Fifth Edition

May 2016

Guidelines and Policies for the

Conduct of Research

in the Intramural Research Program at NIH

National Institutes of Health
Office of the Director

Guidelines and Policies for the Conduct of Research in the Intramural Research Programs at the NIH

The *Guidelines and Policies for the Conduct of Research* (henceforth, "*Guidelines & Policies*") set forth the general principles governing the conduct of good science as practiced in the Intramural Research Programs at the National Institutes of Health (NIH). They address needs arising from the rapid growth of scientific knowledge, the increasing sophistication of scientific tools and approaches, the increasing complexity of laws, rules, and regulations that govern the behavior of scientists, and the influx of scientific trainees with diverse backgrounds.

The *Guidelines & Policies*, originally developed by the Scientific Directors of the Intramural Research Programs (IRP) at the NIH, have been revised for this edition by the intramural scientists on the NIH Committee on Scientific Conduct and Ethics, and approved by the Scientific Directors. General principles are set forth, but policy requirements indicated by an asterisk are also embedded therein, concerning the responsibilities of research staff in the collection and recording of data, publication practices, authorship determination, mentoring, peer review, confidentiality of information, hiring and promotion practices, collaborations, human subjects research, fetal tissue research, use of biospecimens, social responsibility/dual use research, IT security, health & safety, financial conflicts of interest, and animal care and use and Research Material Management & Research with High-Consequence Pathogens.

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

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Introduction

Scientists in the Intramural Research Programs at the National Institutes of Health are responsible for conducting original research consonant with the goals of their individual Institutes and Centers. These *Guidelines & Policies* were developed to promote high ethical standards in the conduct and management of research by intramural scientists at the NIH. It is the responsibility of all supervisory personnel who oversee research groups, core facilities, and others, and successive levels of supervisory individuals (especially Institute and Center Scientific Directors), to ensure that every NIH scientist is cognizant of these *Guidelines & 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 — 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 and further conclusions — are universal, their detailed application may differ in different scientific disciplines and in varying circumstances. 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.

These *Guidelines* & *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 federal employees. ▲

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Mentoring and the Responsibilities of Research Supervisors and Trainees

Research training is a complex process, the central aspect of which is a period of research carried out under the 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, as well as career advice. It should be recognized that the trainee has unique, time-sensitive needs relevant to career progression and advancement. In this regard, guidance and advocacy from the supervisor are essential components of training.

In general, a trainee will have a single primary research supervisor. In addition, trainees should also have other individuals who function as mentors for specific aspects of training or career development. Institutional training directors and offices serve as additional resources. It is the responsibility of the primary supervisor to serve as a role model and provide a rich research environment in which the trainee has the opportunity to acquire both conceptual and technical skills in the research field of interest. In this setting, each trainee should have a clear research training plan and goals developed (*e.g.* Individual Development Plan). A "Welcome Letter" or "Lab Compact" is often a useful tool for mentors or other supervisors to introduce trainees to the specific expectations and responsibilities of both trainees and mentors in their research groups. Several examples are available for supervisors in the NIH Sourcebook. (See https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training/instruction-responsible-conduct-research-postdoc-irta-crta-vf-research/introduction.)

In order to provide a meaningful, high-quality training experience, the mentor should monitor and guide the trainee's progress closely and interact personally on a regular basis to give timely feedback regarding research designs or findings and progress. Good communication is critical to success. It is particularly important that the mentor and trainee review primary data together on a regular basis. Reliance on prepared figures and PowerPoint presentations for lab meetings can mask problems in thinking or data analysis that could undermine the success of both trainee and mentor. Supervisors and mentors should limit the number of trainees in their laboratories, branches, or sections to the number for whom they can provide an appropriate and productive training experience. Mentoring should be adapted to the needs and career stage of each individual trainee.

Specific aspects of the mentor–trainee relationship deserve emphasis. Training should impart to the young investigator appropriate standards of scientific conduct both by instruction and by example of the mentor. They should be particularly diligent to involve trainees in research and related activities that contribute to their careers, including participation in intramural or extramural collaborations, encouragement of presentations at scientific meetings, and networking. Mentors should provide trainees with timely, objective, and realistic appraisals of their performance along with advice regarding career directions, opportunities, and advancement. Trainees have responsibilities to their supervisors as

well as to their institutions. These responsibilities include adherence to these *Guidelines* 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 well as to their supervisors and mentors. Trainees should play active roles in seeking the tools and experiences necessary to accomplish their goals.

