Sponsored Programs Administration
Buzz Session

January 24, 2018

UNMC

Agenda

- NIH updates
- Q&A

NIH Operates Under a Continuing Resolution Through January 19, 2018 (NOT-OD-18-124) – 01/12/2018
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-124.html

- Government operations continue through 12/22/2017 at 99.3209% of FY17 level
- NIH will issue non-competing awards at a level below that indicated on most recent NOAs
  - Generally up to 90%
  - Upward adjustments are possible
  - Institutions should monitor expenditures carefully
- All FY17 legislative mandates remain in effect

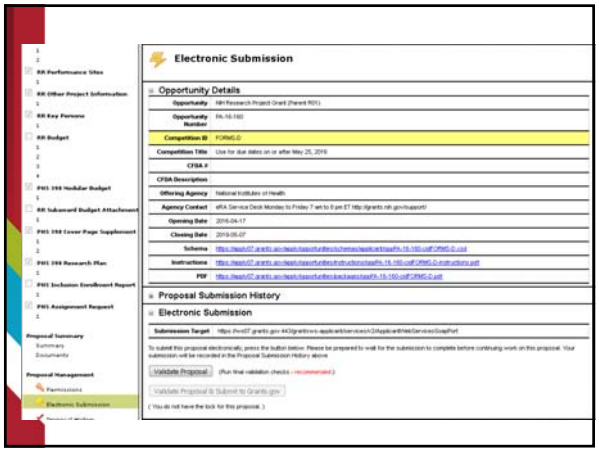
Grant Application Due Dates Following the Recent Lapse in Appropriations (NOT-OD-18-131) – 01/23/2018
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-131.html

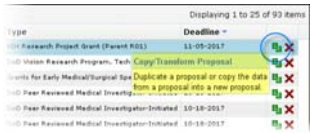
FOAs with 01/22/2018 due date	Moved to 01/24/2018
FOAs with 01/23/2018 due date or later	No change

Reminder: FORMS-E Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2018 (NOT-OD-18-009) – 10/24/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-009.html

Reminder: FORMS-E Grant Application Forms & Instructions Must be Used for AHRQ Due Dates On or After January 25, 2018 (NOT-HS-18-003) – 11/02/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-HS-18-003.html

You are using a FORMS-D application package. If you are submitting to a due date on or before January 24, 2018 you are using the correct forms and no action is needed (NOT-OD-17-062). If you are submitting to a later due date, you are using incorrect forms and MUST move to FORMS-E for submission by the due date.





Reminder: Policy on Funding Opportunity Announcements (FOA) for Clinical Trials Takes Effect January 25, 2018 (NOT-OD-18-106) – 11/30/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-106.html

Activity Code	Not a Clinical Trial	Clinical Trial
R01	PA-18-484	PA-18-345
R03	PA-18-488	N/A
R21	PA-18-489	PA-18-344
R13	02/12/2018	N/A
R15	PA-18-504	N/A
K01	PA-18-369	PA-18-363
K02	PA-18-371	PA-18-370
K08	PA-18-373	PA-18-372
K99/R00	PA-18-398	PA-18-397
F	02/08/2018	N/A
T32	PA-18-403	N/A

Clinical Trials: Special Considerations for Career Development, Fellowship, Training, and Research Education Programs (NOT-OD-18-001) – 11/06/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-001.html

Kirschstein NRSA Individual fellows
- Cannot propose to lead an independent clinical trial
- Can propose research experience in a clinical trial led by a sponsor or co-sponsor

Kirschstein NRSA Institutional trainees
- Cannot lead independent clinical trials
- Can gain research experience in a clinical trial led by a mentor or co-mentor

Institutional Research Education Grants (R25) participants
- Cannot lead independent clinical trials
- Can gain research experience in a clinical trial led by a mentor or co-mentor

Revision: NIAMS Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements (NOT-AR-18-008) – 11/03/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-AR-18-008.html

NHLBI Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for the NIH Parent R01 Clinical Trial Required Announcement (NOT-HL-17-546) – 11/03/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-HL-17-546.html

