences of their research and 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. Scientists who are reviewing proposals for such research should take these potential consequences into account when deciding whether it should be approved for funding.

Media Inquiries

News media inquiries raise important issues concerning social responsibility for NIH scientists. Although communications with the news media are an opportunity to educate the public about important advances in biomedical research, members of the media and the public may sometimes misinterpret or misunderstand the results of research.[86] Also, communications with the news media can have significant impact (positive or negative) on the public's opinion of NIH research and the public's trust in the scientific profession. Intramural investigators should contact their institute's Communications and Public Liaison Office prior to responding to inquiries from the news media and coordinate their responses with that office. Investigators who are being interviewed by the news media should communicate their main points in a manner that is accurate, informative, and understandable to the public.

[86] 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."[87]
Initial and annual Dual Use Research of Concern (DURC) reviews must be completed in the Electronic Registration System.[88] Contact the Division of Occupational Health and Safety for Access to these systems. These reviews must be certified by the PI of record on the recombinant materials or pathogen registration document. The Dual Use Research of Concern-Institutional Review Entity (DURC-IRE) committee is the NIH authoritative review body for any research that may meet the definition of DURC after review by any of the Institutional Biosafety Committees (IBCs) and reviews all projects including the 15 agents as outlined in the USG policy, as well as research that may create a potential pandemic pathogen (PPP).[89] The NIH Intramural Research Program requires that each publication be evaluated for dual use; and, if questions are raised, the research is flagged as potential DURC, or the manuscript involves any of the experimental effects described in the policy, the DURC-IRE may also be convened.[87] The DURC-IRE is the final authority to determine if the research or publication may proceed. Questions regarding DURC can be directed to the Director, Division of Occupational Health and Safety (DOHS), NIH, who serves as the NIH Institutional Contact for Dual Use Research (ICDUR) or the Biosafety Officer from the IBC at your location.

In 2025, an Executive Order, "Improving the Safety and Security of Biological Research," ordered an impending pause on "dangerous gain of function research on biological agents and pathogens" (defined as scientific research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility, including research activities that could result in significant societal consequences and that seek or achieve one or more of a list of specific experimental outcomes). The White House published "Guidance on Termination – Suspension of Dangerous Gain-of-Function Research IAW EO1429236,' ordering a review of potentially dangerous gain-of-function research, a pause on USG funding of dangerous gain-of-function research and ordering the revision or replacement of the 2024 US Government DURC Policy[87], while keeping in place the previous USG policies on DURC and PPP. NIH will update this chapter as new guidance is issued. Any questions about the implementation of a pause on dangerous gain of function research should be directed to the appropriate NIH Biological Safety Officer or the NIH Institutional Contact for Dual Use Research (ICDUR).
▲

[87] 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
[88] Electronic Registration System. Retrieved from https://ers.ors.nih.gov/
[89] Dual-Use Research. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research

Ethical Leadership and Management

Ethical leadership and management play an indispensable role in research integrity and regulatory compliance. Good leadership and management can help prevent fabrication and falsification of data, poor recordkeeping, intractable authorship disputes, harassment, bullying, negligent mentoring, violations of animal or human subjects regulations, and many other ethical problems that can arise in research. Poor leadership and management, by contrast, can encourage or cause unethical behavior. Good leadership and management can also foster scientific productivity, discovery, and innovation, while poor leadership and management can have the opposite effect.

While scientific organizations, such as the NIH, include many different leadership and management positions at different levels, from laboratory director to branch chief to director of Intramural Research, this chapter will focus on leadership and management of the scientific laboratory.[90] The discussion in this chapter is very much in the spirit of the preface to this document, which emphasizes the importance of developing a culture of integrity throughout the NIH.

