PRINCETON UNIVERSITY

Princeton Research

Coffee with ORPA

National Institutes of Health Updates

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Application Types

Number Type	Stage	Description
Type 1	New Competing	Brand, spanking new
Type 2	Renewal (f/k/a Competing Continuation)	Current award ending, applying for renewal of award, competing with everyone else
Type 3	Revision	Request for additional funds *during current project period*. Competing Revisions: Request funds for new/additional activities *outside* of original scope. Administrative Supplements: Request funds for unforeseen circumstances for activities *w/i* original scope.
Type 4	Extension	More time, used only in select programs.
Type 5	Non-Competing Continuation	Request for subsequent budget period *w/i a previously approved project*.
Type 6	Change of org. status (Successor-in-Interest)	Rights/obligations under grant transfer as result of merger, corporate change.
Type 7	Change of Grantee Institution	Transfer of legal/administrative duties to new institution.
Type 8	Change of Institute or Center for noncompeting	Change of awarding institute/center for non-competing continuation.
Type 9	Change of Institute or Center for renewal	Change of awarding institute/center for renewal.

Institutes and Centers (IC)

- **27 Institutes and Centers**
  - **21 Institutes & 6 Centers**
  - Specific research agenda, particular diseases, body systems
  - Each headed by institute director
  - Not all ICs accept applications for all types of grant programs
  - Some may have specialized eligibility criteria
  - FOA will state participating ICs

https://www.nih.gov/institutes-nih/list-nih-institutes-centers-offices

Fellowships (F-Series)

F-Type	Who	What
F30	Predocs	Individual fellowships for predoctoral training leading to combined MD/PhD and other dual clinical/research degrees.
F31	Predocs	Supervised research training to predoctoral individuals
F32	Postdocs	Research training to postdocs broaden scientific background and extend potential for research in specified health-related areas.
F33	Experienced scientists	Support major changes in the direction of research careers or to acquire new research skills.
F99/K00	Pre- to Post-doc transition	Support pre- to post-doctoral transition of highly motivated graduate students.

https://researchtraining.nih.gov/programs/fellowships

Research Career Development Award Programs (K-Series)

- Support senior postdocs or faculty-level candidates.
- Objective is to bring candidates to the point where they can conduct research independently and are competitive for major grant support.
- Applicants must be U.S. citizens, non-citizen U.S. nationals, or permanent residents at time of award. (K99/R00 is exception)
- Only U.S. domestic institutions are eligible.
- There are many types of "K" applications, some mentored (K01, K07 development, K08, K22, K23, K25, K99/R00) and some non-mentored (K02, K05, K07 leadership, K24, K26).

- Most Commonly Submitted at Princeton
  - **K01 – Mentored Research Scientist Career Development Award** –Support and protected time for postdocs or early career researchers for intensive, supervised career development experience leading to research independence.
  - **K99/R00 – Pathway to Independence Award** – Support transition of highly qualified postdocs from mentored research positions to independent, tenure-track or faculty positions: (initial mentored research) K99 – 1-2 years, (independent research) R00 – 3 years

https://researchtraining.nih.gov/programs/career-development

Research Grants (R-Series)

- Largest category of funding by NIH Institutes and Centers.
- R01 – Research Project Grant
  - Most common
  - Supports discrete, specified projects
  - 3-5 years
  - Advance permission for $500k or more in direct costs in any year
- R03 – Small Grant
  - Limited funding
  - Short period of time
  - 2 years
  - Direct costs up to $50k/year
  - Not renewable
- R13 – Supports conferences and scientific meetings
  - Advance permission required from funding IC
  - Supports high quality conferences/scientific meetings relevant to NIH mission and public health

Research Grants (R-Series)

- R21 – Exploratory/Development Research
  - New, exploratory, and developmental research
  - Max 2 years funding
  - Max $275k over 2 years
- R41/R42 – Small Business Technology Transfer (STTR)
  - Supports cooperative research between U.S. small businesses and research institutions.
  - Fosters technology transfer and commercializing innovative technologies
  - PI may be employed with small business or institution.
- R43/R44 – Small Business Innovative Research (SBIR)
  - Supports research by private sector for projects with potential for commercialization.
  - PI must be employed with small business.