*****All NIH supervisors have a special responsibility to cast a wide net to assure recruitment and retention of a diverse and talented scientific community. The NIH is committed to the development of a biomedical research workforce that is representative of the diversity in American society and seeks to promote diversity in all of its training and research programs. This includes following NIH requirements for broadly advertised searches, strict prohibition against giving preference to relatives and friends when filling trainee or employee positions at the NIH (https://oma1.od.nih.gov/manualchapters/person/2300-310-1/), and attention to assuring that all trainees and employees at the NIH are valued and included as respected members of the NIH community. At the Laboratory and Branch level, this includes keeping records, conducting research, and interacting with colleagues in our common language, English (https://oir.nih.gov/sourcebook/personnel/recruitment-processes-policies-checklists/policy-use-english-official-scientific-communication-nih-laboratories). ▲

Data Management and Archiving

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

*****The results of all research should be carefully recorded and retained in a form that will allow continuous access for analysis and review. When possible, it is best to store data in both electronic and hard-copy form. Attention should be given to annotating and indexing notebooks and documenting computerized information 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. All intramural research records remain the property of the NIH and must be maintained for at least 7 years after completion of the project (e.g., publications of the final results); records that support patent or invention rights must be maintained for 10 years after the patent expires or is abandoned; and records of historical significance should be transferred to the National Archives and maintained permanently. More details regarding research retention schedules can be found at https://oma.nih.gov/dms/programs/rm/SitePages/Home.aspx.

*****All primary data, including those from observations and experiments not directly leading to publication, must be retained. For example, all usable imaging files should be retained, in their original format except for technically problematic data that can be immediately discarded. When acquired images or image sequences become prohibitively large, it may be acceptable to keep a subset of images as recorded, while compressing others. The volume of imaging data acquisition continues to expand explosively, and PIs wrestle with how much they can reasonably store. This will remain a moving target as both storage capacity (e.g., cloud storage, which has its costs) and acquisition rates of data continue to rise. There should be an agreement within concerned Institute- or Center-based intramural research programs of what is agreed to be "prohibitively large." We suggest this issue be discussed with your Scientific Director.

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

*****The NIH IRP supports increased efforts to ensure rigor, reproducibility, and transparency of research. In general**,** notebooks, other research data including computer files and supporting materials, such as unique reagents, should be maintained and made available by the laboratory in which they were developed. Departing scientists may take copies of notebooks and other data for further work. Under special circumstances, such as when required for continuation of research, departing investigators may

take primary data or unique reagents with them if adequate arrangements for their safekeeping and availability to others are documented by the appropriate Institute or Center official. Transfer of reagents outside of NIH should be documented through Material Transfer Agreements (MTAs).

*Data management, including the decision to publish, is the responsibility of the principal investigator. After publication, the research data and any unique materials that form the basis of that communication should be made available promptly and completely to all qualified scientists seeking further information. Exceptions may be necessary to maintain confidentiality of clinical data or if unique materials were obtained under agreements that preclude their dissemination. ▲

Publications

Publication of results is an integral and essential component of 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.***** All NIH publications must be reviewed by each IC Scientific Director or a delegated official to assure quality and compliance with applicable requirements such as consideration of sex as a biological variable and to identify dual-use concerns. (See https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research; see also Social Responsibilities and Dual Use, p. 27.) If the publication describes a possible patentable invention, contact the IC Technology Transfer Office prior to public release.

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. The NIH position on reproducibility encourages that all essential data 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 scientist. Consult the PHS policy relating to the distribution of unique research resources for further guidance (http://grants.nih.gov/grants/sharing.htm).

Timely publication of new and significant results is important for the progress of science. (See NIH policy for submitting research publications https://oir.nih.gov/sourcebook/submitting-research-publications.) Although generally considered the end point of a particular 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.

Fragmentary publication of the results of a scientific investigation, sometime referred to as 'salami slicing', or multiple publications based on the same or similar data are inappropriate. Each publication should make a distinct and substantial contribution to its field. As a corollary to this principle, tenure appointments and promotions should be based on the importance of the scientific accomplishments and not on the number of publications in which those accomplishments were reported. Equally, authors should avoid publishers who entrap researchers into submitting their work and then charge them publishing fees but do not undertake serious peer review. Such venues are unlikely to be counted as legitimate publications.