Although almost anything involving conducting research or the environment within a lab can have ethical dimensions, the following issues can typically arise in managing a scientific laboratory:

- **Human resources**: Recruitment, hiring, promotion, salaries; accommodating disabilities; power structure and imbalance; harassment; discrimination; inappropriate relationships; physical and mental health; sick leave and parental leave.
- **Laboratory management**: Leadership; laboratory culture; priority-setting; data management, teamwork and collaborations; conflict management; work assignments and deadlines.
- **Research integrity**: Research misconduct; data integrity and management; sharing of data and materials; research recordkeeping, authorship; publication; conflict of interest.
- **Mentoring**: Mentoring and training; advising and career development; skill building; career opportunities.
- **Resources**: Funding, budgeting, and purchasing; equipment, materials, and supplies.
- **Compliance and Safety**: Complying with laws, regulations, policies, guidelines, and best practices involving human and animal subjects and hazardous materials; adherence to material transfer and technology transfer agreements; laboratory safety, radiation safety, biosafety, and occupational health; management of conflict of interest.

From this list, one can see that scientists clearly face numerous complex ethical issues when managing a research laboratory. To deal with these issues appropriately and effectively, it is essential for investigators (and administrators) who occupy leadership positions to remain abreast of new developments and training in research ethics and management; to reflect on the ethical values that guide their leadership and decision-making; and to seek advice when faced with problems that are difficult to handle. The following are some ways that scientists can promote a culture of integrity within

[90] "Laboratory" is understood to mean a group of people working together to conduct research. A laboratory, in this sense, is not a physical place but an organizational unit. Many scientists at NIH, including epidemiologists, biostatisticians, clinicians, and bioethicists conduct research outside of traditional, physical laboratories.

their laboratory:

- Set an ethical tone within the laboratory by providing a good example of ethical behavior for others to follow; stress the importance of ethics during lab meetings and other activities and enforce ethics training requirements.
- Promote effective communication within the laboratory by holding regular meetings; establishing clear expectations concerning responsibilities, performance, and evaluation; and instituting open door policies (i.e., keeping one's office door open to encourages people to drop by to talk freely about problems or concerns) and open notebook policies (i.e., research records can be accessed by other members of the research group, especially the PI; see chapters on scientific recordkeeping and data management).
- Avoid and actively discourage any form of discrimination based on race, sex, religion, or other characteristics that are irrelevant to scientific performance.
- Treat all people fairly and avoid favoritism. Fairness can be an important concern in many different areas, including work assignments, authorship, allocation of resources, and sick leave. There is no simple formula for treating people fairly. Establishing clear expectations and policies that apply equally to all members of the lab is crucial for treating people fairly, but good mentoring can also consider each person's needs, talents, or circumstances.
- Develop written policies concerning recordkeeping, review of data, division of labor and authorship, allocation of resources, publication, parental leave, and other topics, provided they are consistent with laws, regulations, and NIH policies.
- Strive for productivity and efficiency but not to the point where people cut corners, compromise quality, or feel pressured to work faster or harder than they are comfortable doing.
- Respect the proprietary nature of research but encourage a collaborative environment in the laboratory. Encouraging researchers to assist each other with methods and ideas increases productivity and fosters goodwill within the laboratory.
- Do not expect or imply that specific results must be obtained; scientific investigation should be conducted to answer a question, not to produce a particular outcome. Experiments that fail to turn out as planned can lead to innovation and novel discoveries. Pressuring people to obtain specific results can lead to fabrication or falsification.
- Make good use of financial and other resources; don't waste time, money, or materials.
- Support activities that promote regulatory compliance and best practices, including training, auditing, and reporting of violations of laws, regulations, and NIH policies.

Seek ethics advice, counsel, or coaching from an experienced, outside party, such as another PI, ethics official, or ombudsperson;[68] or someone from the Employee Assistance Program[69] or Civil Program.[67] Executive coaching[91] and an ethics audit[92] can be useful tools for promoting ethical laboratory management. Participate in training activities that promote ethical management, such as training in conflict resolution, leadership, and business (e.g., accounting and budgeting).▲

[91] An executive coach is a qualified professional who works with individuals to help them clarify their goals and objectives, gain self-awareness, and unlock their potential. An executive coach can also serve as a sounding board or mentor. The NIH offers executive coaching. Retrieved from https://hr.nih.gov/training-center/leadership/nih-continuum-leadership

[92] An ethics audit is an audit of the ethical climate of an organization by an outside party. The auditor can interview members of the organization to identify ethical successes, problems, and concerns.