NIMH Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements (NOT-MH-18-004) – 11/03/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-MH-18-004.html

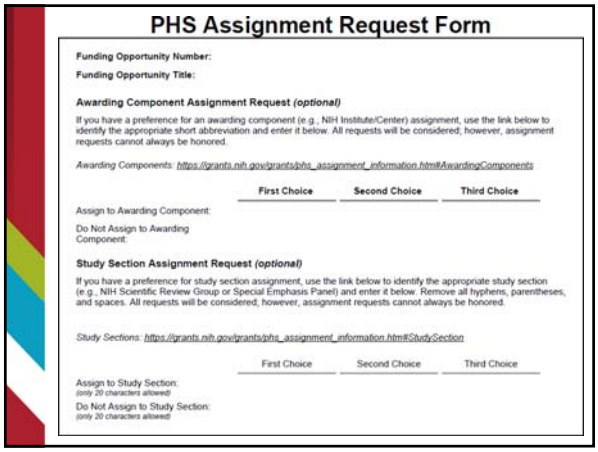
NCCIH Policy for Submission of Parent R01 Applications Proposing Clinical Trials (NOT-AT-18-001) – 11/03/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-AT-18-001.html

Clinical trial

Is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

Mechanistic study

Is designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention



PHS Assignment Request Form

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

If you have a preference for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation and enter it below. All requests will be considered; however, assignment requests cannot always be honored.

Awarding Components: https://grants.nih.gov/grants/phs_assignment_information.html#AwardingComponents

	First Choice	Second Choice	Third Choice
Assign to Awarding Component:			
Do Not Assign to Awarding Component:			

Study Section Assignment Request *(optional)*

If you have a preference for study section assignment, use the link below to identify the appropriate study section (e.g., NIH Scientific Review Group or Special Emphasis Panel) and enter it below. Remove all hyphens, parentheses, and spaces. All requests will be considered; however, assignment requests cannot always be honored.

Study Sections: https://grants.nih.gov/grants/phs_assignment_information.html#StudySection

	First Choice	Second Choice	Third Choice
Assign to Study Section: *(only 20 characters allowed)*			
Do Not Assign to Study Section: *(only 20 characters allowed)*			

NIH's Definitions	
Clinical trial	A research study in which one or more human subjects are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **health-related biomedical or behavioral outcomes**
Prospectively assigned	Pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial
Intervention	Manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints Examples: Drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and diagnostic strategies
Health-related biomedical or behavioral outcome	Pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life Examples: Positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and positive or negative changes to quality of life.

Is it a clinical study or a clinical trial?

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is "yes," your project meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

***Not* considered clinical trials**

- Studies intended solely to refine measures
- Studies that involve secondary research with biological specimens or health information

Instructions	https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm
Case studies	https://grants.nih.gov/policy/clinical-trials/case-studies.htm
FAQs	https://grants.nih.gov/policy/clinical-trials/faq-list.htm
Training resources	https://grants.nih.gov/policy/clinical-trials/training-resources.htm
Glossary	https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm

Revision: The NIH Announces Additional Review Criteria for Career Development Award Applications Involving Clinical Trials
(NOT-OD-18-109) – 12/01/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-109.html

Scored Review Criteria (Independent Clinical Trial Required)

- Candidate
  - Does the candidate have the potential to organize, manage, and implement the proposed clinical trial, feasibility or ancillary study?
  - Does the candidate have training (or plans to receive training) in data management and statistics including those relevant to clinical trials?
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
  - Does the mentor or mentoring team have the expertise, experience, and ability to guide the applicant in the organization, management and implementation of the proposed clinical trial, ancillary, or feasibility study and help him/her to meet the timelines?
- Environment & Institutional Commitment to the Candidate
  - Are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
  - Does the application adequately address the capability and ability to conduct the trial, feasibility or ancillary study at the proposed site(s) or centers? If applicable, are the plans to add or drop enrollment centers, as needed, appropriate?
  - If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

Revision: The NIH Announces Additional Review Criteria for Career Development Award Applications Involving Clinical Trials
(NOT-OD-18-109) – 12/01/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-109.html