*****All NIH-funded investigators are required to make their final peer-reviewed manuscripts available to other researchers and the public at the NIH National Library of Medicine's (NLM) PubMed Central (PMC) (http://www.ncbi.nlm.nih.gov/pmc/) immediately after publication of the final version. Authors are given the option to release their manuscripts at a later time, up to 12 months after the official date of final publication. NIH expects that only in limited cases will authors deem it necessary to select the longest delay period. ▲

Authorship

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

Strictly speaking, authorship refers to the listing of names of study researchers. In any communications, either oral or written, of experimental results and their interpretation. This is the most frequent point of contention in many laboratories. For each individual the privilege of authorship should be based on a significant contribution to the conceptualization, design, execution, or interpretation of the research, as well as to the drafting or substantively reviewing or revising the research article. Authorship also conveys responsibility for the study. Individuals who do not meet these criteria but who have assisted the research by their encouragement and advice or by providing space, financial support, reagents, occasional analyses or patient material should be acknowledged in the text but not be authors. The Committee on Scientific Conduct and Ethics (CSCE) devised general guidelines to assist with determination of who deserves to be an author. These guidelines can be found in the NIH Sourcebook (https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-authorship_contributions.pdf).

Disputes over authorship order are not uncommon, most often after a contributor leaves the lab. NIH developed a policy and recommendations for resolution of authorship disputes, using a four-tiered process involving discussion, mediation, the option for peer review of the publication and authorship, and if unsuccessful, a final decision by the IC Scientific Director or the Deputy Director for Intramural Research (DDIR). This process is outlined in detail also in the NIH Sourcebook (https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training/processes-authorship-dispute-resolution).

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

The corresponding author should be considered the primary author (but is not necessarily the first author), with the additional responsibilities of coordinating the completion and submission of the work, satisfying pertinent rules of submission, and coordinating responses of the group to inquiries or challenges. The corresponding author is responsible for the following: (1) the contributions of all collaborators (intramural and extramural) are appropriately recognized; (2) each author has reviewed

and authorized the submission of the manuscript in its original and revised forms; (3) the data in the manuscript have been reviewed if revised; and (4) the data in the manuscript and all analyses are reproducible. *All manuscripts and abstracts coming from the IRP must be cleared in accordance with the instructions included at http://od.nih.gov/oir/sourcebook/oversight/pub-clear.htm. ▲

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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 is an essential component of the conduct of science. Decisions on the funding of research proposals and on the publication of experimental 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.

An underlying principle for performing peer review is that one should not benefit unfairly from the information available. 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 any 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. Authors should never serve as reviewers for their own manuscripts, nor should they set up fake reviewer accounts or otherwise subvert the transparency of the peer-review system. Some specific review activities may require review and approval by a supervisor and/or deputy ethics counsellor in an IC (https://ethics.od.nih.gov/topics/ODA/2-ODA-Chart.pdf).

The review should be fair and unbiased. 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 scientific information unavailable publicly. All material under review is privileged information. It should not be used to unfairly benefit the reviewer unless it previously has been made public. Material from the review should not be used by the reviewer as a basis for decisions in 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 the author. ▲

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 and specialized and resources diminish, 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. See http://1.usa.gov/RE6tRe .

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 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 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. For example, if you request a reagent from, or give one to, a colleague outside the NIH, or provide blood samples to be analyzed as part of a multi-study collaboration. For transfers within the NIH, no MTA is required but the transfer should be documented, for example in an email and retained for records.

Data Transfer Agreements (DTAs) are used for the transfer of existing data collected from human subjects, clinical studies, or laboratory experiments for research purposes.

Cooperative Research and Development Agreements (CRADAs) are used for agreements between one or more NIH laboratories and at least one non- federal group (private sector, university, not-for-profit, non-federal government). CRADAs provide a protected environment for long-term collaborations; they confer intellectual property rights to NIH inventions.

The Office of Technology Transfer developed a set of FAQs to help investigators determine which instrument is most appropriate. See http://www.ott.nih.gov/crada-mta-faqs. ▲

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Conflicts of Interest

Financial

Real or perceived conflicts of interest due to financial relationships with outside organizations may not be apparent to others unless sufficient, specific information is provided as required. Therefore, the scientist 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, collaboration agreements, honoraria, service on advisory boards, or management appointments having fiduciary responsibilities.