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.

Animal care and use program responsibilities are delineated in NIH Policy Manuals and guidance documents.[93] 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.[94] 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.[95]

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, trained in the specific animal procedures used in the study, and enrolled in an Animal Exposure Program (AEP).

√ When developing an Animal Study Protocol, investigators should adhere to the following principles:[96]

> 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

[93] NIH Policy Manual, 3040-2-Animal Care and Use in the Intramural Program. Retrieved from https://oacu.oir.nih.gov
[94] NIH Office of Animal Care and Use. Retrieved from https://oacu.oir.nih.gov/
[95] NIH Manual Chapters and Other Relevant NIH Policies on Animal Care and Use are Summarized. Retrieved from https://oacu.oir.nih.gov/nih-policies
[96] Guide for the Care and Use of Laboratory Animals, 8th Edition. Retrieved from https://olaw.nih.gov/policies-laws/guide-care-use-lab-animals

subjects.

Replace study animals with animals of a lower phylogenetic ranking or non-animal models whenever possible: e.g., insects, cell lines, computational models.

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.[97]

All staff participating in animal research must initially complete the course "Using Animals in Intramural Research: Guidelines for Animal Users."[98] 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."[99]

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.

NIH prioritizes human-focused research methods to reduce animal use in research[100]. When developing animal-based research projects, researchers must consider human-focused approaches, such as clinical trials, real-world data, or new approach methods (NAMs, such as ex vivo human-based approaches, in vitro methods including microphysiological systems and organoids, as well as computational and AI-based approaches). ▲

[97] 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
[98] Training Resources. Retrieved from https://oacu.oir.nih.gov/training-resources
[99] NIH Office of Animal Care and Use Training. Retrieved from https://oacutraining.od.nih.gov/public_menu.aspx
[100] U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Retrieved from https://olaw.nih.gov/policies-laws/guide-care-use-lab-animals

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.[101] 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.[102]

NIH has developed a policy[103] that describes the requirements of the NIH IRP to oversee, and store, track, and report human biospecimens and to submit an annual NIH Human Biospecimen Storage and Tracking Report to U.S. Congress, in compliance with the NIH Reform Act of 2006.[104]

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

[101] Manual Chapter 1189; Policy for the Management of and Access to Scientific Collections. Retrieved from https://policymanual.nih.gov/1189
[102] 45 CFR 46; Protection of Human Subjects. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
[103] Manual Chapter 3008; NIH Human Biospecimen Program. Retrieved from https://policymanual.nih.gov/3008
[104] Biennial Report of the Director

- 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.

When an investigator departs NIH, unless the IC has agreed to allow the investigator to properly transfer the biospecimens, the IC will coordinate with another investigator to assume custodianship of the biospecimens.▲

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.[105]

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.[106]

√ 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.[105]

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.[107]

- 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

[105] Manual Chapter 1340; NIH Occupational Safety and Health Management Program. Retrieved from https://policymanual.nih.gov/1340#06CAE9F2
[106] NIH Office of Management; Training Requirements & Available Courses. Retrieved from https://www.safetytraining.nih.gov/
[107] 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.[108]

• 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.[109]

• 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.[110]

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.[111]

• 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.[112]

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

[108] DOHS Occupational Medical Service. Retrieved from https://www.ors.od.nih.gov/sr/dohs/HealthAndWellness/OccupationalMedical/Pages/oms_main.aspx
[109] Division of the Fire Marshal. Retrieved from https://www.ors.od.nih.gov/ser/dfm/Pages/default.aspx
[110] Division of Radiation Safety. Retrieved from https://drs.ors.od.nih.gov/Pages/default.aspx
[111] Occupational Safety and Health Committee. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/Pages/Occupational-Safety-and-Health-Committee.aspx
[112] 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.[113]

√ 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.[113] Researchers are also required to report annually on their acquisition, use or storage of HFT.[103] Use of HFT is reported annually on the publicly facing Research, Condition, and Disease Categories (RCDC) by intramural project number.[114] 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.[102,115] 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.[113]

Derivation of human Embryonic Stem Cells (hESCs) from human embryos in the intramural program is