Institutional Training Grants (T-Series)

- Several "T" program types
  - T32 – NRSA Institutional Research Training Grant: PI selects trainees and develops a program of coursework, research experiences, and technical and/or professional skill developments.
  - T34 – Undergraduate NRSA Institutional Research Training Grant: Research training for undergraduates from underrepresented groups in biomed and behavioral health sciences for research doctorate degree program.
  - T35 – Short term Institutional Research Training Grant: 8-12 weeks in duration, training off quarters or during summer to encourage research careers and/or research in areas of national need
  - For T-series applications submitted on or after January 25, 2019, a letter describing the institutional commitment to preventing discrimination and harassment will be required.
    - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-029.html

U-Series

- Many, many U's
- All Cooperative Agreements
- U01 most common
- U01 – Research Project Cooperative Agreement
  - Supports discrete and specified projects in PIs specific area of interest.
  - Substantial involvement from awarding Institute and Center
  - No specific dollar limit unless specified in FOA

Multi-PI Applications

- Each PD/PI is responsible and accountable for the proper conduct of the project or program, including the submission of all required reports.
- The PIs may be from one institution or multiple institutions.
- One PI from the lead institution must be designated as Contact PI.
- Each PI must have an eRA Commons ID.
- The application must include a Multi-PI Leadership Plan (field # 7 on the Research Plan Form).
- Any PI-related changes requiring prior approval at the award stage (e.g. change in status, reduction of effort) apply equally to each PI, and a revised Leadership Plan is required as part of the prior approval request.

Modular Budgets

- Required in R-series applications requesting $250,000 or less in direct costs in each budget period (unless otherwise noted in the funding announcement)
- Subrecipient indirect costs (aka Consortium F&A) are not included in the Direct Costs limit. Therefore, you may have a Total Direct Costs amount that exceeds $250,000 per budget period.
- The Direct Cost amount in each period may only be in increments of $25,000.
- Cost category details are not required. Rather, only the total direct costs and indirect costs details (rate type, rate, base, amount requested) are entered for each period.
- A Personnel Justification is submitted in place of a full Budget Justification.
- Additional justifications are used for subcontracts (Consortium Justification) or to explain any other details as necessary (Additional Narrative Justification).

R&R Budget Form

- Used when a modular budget is not an option (e.g. if direct costs exceed $250,000 per year, or as indicated in the funding announcement).
- A full breakdown of cost categories is required, including effort in person months for all personnel types.
- Equipment should be itemized; the form allows for up to ten separate items per budget period.
- A Budget Justification detailing all direct and indirect costs is required.
- If the application includes subawards, a complete R&R Budget Form, with budget justification, must be included for each subrecipient using the Subaward Budget Attachments Form.
- Be sure to check the appropriate box on page 1 of each period ("Project" for Princeton, "Subaward/Consortium" for subrecipients").

NRSA Stipend Levels

- Each fiscal year, NIH updates the maximum allowable amounts for stipends, tuition, and institutional allowance on National Research Service Awards (NRSAs).
- The NRSA program funds both predoctoral and postdoctoral fellowships, and stipend levels are set according to rank, and in the case of postdoctoral research fellows, year of experience.
- Undergraduate levels are also defined for certain types of institutional training grants.

Current FY18 Levels

Predoctoral Stipend	$24,324
Predoctoral Tuition	60% of actual tuition up to $21,000
Predoctoral Inst. Allowance	$4,200
Zero-Level Postdoc Stipend	$48,432
Postdoctoral Inst. Allowance	$9,850

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-175.html

Graduate Student Compensation

- NIH limits total graduate student compensation, inclusive of salary, tuition, and fees, to the zero-level NRSA postdoc stipend level.

NRSA zero-level PD Stipend: **$48,432**

Princeton grad student at 100% effort based on current rates:
$29,000 AY + $8,000 Summer + $25,625 Tuition = **$62,625**

- At the award stage, grantees are permitted to re-budget funds, without NIH prior approval, to support graduate students at a level not to exceed that of a Level 1 postdoc based on the NRSA scale, inclusive of applicable fringe benefits.