Failure to disclose conflicts of interest can threaten the integrity of, and undermine the public's trust in, intramural research activities at the NIH. When there is a potential conflict of interest, full disclosure and complete transparency is always the best policy. The NIH's Ethics Program (https://ethics.od.nih.gov/default.htm) has specific rules concerning conflicts of interest, 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 online ethics training. Intramural researchers should know these rules and, when in doubt, refer any questions to the Deputy Ethics Counselor of their Institute or Center.

Non-Financial

It is also essential to avoid non-financial conflicts of interest. Personal relationships, strongly held personal beliefs, or offers of honors from stakeholders can improperly influence scientific judgment or objectivity. Other examples could include unauthorized accessing of confidential information about friends or acquaintances who are participating in clinical research, or giving preference to them for inclusion in such studies. The possibilities are endless—so be on guard.

Conflicts of commitment can occur when researchers devote excessive time to activities that have no direct bearing on their employment responsibilities. Outside activities (with or without compensation) are not permitted during work hours. All of these can take away time from primary responsibilities, 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 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 become

unable to give a best effort to all of them. Examples of strong signs of over commitment are 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.

The "Guide to Preventing Financial and Non-Financial Conflicts of Interest in Human Subjects Research at NIH" covers participation in human subjects research in the Intramural Research Program. See http://www.genome.gov/Pages/Research/Intramural/IRB/COI_GUIDE_MARCH_2008.pdf. ▲

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Human Subjects Research

The NIH defines three categories of Clinical Research with human subjects:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: a) mechanisms of human disease, b), therapeutic interventions, c) clinical trials, and d) development of new technologies;

2) Epidemiological and behavioral studies;

3) Outcomes research and health services research. All intramural investigators conducting research of this type are expected to consult with the Office of Human Subjects Research Protections (OHSRP) if the proposed research will not be directly overseen by an NIH Institutional Review Board (IRB). No research involving human subjects, their data, specimens or materials may commence prior to obtaining IRB review or an OHSRP determination. The OHSRP administers NIH's 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 Standard Operating Procedures. See https://federation.nih.gov/ohsr/nih/pnp.php.

All IRP scientists are required to complete training in order to assure that they understand when research activities involve human subjects research and what is required when they conduct this type of research. Clinical researchers are required to have additional training commensurate with their roles and responsibilities. See SOP 25 - Training Requirements for the NIH HRPP. See https://federation.nih.gov/ohsr/nih/ohrdocs/SOP_25_v4_2-29-16_508.pdf . Additionally when conducting FDA-regulated research, PIs must complete Good Clinical Practice (GCP) training, as applicable (https://federation.nih.gov/ohsr/nih/investigator-training.php).

PIs also have special responsibilities to provide leadership and oversight over the conduct of the research and the research team. It is the policy of the NIH HRPP that each protocol approved by an NIH IRB have a single PI who is responsible for its design and conduct. Upon IRB approval, the PI may delegate specific aspects of the conduct of the research to other members of the research team, but the PI retains overall responsibility. When conducting FDA-regulated research, the PI also ensures that the team follows FDA Guidance for Industry: E6 Good Clinical Practice Consolidated Guidance and FDA requirements. See http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219488.htm.

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Collection, Sharing and Storage 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 keeping specimens, records, data, and information in secure systems and locations and limiting who may have access to the specimens or data. For more information, see HRPP SOP 18 - Privacy and Confidentiality (http://ohsr.od.nih.gov/OHSR/pnppublic.php).
- Appropriate storage and retention of research records, data, and samples, in accordance with NIH policy and FDA regulations, as applicable.
- A Plan for Data Sharing, approved by the IC Scientific Director or designee, as required by the Intramural data sharing policies, including:
    - Human Data Sharing (HDS) Policy (July 31, 2015); 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 (https://gds.nih.gov/03policy2.html). 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

For more information about Intramural Data Sharing Policies, see 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 research studies at ClinicalTrials.gov (https://clinicaltrials.gov) when NIH is identified as the responsible party. Clinical trials must also comply with NIH and Food and Drug Administration Amendments Act (FDAAA) requirements for reporting of results. The PI must ensure that trials reports are submitted within the required times frames. The PI may consult the IC Clinical Director for additional information. See https://oir.nih.gov/sourcebook/intramural-program-oversight/intramural-data-sharing/guide-fdaaa-reporting-research-results. ▲

Fetal Tissue Research

*NIH-intramural investigators and contractors should be mindful that research involving human fetal tissue (HFT) must be conducted in accordance with applicable federal, state, and local laws, regulations, and policies. These legal requirements can be found in the NIH Sourcebook at https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/fetal-tissue-research.