Scored Review Criteria (Independent Clinical Trial Required)

- Research Plan
  - Are the scientific rationale and need for a clinical trial, feasibility or ancillary study well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
  - If proposing a small feasibility study, will it contribute to planning and preliminary data needed for design of future larger scale clinical trials?
  - Is the clinical trial or ancillary study necessary for testing the safety, efficacy or effectiveness of an intervention, or in the case of a feasibility study, necessary to establish feasibility of a future clinical trial?
  - Is the study design justified and relevant to the clinical, biological, and statistical hypothesis(es) being tested?
  - Are the plans to standardize, assure quality of, and monitor adherence to, the protocol and data collection or distribution guidelines appropriate?
  - Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions, if interventions are delivered?
  - For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Revision: The NIH Announces Additional Review Criteria for Career Development Award Applications Involving Clinical Trials (NOT-OD-18-109) – 12/01/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-109.html

Scored Review Criteria (Independent Clinical Trial Not Allowed)

- Career Development Plan/Career Goals and Objectives
  - If proposed, will the clinical trial experience contribute to the applicant's research career development?
- Research Plan
  - If proposed, will the clinical trial experience contribute to the proposed research project?
- Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)
  - If the applicant is proposing to gain experience in a clinical trial as part of his or her research career development, is there evidence of the appropriate expertise, experience, and ability on the part of the mentor(s) to guide the applicant during participation in the clinical trial?

Revision: The NIH Announces Additional Review Criteria for Career Development Award Applications Involving Clinical Trials (NOT-OD-18-109) – 12/01/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-109.html

Additional Review Criteria (both)

- Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?
- Is the projected timeline feasible and well justified?
- Does the project incorporate efficiencies and utilize existing resources to increase the efficiency of participant enrollment and data collection, as appropriate?
- Are potential challenges and corresponding solutions discussed?

Grant Application Instruction Correction for Training Grants with Human Subjects Involvement (NOT-OD-18-128) – 12/18/2018
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-128.html

- Most Training grant packages don't include the new "PHS Human Subjects and Clinical Trials Information" form
- Applicants can provide additional information regarding potential involvement of trainees in human subjects research in the "Proposed Training" section of the "Program Plan" attachment on the "PHS 398 Research Training Program Plan" form

PHS Human Subjects and Clinical Trials Information form

1. Basic information
2. Study population characteristics
   - Inclusion enrollment report
3. Protection and monitoring plans
4. Protocol synopsis
5. Other clinical trial related attachments

Reminder: Updated Appendix Policy Eliminates Clinical Trial-Related Materials for NIH/AHRQ/NIOSH Applications Submitted to Due Dates on or After January 25, 2018 (NOT-OD-18-126) – 01/12/2018
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-126.html

- Blank data collection forms, blank survey forms, and blank questionnaire forms
- Simple lists of interview questions
- Blank informed consent/assent forms
- Items specified in the FOA

Do not include: Data, data compilations, lists of variables or acronyms, data analyses, publications, manuals, instructions, or descriptions or drawings/figures/diagrams of data collection methods or machines/devices

Exemption number: 1, 2, 3, 4, 5, 6, 7, 8

➢ Don't use 7 or 8 yet

If your project
- Involves human specimens and/or data, and
- Is exempt from federal regulations

Provide a justification that includes:
- Information on who is providing the data/biological specimens and their role in the proposed research
- Description of the identifiers that will be associated with the human specimens and data
- List of who has access to subjects' identities
- Information about the manner in which the privacy of research participants and confidentiality of data will be protected

NIH requires a data and safety monitoring plan (DSMP) commensurate with the trial's risks, size, and complexity

- The overall framework for safety monitoring and what information will be monitored
- The frequency of monitoring, including any plans for interim analysis and stopping rules
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity

Potential monitoring options include:

- PD/PI
  - Might be acceptable n some cases (e.g., low risk trials, not blinded)
- Independent safety monitor/designated medical monitor
  - A physician or other expert who is independent of the study
- Independent Monitoring Committee or Safety Monitoring Committee
  - A small group of independent experts
- Data and Safety Monitoring Board (DSMB)
  - A formal independent board of experts including investigators and biostatisticians
  - NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants and for Phase III clinical trials
  - Phase I and Phase II clinical trials may also need DSMBs
  - Describe the general composition without naming specific individuals