NRSA Level 1 Postdoc: $48,804 + $17,569 (Fringe Benefits at 36%) = **$66,373**

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html

Executive Level Salary Cap

- NIH, per congressional legislation initiated in 1990, limits direct salary for individuals under NIH grant and cooperative agreement to Executive Level II of the Federal Executive pay scale.
- The current FY2018 limit is $189,600.
  - This amount is prorated to a monthly limitation of $15,800, and further prorated based on the level of effort of the researcher.
  - Thus, one may not simply reduce their effort to bring their salary under the cap.

Example:
A PI has a 9-month base salary of $175,000.
The prorated monthly amount is $19,444.

- Salaries in proposal budgets may not exceed this limitation, and at the award stage, salary amounts in excess of the cap must be charged to a non-sponsored research funding source.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html

Budget Escalation

- In the years following the financial downturn of 2008-2009, NIH instituted a policy that prohibited escalation of budget costs in out years.
- This policy has since been rescinded, and the current NIH guidance on this topic is as follows:

"In general, NIH does not have policy on salary escalation submitted in an application. We advise applicants to request in the application the actual costs needed for the budget period and to request cost escalations only if the escalation is consistent with institutional policy."

- Therefore, any escalation in out years should be in accordance with the guidance on the ORPA website and Rate Sheet.

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/develop-your-budget.htm#years

Human Subjects Research

- With the transition to the FORMS-E application package, NIH consolidated the human subjects sections into a single component, the **PHS Human Subjects and Clinical Trials Information Form**.
  - The form first auto-populates answers from the **Other Project Information Form** as to whether or not the proposed research involves human subjects.
  - If the answer was "no," you now must also answer if human specimens or data are involved.
    - If you answer "yes" to human specimens or data, you must provide a justification for your claim that no human subjects are involved.
  - If the answer to the human subjects question was "yes," you must add a **Study Record** for each proposed study involving human subjects.
    - The **Study Record** is a self-contained unit that includes all of the information that previously resided in the four human subjects research attachments in the old version of the **Research Plan Form**.

Vertebrate Animals Research

- If you answer "yes" to the Vertebrate Animals question on the Other Project Information Form, you must upload an attachment in field 5 of the PHS 398 Research Plan Form.
  - The document must address the three criteria specified in the NIH guidelines:
    - Description of procedures
    - Justifications for the species being used
    - Minimization of pain and distress

Project Summary/Abstract

- Required field in the R&R Other Project Information component
- Publicly viewable if funded through NIH's Research Portfolio On-line Reporting Tools (RePORT)
- 30 lines or less
- Understandable to scientists and non-scientists
- Include objectives, aims, research design and methods
- No proprietary/confidential information or trade secrets
- Varies with funding program
  - Career: Include description of candidate's career development plan, goals, and environment
  - Training: Describe levels and duration of training and number of trainees
  - Fellowship: Describe fellowship training plan and research environment

Project Narrative

- Required field in the R&R Other Project Info component
- Relevance of research to public health
- 3 sentences
- Publicly releasable if funded

Specific Aims

- Required field in the Research Plan component
- Typically 1 page limit
- State goals of research
- Summarize expected outcomes
- Describe impact to research field

Research Strategy

- Required field in the Research Plan component
- Page limit varies by program.
  - F – 6 pages
  - T – 25 pages
  - R – 5, 6, 10, 12 pages – depends on program
- Specified order headers – Significance, Innovation, Approach
- Different requirements for R-series, SBIR/STTR
- Progress Report section is required only for renewal/revision applications
- PI's preliminary studies, data, and experience should be included if applicable

Cover Letter

- Attach to field 21 on SF424 Cover component (Not field 20)
- Kept separate from rest of application – not shared with peer reviewers
- Address to Division of Receipt and Referral
- Cover letter must be included in following situations:
  - Late applications
  - Changed/corrected applications submitted after due date
  - When there are subaward budget components that are not active for all budget periods
  - Documentation of agency approval for application
  - Intent to submit video (video not accepted if not stated in cover letter)
  - If studies will generate large-scale human or non-human genomic data
- Information to include:
  - Explanation/Justification of situations
  - Application title
  - Title of FOA
- Mandatory for certain applications – Mentored Career Development Award and Fellowships

PHS Assignment Request Form

- Optional form
- Info used to be collected on Cover Letter Attachment
- Request assignment preferences
- List individuals who should not review and why
- Identify scientific areas of expertise needed for review
- Some fields are optional, and it is not necessary to complete entire form