"Human fetal tissue" is defined as tissues or cells obtained from a dead human embryo or fetus after spontaneous or induced abortion, or after a stillbirth. Restrictions and requirements on research using HFT do not extend to secondary sources of tissues, such as established cell lines or animal models containing HFT, or derivatives of HFT, such as DNA or RNA, slides or sections of HFT, paraffin blocks, or fixed materials.

*All experiments using HFT must be reviewed and approved either by OHSRP, via a Determination for Exemption of IRB Review for de-identified tissue, or via a protocol approved by the appropriate IC IRB, when tissues have associated identifiable information. Following review, the investigator will obtain an Attestation document that must be filed with the IC and 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 are in compliance with the applicable Federal laws and policies.

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

*Investigators are required to submit all documentation regarding their use of HFT to their Scientific Director and to the NIH Intramural Compliance Officer (https://oir.nih.gov/about/leadership-staff/melissa-colbert) that includes copies of:

- the Attestation Form (I and/or II);
- the OHSRP Determination or IRB protocol approval letter with précis;
- all documentation from the supplier of the research material

Investigators are required to indicate on their annual report (via a checked box) in the NIH Data Base (NIDB) whether HFT was acquired or used for a specific research project in the current fiscal year.▲

Human Biospecimen Tracking and Storage

*Biological specimens (or "biospecimens") from study participants must be handled 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. 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.

NIH has developed detailed Guidelines for storage and tracking of human biospecimens (https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-biospecimen.pdf) as is required by Congress, in Section 104 of the National Institutes of Health Reform Act of 2006 (Pub. L. 109-482), enacted on January 15, 2007, https://report.nih.gov/biennialreport10-11/appendices/NIH_Appendix_A.html .

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 a properly obtained informed consent signed by the subject, or under a 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 NIH IRB review and approval, or an exemption from the NIH Office for Human Subjects Research Protection, 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;

- Packed and shipped conforming to all applicable regulations and standards, including the U.S. Department of Transportation and International Air Transport Association standards; and

- Stored with an individual computer-generated label or electronic tracking device with a unique identifier, which enables the investigator to link to a basic set of information on specimen acquisition or the protocol and informed consent (or waiver) under which the specimen was collected, as well as the NIH Clinical Center Clinical Research Information System patient

identification number, as appropriate, and which is able to withstand all potential storage conditions.

Health & Safety

The promotion of safety and health 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.

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 (https://www.safetytraining.nih.gov/), wearing appropriate personal protective equipment (PPE), and following safety procedures established by the NIH, their IC, and their specific laboratory.

*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 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. These responsibilities are spelled out in NIH Policy Manual Chapter 1340, NIH Occupational Safety and Health Management Program (https://oma1.od.nih.gov/manualchapters/management/1340/).

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) (http://www.ors.od.nih.gov/sr/dohs/aboutDOHS/Pages/about_dohs.aspx) 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.

- Additionally, the DOHS Occupational Medical Service (OMS) (http://www.ors.od.nih.gov/sr/dohs/OccupationalMedical/Pages/oms_main.aspx) 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 and illnesses. All injuries and illnesses must be reported to the OMS.

- The Division of the Fire Marshal (DFM) (http://www.ors.od.nih.gov/ser/dfm/Pages/default.aspx) 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.

• The Division of Radiation Safety (DRS) (http://drs.ors.od.nih.gov/Pages/default.aspx) 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.

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

• The NIH Occupational Safety and Health Committee (OSHC) (http://www.ors.od.nih.gov/sr/dohs/SafetyResources/committees/Pages/occupational_safety_health_committee.aspx). The OSHC provides safety policy recommendations to the Director of the NIH in matters pertaining to occupational health, accident control and fire prevention.

• 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 (http://www.ors.od.nih.gov/sr/dohs/Training/Pages/student_labtraining.aspx). 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.