[113] Special Research Considerations. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/special- research-considerations
[114] Estimates of Funding for Various Research, Condition, and Disease Categories (RCDC). Retrieved from https://report.nih.gov/funding/categorical-spending#/
[115] 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

prohibited by the annual appropriations restriction on funding of human embryo research. Researchers may acquire existing, approved hESCs from a commercial source or through an MTA, following intramural guidelines and processes.[116] ▲

[116] 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)[102] 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.[117] 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.[118]

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*].[102]

For information on whether a specific activity might constitute human subjects research or not, refer to guidance available on the Office of IRBO website.[119]

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

[117] NIH HRPP Policy and Guidelines. Retrieved from https://irbo.nih.gov/hrpp-policy-guidelines/
[118] Exempt Research Retrieved from https://irbo.nih.gov/irb-review/exempt-research/
[119] Do you need to submit to the IRB? Retrieved from https://irbo.nih.gov/irb-review/do-you-need-to-submit-to-the-irb/

they conduct this type of research.[120] 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.[121] 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.[11]
- 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;[8] 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.[8]

More information about Intramural data sharing policies can be found in the Sourcebook.[122]

[120] HRPP Policy Number 103; Education Program. Retrieved from https://irbo.nih.gov/education/nih-citi-training/
[121] HRPP Policy Series 300; Investigator Responsibilities. Retrieved from https://irbo.nih.gov/hrpp-policy-guidelines/
[122] 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[123] 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)[124] and NIH policy requirements for reporting of results.[125] 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. ▲

[123] 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

[124] 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

[125] 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.[105]

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.[126] 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.[127]

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.[128]

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.[129] 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

[126] NIH Guidelines. Retrieved from https://osp.od.nih.gov/biotechnology/nih-guidelines/
[127] Manual Chapter 3035; Working Safely with Potentially Hazardous Biological Materials. Retrieved from https://policymanual.nih.gov/3035
[128] Biological Safety. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/bio_chem_safety.aspx
[129] 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[130] and the DOHS Select Agent Program website.[131]

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.[132]

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.[133] 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.[134] ▲

[130] Federal Select Agent Program. Retrieved from https://www.selectagents.gov/
[131] Select Agent Program. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/select_agents.aspx
[132] Manual Chapter 3037; NIH Biological Surety Program. Retrieved from https://policymanual.nih.gov/3037
[133] Biological Materials Shipping. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/shipping_biological_material.aspx
[134] 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.[135]

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.[136]

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.

[135] IT Governance & Policy; IT Policy, Standards and Guidance. Retrieved from https://ocio.nih.gov/it-governance/it- policy-standards-and-guidance

[136] 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).[137]

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[138] is minimally disruptive to personnel productivity; does not interfere with the mission or operations of HHS; and follows the guidance provided by the Cybersecurity Information Security and Privacy Program[139] and the *Rules of Behavior for Use of HHS Information Resources*.[140] It is important to remember that the privilege of using NIH computers, tablets, 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

[137] IT Governance & Policy; Section 508: Accessibility at NIH. Retrieved from https://ocio.nih.gov/ITGovPolicy/NIH508/Pages/default.aspx
[138] HHS Policy for Personal Use of Information Technology Resources. Retrieved from https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-ocio-policy-for-information-technology-it-policy-development.html
[139] Cybersecurity Information Security and Privacy Program. Retrieved from https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/index.html
[140] Rules of Behavior for Use of HHS Information Resources. Retrieved from https://orr-uc-apps.acf.hhs.gov/s/ROB

their ethical use.[141]

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.[142]

Artificial Intelligence

Many NIH investigators use different forms of artificial intelligence (AI) to assist with various research tasks, including analyzing research data, interpreting data derived from biomedical devices, modelling complex phenomena, reviewing the scientific literature, generating figures, and writing and editing articles, reports, and computer code. While AI can enhance the efficiency and productivity of research, it can also create risks to data security and integrity, as well as research trustworthiness and accountability. These risks must be minimized and managed. Because AI is a rapidly evolving technology, it is difficult to craft definitive rules for its use. The following are some current guidelines for responsible use of AI in the NIH IRP:

1. **Because non-NIH AI tools (including commercial and academic systems) may not maintain the confidentiality of data, NIH researchers are only allowed to use AI systems that have been approved by the NIH Office of the Chief Information Officer (OCIO) for analyzing, managing, or processing confidential or sensitive NIH data or text.** For example, ChIRP (Chatbot for Intramural Research Program) https://chirp.od.nih.gov/index.php is available to NIH staff and trainees. ChIRP stores all data locally within NIH servers and uses a secure account to host AI models. NIH staff can use ChIRP for confidential or sensitive data workloads including a) de-identified and anonymized clinical data; b) pre-decisional and draft policy; and c) non-public data including scientific data and draft manuscripts. At present, **NIH researchers should not upload personally identifiable information (PII), such as name, social security or medical record number, into ChIRP.**

2. **Because AI tools can make mistakes of fact, reasoning, analysis, or citation (including fake citations and plagiarism), NIH investigators must carefully oversee and review AI output and take responsibility for all work produced with the assistance of AI.**

3. **Because AI tools may produce results that are skewed, irreproducible, or unreliable, researchers should take appropriate steps to identify and control these problems, such as auditing the data used in the research, evaluating the AI tool's training data, and using multiple methods to analyze and interpret data and images, including non-AI methods.**

4. AI-generated synthetic data and images (such as "digital twins") can be useful in the development

[141] NIH Information Technology General Rules of Behavior. Retrieved from https://intranet.hhs.gov/policy/hhs-policy-rules-behavior-use-information-and-it-resources

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

and preliminary testing of hypotheses, models and methods and in the analysis and interpretation of real data and images. **To ensure that synthetic data and images are not mistakenly treated as real, researchers should clearly mark synthetic data and images and explain how and why they are using synthetic, AI-generated data and images in research. Researchers who intentionally, knowingly, or recklessly misrepresent synthetic, AI-generated data or images as real may be liable for research misconduct.**

5. **Substantial uses of AI in research or writing must be appropriately disclosed in manuscripts and presentations.** A 'substantial' use of AI is when it 1) produces evidence, analysis, or discussion that supports or elaborates on the conclusions (or findings) of a study; or 2) directly affects the content of the research or publication. Some examples of substantial uses of AI include:

    a. Using AI to analyze, interpret, synthesize, code, extract, process, or generate data or images.
    b. Using AI to generate hypotheses, model complex phenomena, or design experiments.
    c. Using AI to substantially write, edit, or translate text.

    Non-substantial uses of AI may not need to be disclosed unless appropriate (e.g., as required by a journal). Some non-substantial uses of AI include:

        a. Using AI to do background research for an article.
        b. Using AI to edit text for grammar, spelling, or clarity.
        c. Using AI as a digital assistant; for example, as a project timeline manager.

    Disclosure should occur in the body of the paper (for example in the Materials and Methods section), the Acknowledgments section, or in a separate part of the paper that discloses AI use. Disclosure should include enough information to allow other scientists to know how and why AI was used, as well as how to reproduce or verify its results. Since some journals place limitations on the use of AI in research or have specific AI disclosure requirements, scientists are advised to consult and follow journal policies for AI use and disclosure.
    The following is some suggested disclosure language " *AI Usage Disclosure: This document was created with assistance from AI tools. The content has been reviewed, edited, and approved by all authors. For more information on the extent and nature of AI usage, please contact the author(s)."*[143]

    Researchers should be aware that some journals and funding organizations may not permit substantial uses of AI in preparing submissions. The NIH Extramural Program, for example, does not accept funding applications that have been substantially developed by AI.[144]

6. **Use of AI to conduct research must be properly documented within research records, including Electronic Notebooks.** Researchers should consult with their supervisors to determine the best methods for recording their use of AI in their work at NIH. When using generative AI or Large Language Models for coding, generating synthetic data, or interpreting images, researchers can

[143] Why We Should Normalize Open Disclosure of AI Use. Retrieved from https://www.chronicle.com/article/why-we-should-normalize-open-disclosure-of-ai-use

[144]Supporting Fairness and Originality in NIH Research Applications. Retrieved from NOT-OD-25-132 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-132.html

document their workflow in a script or on an electronic platform like Jupyter, with a link to this entry included in the ELN. If AI is used for coding, and the code is too large for traditional ELNs like LabArchives, the code can be saved in a repository like GitHub with a link provided in the ELN for reference. Researchers may consider using the Generative AI Usage Toolkit and the Generative AI Documentation Form for guidance regarding proper documentation.