Fixed Price Subawards

- Require NIH prior approval
  - Rationale should be explained in budget justification at proposal stage, which will facilitate sponsor approval at award stage.
  - "The subaward to [Name the subrecipient here] documented in this proposal meets the criteria described in Subpart C- 200.201(b) and Princeton University is therefore requesting prior agency approval of this Fixed Price Subaward. The University will consider the subrecipient's budget for the entire period of performance approved if an award is made and no contrary guidance from the agency is included in the award notice."
- Fixed Price Subawards may not exceed $250,000 (which is the current simplified acquisition threshold, most recently updated by OMB June 20, 2018).
- Per 45 CFR Part 75.2,Fixed Price Subawards must have (1) a clearly defined scope of work, (2) payments tied to specific deliverables, and (3) accountability based on performance and results, and are typically used with foreign subs and small businesses to minimize risks to Princeton
- Prohibited in programs requiring mandatory cost share or matching
- Total value of award is negotiated upfront.
  - Partial payments tied to milestones
  - 1 payment at subaward completion

ASSIST

Application Submission System & Interface for Submission Tracking

- ASSIST is NIH's proposal submission portal. Here you can prepare, submit and track a grant application.
- Proposals submitted via ASSIST are routed thru Grants.gov and tracked in eRA Commons.
- Features
  - Multi-user access
  - Pre-submission validation of many NIH and Grants.gov application requirements
  - Pre-population from eRA Commons profiles
  - Pre-submission preview in agency format
  - Track application status in a single system
  - Copy data to different application package

https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options/assist.htm

eRA Commons

- eRA (electronic Research Administration) Commons is the NIH online grant tracking system.
- Here authorized users can track applications through the grants lifecycle from application receipt to closeout.
  - Some Common User Roles
    - **Signing Official (SO)** – The signing official (SO) has institutional authority to legally bind the institution in grants administration matters. Princeton's SO is Elizabeth Adams
    - **Principal Investigator (PI)** – A Principal Investigator (PI) is designated by the grantee organization to direct the project or activity being supported by the grant.
    - **Account Administrator (AA)** – The account administrator role can create/edit all Commons accounts (except an SO account and IAR accounts). Princeton's AA is currently Robin Fitzgerald-Frink.

eRA Commons

- Examples of eRA Commons Information/Functions
  - Application Tracking – Once an error free application is received by NIH the eRA system will send status email notifications and post application in the PI's eRA Commons account.
  - Grant Document Retrieval – Award documents can be found in Commons once the application is approved
  - No Cost Extension Requests
  - Submission of Additional Application Materials – Just-in-time, Reference Letters
  - Submission of Research Performance Progress Report (RPPR)
  - Closeout – The terms and conditions of an award require certain closeout documents. Failure to submit closeout documents in a timely manner can result in Unilateral Closeout, which is a BAD thing, and can affect future funding for the PI or the University.

https://era.nih.gov/index.cfm

NIH Grants Policy Statement

- The NIH Grants Policy Statement (or GPS) is a single document that serves as primary reference source for all NIH policies, procedures, and terms and conditions of NIH grants and cooperative agreements.

- The current GPS applies to NIH grants and agreements with budget periods beginning on or after October 1, 2018.

- The GPS is updated at least annually, and each new iteration includes a "Significant Changes" document, located on the NIH GPS website, which calls out the most important changes from made from the last version.

https://grants.nih.gov/policy/nihgps/index.htm

Biographical Sketch

- NIH, requires Biosketches for all senior/key personnel listed in applications and progress reports.
- Why? Biosketches describe the magnitude and significance of their scientific contributions and provides more detailed information about their research experience
- There are specific formats for fellowship and non fellowship applications – no figures or tables allowed.
- Biosketches are limited to 5 pages, and the required components vary depending on the application type (for example, F-series predoctoral bio sketches require all undergraduate and graduate courses with grades).