Dissemination plan

- Ensure that clinical trials are registered in and results information is submitted to ClinicalTrials.gov
- Include specific statement relating to posting of clinical trial information at ClinicalTrials.gov in informed consent documents
- Has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements

Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (NOT-OD-18-014) – 11/28/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html

Effective 12/13/2017

- Recipients conducting **applicable NIH-defined Phase III clinical trials** must ensure results of **valid analyses** by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov

Applicable clinical trial	• As defined in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA • In general, clinical trials of drug, biological, and device products regulated by the Food and Drug Administration (FDA) • Also, pediatric post-market surveillance study of a device product required by the FDA
NIH-defined Phase III clinical trial	• Broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments • Often aims to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care • Includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy • Also, community trials and other population-based intervention trials

Valid analysis	• Unbiased assessment, which requires
	  • Allocation of study participants of both sexes/genders (males and females) and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization
	  • Unbiased evaluation of the outcome(s) of study participants
	  • Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex/gender, race, and/or ethnicity

Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-18-004) – 10/11/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-004.html

For due dates on or after January 25, 2018
Multi-site study in which each site will conduct the same protocol involving non-exempt human subjects research must utilize a sIRB

- Must
  - Be registered with the HHS Office for Human Research Protections
  - Have membership to adequately review the proposed study
- Can be
  - An institutional IRB that is associated with either
    - Awardee
    - Participating site
  - An independent, commercial, or unaffiliated IRB
  - A central IRB organized to review the proposed study

Guidance on Exceptions to the NIH Single IRB Policy (NOT-OD-17-119) – 09/25/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-119.html

- Does not apply to
  - Foreign sites
  - Career development (K), institutional training (T), or fellowship (F) awards
- Exceptions
  - Policy-based
    - Prohibited by a federal, state, or tribal law, regulation, or policy
  - Time-limited
    - Ancillary studies to ongoing research without a sIRB
  - Other
    - Must request prior approval
  - Post-award
    - Addition of a new domestic site unable to use sIRB

Publication of the Revised NIH Grants Policy Statement (Rev. October 2017) for FY 2018 (NOT-OD-18-005) – 10/12/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-005.html

For budget periods beginning on or after 10/01/2017
- Good Clinical Practices
  - All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials must be trained in GCP

Notice of Requirement for Electronic Submission of Research Supplements to Promote Diversity in Health-Related Research and Upcoming System Validation (NOT-OD-18-111) – 12/07/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-111.html

Administrative supplements
- NIH ASSIST
- **Institutional system-to-system (S2S)**
- Grants.gov Workspace
- **Streamlined system through eRA Commons**

Update: Notice of NIH's Interest in Diversity (NOT-OD-18-122) – 01/03/2018
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-122.html

NIH encourages institutions to diversify student and faculty populations to enhance the participation of individuals:
- From underrepresented racial and ethnic groups
- With disabilities
- From disadvantaged backgrounds

NIH Enforcement of Closeout Policies (NOT-OD-18-107) – 11/30/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-107.html

Due within 120 days of end date
- Final Federal Financial Report (FFR)
- Final Research Performance Progress Report (F-RPPR)
- Final Invention Statement and Certification (FIS)

NIH will Make the Project Outcomes Section of all Interim and Final RPPRs Submitted on or After October 1, 2017 Available via the NIH RePORTER (NOT-OD-18-103) – 11/16/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-103.html

NIH
- Will review Project Outcomes narrative
  - Written for the general public in clear, comprehensible language
  - Without proprietary, confidential, or trade secret information
- May request revised narrative
  - Using the "Additional Material" functionality in place for the Final and Interim RPPR

Examples:
https://grants.nih.gov/grants/rppr/sample_project_outcomes_RPPR.htm

Standards for Documentation of Personnel Expenses (NOT-OD-18-108) – 11/30/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-108.html