Maintaining a safe and healthy research environment is an important responsibility that is shared by all NIH personnel. This included regular review of all stored materials, keeping a registry of all biological materials, and appropriate disposal 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 done using proper equipment that minimizes variables and compensates for the unexpected. Safe science is good science.▲

Research Material Management and Research with High-Consequence Pathogens

It is a requirement at NIH that Principal Investigators register with the NIH Institutional Biosafety Committee (IBC) any recombinant DNA experiments covered under the NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules (http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html.) 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. A spreadsheet template necessary for recording inventory data is available from the Division of Occupational Health and Safety (DOHS) staff along with instructions for uploading the data to the centralized NIH biological inventory system. Updates to the inventories may be made directly in the inventory system. ICs must develop policies that assure that unneeded or unwanted materials are not abandoned by research personnel. Annual inventory updates are required. Additional information can be found in NIH Manual Chapter 3035 - Working Safely with Potentially Hazardous Biological Materials (https://oma1.od.nih.gov/manualchapters/intramural/3035/)

The DOHS implements various programs and policies across the NIH campuses dealing with, or 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, 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. Additional information can be found at http://www.ors.od.nih.gov/sr/dohs/aboutDOHS/Pages/biorisk.aspx.

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 are known as select agents/toxins. 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 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: http://www.selectagents.gov and http://www.ors.od.nih.gov/sr/dohs/BioSafety/SA/Pages/select_agents.aspx.

Biological Surety Program

The NIH Biological Surety Program (BSP) is 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. The roles and responsibilities of participants in the Biological Surety Program are spelled out in NIH Policy Manual Chapter 3037, NIH Biological Surety Program (https://oma1.od.nih.gov/manualchapters/intramural/3037/).

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. Upon review of submitted forms, QPSO will determine whether the intended importation requires the issuance of a CDC import permit and label or a NIH Letter for Non-Infectious Importation. QPSO will provide 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. Additional information can be found at http://www.ors.od.nih.gov/sr/dohs/BioSafety/QPSO/Pages/import_permits_export_declarations.aspx.

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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, is defined as in vivo research performed on laboratory animals in order to develop knowledge that contributes to improvement of health and well-being of humans as well as other animals. The NIH Office of Animal Care and Use (OACU) (http://oacu.od.nih.gov) 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. The animal care and use program of each NIH Institute and Center (IC) is directed by a senior veterinarian, the Animal Program Director, and falls under the oversight of an Animal Care and Use Committee (ACUC). The animal care and use program of each IC is directed by a senior veterinarian, who serves as the Animal Program Director, and is overseen by the Institute Scientific Director. All components of the intramural NIH Animal Care and Use program are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

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

When developing an Animal Study Protocol, investigators should adhere to the following principles:

> Reduce the number of animals used to the minimum required – as dictated by the amount and statistical power of data required to achieve the experimental goals;
>
> Refine the way experiments are conducted in order to minimize the pain and suffering of animal subjects;
>
> Replace animals with alternatives (e.g., cell lines, computational models, phylogenetically lower species) whenever possible.

*****In addition, NIH policy requires that all animal studies consider sex as a biological variable, or an adequate explanation be provided of why this is not possible. (See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html.)

All staff participating in animal research must initially complete the course "Using Animals in Intramural Research: Guidelines for Animal Users" (For information on training, see http://oacu.od.nih.gov/training/users.htm.) 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." (For information, see http://oacu.od.nih.gov/training/pi.htm.)

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 is important for securing the public's continued trust and support for these important activities.▲

Social Responsibility and Dual-Use Research

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

Scientific research conducted by NIH intramural investigators often provides information used to treat or prevent diseases and advance human health and well-being. However, research may sometimes have unintended adverse social impacts. For example, publishing a study of genetic and environmental influences on criminal behavior might contribute to discrimination or profiling, and publicly sharing the genomic sequence of a new strain of *Clostridium botulinum* might enable others to make a deadly bioweapon from toxins produced by this microorganism. NIH intramural investigators therefore have a responsibility to anticipate the possible social consequences of their research and to take steps to minimize their potential for harm. Scientists who are studying identifiable communities or populations, for example, should be aware of the potential impact of their research on those communities and, when appropriate, work with community leaders to ensure that their research addresses important community needs.

In some cases it may be necessary to delay publication of research to allow for additional review and comment by NIH committees, 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.