7. **An AI tool cannot take moral or legal responsibility or be held accountable for the work described in a manuscript; therefore, it does not meet NIH's authorship criteria and may not be named as an author.**

8. **Due to confidentiality concerns, peer review documents, such as manuscripts or grant proposals, should not be uploaded into AI systems that have not approved by the NIH OCIO.** Researchers should consult with and follow journal and sponsoring agency policies before considering using AI tools to assist with peer review of manuscripts or research funding proposals. The NIH Extramural program prohibits the use of generative AI to assist with peer review. "The Use of Generative Artificial Intelligence Technologies is Prohibited for the NIH Peer Review Process." NOT-OD-23-149. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-149.html Additionally, because AI can produce biases and mistakes that may unfairly affect authors and grant applicants, AI use in peer review is strongly discouraged, even if journals or funding agencies allow it.

9. **Researchers should follow other NIH policies that apply to AI use, such as research misconduct policies, institutional review board policies, dual use research policies, recordkeeping policies, data security policies, and technology transfer policies.**

10. **Researchers should be aware that when developing or evaluating AI tools or systems that might be used for diagnosing, curing, mitigating, treating, or preventing human diseases, the research may be regulated by the Food and Drug Administration and/or require IRB approval even if the researcher is using de-identified data.** Before undertaking such a project, the researcher should consult with the NIH Office of IRB Operations.

11. For additional guidance, see:

    NIH Artificial Intelligence (AI) Cybersecurity Guidance.
    https://wiki.ocio.nih.gov/index.php/NIH_Artificial_Intelligence_(AI)_Cybersecurity_Guidance

    Artificial Intelligence in Research: Policy Considerations and Guidance.
    https://osp.od.nih.gov/policies/artificial-intelligence/

    HHS Policy for Securing Artificial Intelligence (AI) Technology.
    https://intranet.hhs.gov/policy/hhs-policy-securing-artificial-intelligence-technology ▲

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[145]
- U.S. Office of Special Counsel hotline[146]

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[147]

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

- Intramural Animal Welfare Concerns[148]
- Intramural Human Research Subject Protections[102]
- Intramural Unsafe or Unhealthful Conditions[149]
- Intramural Research Misconduct concerns[150]
- Intramural Harassment or Civility concerns[151]
- Intramural EEO discrimination concerns[152]

[145] HHS Office of Inspector General; Submit a Hotline Complaint. Retrieved from https://oig.hhs.gov/fraud/report-fraud/index.asp
[146] U.S. Office of Special Counsel Complaint & Disclosure Form. Retrieved from https://osc.gov/Pages/File- Complaint.aspx
[147] Division of Program Integrity. Retrieved from https://oma.od.nih.gov/DPI/Pages/Home.aspx
[148] Anonymous Reporting of Animal Welfare Concerns. Retrieved from https://oacu.oir.nih.gov/nih-policies/reporting-concerns-regarding-animals-nih
[149] Unsafe or Unhealthful Conditions Reporting. Retrieved from https://www.ors.od.nih.gov/sr/dohs/safety/incidents_accidents/Pages/Report-of-Unsafe-Condition.aspx
[150] Anonymous Reporting of Research Misconduct Concerns. Retrieved from https://oir.nih.gov/sourcebook/ethical-conduct/research-misconduct/anonymous-reporting-research-misconduct-concerns
[151] Civil Intake Form. Retrieved from https://hr.nih.gov/working-nih/civil/intake-form
[152] EEO Process. https://eeo.nih.gov/services/federal-EEO-complaint-process

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.[153]

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,[154] 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. ▲

[153] 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

[154] 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,[155] with your Scientific Director, or with your Training Director. Support is also available from the NIH Office of the Ombudsman.[68] ▲

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