Records of personnel expenses must:
- Be supported by a system of internal control which provides reasonable assurance that the charges are accurate, allowable, and properly allocated
- Be incorporated into the official records of the university
- Reasonably reflect the total activity for which the employee is compensated by the university, not exceeding 100% of IBS
- Encompass both federally assisted and non-federally assisted activities Comply with the established accounting policies and practices of the university
- Support the distribution of the employee's salary or wages among specific activities

Salaries used in meeting cost-sharing requirements must be supported in the same manner

Statement on Article Publication Resulting from NIH Funded Research (NOT-OD-18-011) – 11/03/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-011.html

To protect the credibility of published research, authors are encouraged to publish papers arising from NIH-funded research in reputable journals

Best practices
- The National Library of Medicine encourages publishers to follow established industry best practices, including:
  - Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals [PDF] from the International Committee of Medical Journal Editors (ICMJE)
  - Principles of Transparency and Best Practice in Scholarly Publishing, the joint statement by the Committee on Publication Ethics (COPE), the Directory of Open Access Journals (DOAJ), the Open Access Scholarly Publishers Association (OASPA) and the World Association of Medical Editors (WAME)

Statement on Article Publication Resulting from NIH Funded Research (NOT-OD-18-011) – 11/03/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-011.html

Red flags
- Misleading pricing (e.g., lack of transparency about article processing charges)
- Failure to disclose information to authors
- Aggressive tactics to solicit article submissions
- Inaccurate statements about editorial board membership
- Misleading or suspicious peer-review processes

Resources
- Think Check Submit, a publishing industry resource
- "Academics and scientists: Beware of predatory journal publishers," information from the Federal Trade Commission

Maintaining Integrity in NIH Peer Review: Responsibilities and Consequences (NOT-OD-18-115) – 12/22/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-115.html

PIs and AORs
- *Should not* contact reviewers on the study section evaluating their application or proposal to request or provide information or materials related to the review, or to otherwise attempt to influence the outcome of the review or the reviewer(s), or to access information or materials related to the review by any other means until/unless provided directly to them through NIH-approved communication channels
- *Should not* send information or data directly to a reviewer on the study section evaluating his/her application or proposal
- *Should* immediately contact the SRO who is managing the review of his/her application or proposal if contacted by a reviewer or by an individual named in another application or proposal for purposes of obtaining or exchanging information outside of the channels described above

Maintaining Integrity in NIH Peer Review: Responsibilities and Consequences (NOT-OD-18-115) – 12/22/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-115.html

Possible Consequences

- Notifying the individuals and institutions involved
- Terminating the reviewer's or Council member's service in peer review
- Pursuing a referral for government-wide suspension or debarment
- Referring the matter to the NIH Office of Management Assessment and possibly to the Office of Inspector General, U.S. Department of Health and Human Services, which could result in criminal penalties, fines, imprisonment, and/or other action(s)

Revision: NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects (NOT-OD-18-116) – 12/19/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html

Effective 01/25/2019
Individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them:

- Disease or condition does not occur in the excluded age group, or the research topic is not relevant to the excluded age group.
- Knowledge being sought in the research is already available for the excluded age group or will be obtained from another ongoing study
- Separate, age-specific study in the excluded age group is preferable
- Study will collect or analyze data on pre-enrolled study participants (e.g., longitudinal follow-up studies that did not include data on children, or analysis of an existing dataset) and data inclusive of individuals across the lifespan are not available to address the scientific question
- Laws or regulations bar the inclusion of individuals in a specific age group
- Study poses an unacceptable risk to the excluded group, such that their participation would not be considered ethical by the local IRB, peer review and/or NIH staff

Request for Information on Developing Experimental Design "Emoji" Symbols for Use in Scientific Presentations (NOT-OD-18-014) – 11/07/2017
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html

12/15/17 deadline

- The potential utility of emojis as a simple, time-saving means to convey information about study design during oral and poster presentations
- A list of experimental design elements that would benefit from having such an emoji
- Ideas for the visual design of suggested emojis
- Examples
  - Dice to indicate randomization
  - Covered eye to indicate blinding of experimental groups