*****The NIH Intramural Research Program requires that each publication be evaluated for dual use and if questions are raised, a central committee works with the author to assure that information contained within the manuscript does not support nefarious use. See https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research. See also United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern at http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf. News media inquiries also raise issues concerning social responsibility for NIH scientists, since communications with the news media are an opportunity to educate the public about important advances in biomedical research. Communications with the news media can also have a significant impact on the public's opinion of NIH research. Intramural investigators should contact their institute's communications office concerning media inquiries prior to responding. Investigators who are being interviewed by the news media should communicate their main points in a manner that is understandable to the public.▲

Research Misconduct

The scientific community and general public rightly expect adherence to exemplary standards of intellectual honesty in the formulation, conduct, reporting, and reviewing of scientific research. Investigators must act with honesty and integrity when editing, analyzing, and presenting data. Deceptive manipulation of data, be it misreporting of data, inappropriate exclusion of outlying data points, or enhancement of images, is research misconduct. The manipulated data need not be published or presented to constitute research misconduct.

*Research misconduct is defined as fabrication, falsification, or plagiarism 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 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. This includes even taking even a few sentences from published papers, without attribution. There are several programs available which scan for short phrases and used by journals to scan for plagiarized materials.

*The Research Record is the record of data or results, both physical and electronic, that embody the facts resulting from scientific inquiry; including but not limited to, emails, research proposals, laboratory records, progress reports, abstracts, theses, presentations, internal reports, journal articles, and any additional materials obtained during research misconduct proceedings. Research misconduct does not include honest error or honest difference of opinion.

Although not research misconduct, certain behaviors fall into the category of Questionable Research Practices (QRP). Perhaps the most common QRP is self-plagiarism, re-using favorite sections of previously published papers, most notable materials and methods. Inadvertent or misappropriation of someone else's ideas, sometimes discussed during an offhand conversation with a colleague. Selectively reporting of only the experimental results supporting a favored hypothesis. "Falling in love" with one's hypothesis can lead to the exclusion of inconclusive or weak data and have a strong negative affect on trainees, who may feel expected to prove a favored hypothesis.

*The NIH takes all allegations of research misconduct very seriously. All NIH personnel have a duty to report any suspected research misconduct to the NIH Agency Intramural Research Integrity Officer (AIRIO). The procedures followed at the NIH are designed to permit allegations of scientific 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 allows those who are incorrectly implicated to prevent damage to their careers as a result. The AIRIO will also take action to prevent retaliation against any complainant who brings an allegation in good faith.

Sections marked by an asterisk (*) indicate policy statements.

*Discussion of research ethics, including the required annual case studies found in Responsible Conduct of Research, (https://oir.nih.gov/sites/default/files/uploads/ethical_conduct/responsible_conduct-research-training/annual-review-ethics-case studies (https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training/annual-review-ethics-case-studies) should be held regularly by NIH Institutes and Centers. 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. 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.

For more information, refer to Guide to handling Research Misconduct Allegations at the NIH, https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guide-handling_research_misconduct_allegations.pdf.

Also, refer to Federal Policy on Research Misconduct, http://www.ori.dhhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf. ▲

***IT Security Awareness**

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. Recognizing that information technology touches every aspect of research and discovery, the NIH works continuously to improve information security posture, and proactively manage risk while supporting and safeguarding the NIH community, culture, and mission.

Our first line of defense is always our investigators. 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 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. For more information, please see http://irtsectraining.nih.gov/.

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.

Know When and How to Get Help

- When? Get help immediately if you encounter problems with system access, can't 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/.

Selected Tips

- Use a strong password or pass-phrase containing a sequence of words that is easy to remember and type.
- Be conscious of any sensitive information or data to which you have access. If you do need to distribute sensitive information, make use of encryption procedures.
- When using portable equipment, be extra-careful. Often times, 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.▲

Concluding Statement

These Guidelines remind NIH scientists of applicable rules and policies to incorporate compliance into our scientific culture. 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 can be obtained from the offices cited. You also can consult with members of the NIH Committee on Scientific Conduct and Ethics (https://oir.nih.gov/sourcebook/committees-advisory-ddir/committee-scientific-conduct-ethics-csce), with your Scientific Director, or with your Training Director. Advice is also available from the NIH Office of the Ombudsman (https://ombudsman.nih.gov/index.html). ▲

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