Biographical Sketch

- SciENcv, is a tool to help you develop your biosketch and automatically format it according to NIH requirements. - https://www.ncbi.nlm.nih.gov/sciencv/
- Sample and blank forms can be found on the NIH website
- The blank format pages and sample biosketches have been updated to reflect the new expiration date of 03/31/2020. Biosketches created using format pages with an expiration date of 10/31/2018 can not be used after that date.

https://grants.nih.gov/grants/forms/biosketch.htm

Warnings vs. Errors

- Any corrective submissions must be made ***BEFORE*** the submission deadline date.
- WARNINGS
  - Warnings do not stop the application processing and maybe be corrected at your discretion
  - Reviewers do not see application warnings, nor can they tell how many submission attempts were needed to complete the submission process
- ERRORS
  - Prevents the application from being reviewed. Errors MUST be corrected in order for the application to be successfully submitted.
- Corrections/Updates
  - Any revisions must be done via a Change/Corrected application.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html

Changed/Corrected Application

- Any corrective submissions must be made BEFORE the submission deadline date!
  - ASSIST users: You must put change your application status to "Work In Progress" in order to edit forms.
  - Change the "Type of Submission" to "Changed/Corrected"
  - Enter "Grants.gov Tracking ID" (e.g., GRANT12345678) of initial submission in "Previous Grants.gov Tracking ID field
- Submit the entire Changed/Corrected application back through Grants.gov ***before*** the deadline
- Track submission through to eRA Commons
  - Be sure to check eRA commons for the final submission status and not rely on the system generated emails.

https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/changed-corrected-application.htm

Just-in-Time

- NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding.
- JIT information is submitted via eRA Commons.
- JIT Components vary based on the proposal but typically includes:
  - Other Support/Current and Pending
  - Certification of IRB Approval
  - Verification of IACUC Approval
  - Human Subject Approvals
  - Other Information as requested

https://grants.nih.gov/grants/forms/othersupport.htm

Other Support

- NIH requires information on other support (also referred to as Current and Pending) for all applications that are to receive awards.
  - Other support is not required for Program Directors, training faculty and other individuals involved in the oversight of training grants.
- Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.
- Information on Other Support is also required in the progress report for all senior/key personnel, excluding consultants, when there has been a change in active other support.
- At a minimum Other Support information should include Project number, Contact PI, source of support, title of project/subproject, dates of approved/proposed project and person months.

https://grants.nih.gov/grants/forms/othersupport.htm

Notice of Award

- NIH notifies the recipient organization via e-mail when an award has been issued.
- NOA Contents
  - Cover Letter
  - Basic Award information: Grant Number, PI/Key Personnel, Period of Performance, Funding amount, Budget
  - Standard and Special Terms and Conditions – related to carry over, prior approvals, subcontracts, etc.
  - NIH Staff Contacts - Program Official and Grants Management Specialist.
- How is the NOA processed at Princeton?
  - NIH award document arrives via awards@princeton.edu.
  - NIH award is matched to Coeus proposal or PeopleSoft award, and ORPA GCA.
  - GCA reviews award and, if acceptable, completes award setup or modification paperwork and passes it on to the Sponsored Research Specialist for processing.
  - The PeopleSoft NOA is then distributed to the PI, Departmental Contacts, and SRA.

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html

Conflict of Interest

- NIH, per 42 CFR Part 50 Subpart F (grants and cooperative agreements) and 45 CFR Part 94 (contracts) requires that any institution applying for or receiving NIH funding from a grant or cooperative agreement must be in compliance with all of the PHS FCOI regulatory requirements.
  - **Purpose?** This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research supported with NIH funds will be free from bias resulting from Investigator financial conflicts of interest.

Conflict of Interest

- How is COI managed at Princeton?
  - RIA is Princeton's department responsible for reporting financial conflicts of interest for all recipients of Public Health Service funding.
  - This regulations require FCOI training; Investigators working on PHS funded projects are required to complete Princeton's web-based FCOI training module. FCIO training is required at least every four years.
  - Investigator means the project director or principal investor and any other person, regardless of title or position, who is responsible for design, conduct, or reporting research funded by PHS.

https://grants.nih.gov/grants/policy/coi/index.htm

https://ria.princeton.edu/conflict-of-interest

Research Performance Progress Reports (RPPR)

- The RPPR module is used by grantees to submit progress reports to NIH in the eRA Commons.
- Types of RPPRs
  - Annual RPPR – Use to describe scientific progress, significant changes, report on personnel, and describe plans for the subsequent budget period or year.
  - Final RPPR – Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR.
  - Interim RPPR - Use when submitting a renewal (Type 2) application.
- Due Dates for Annual and Interim RPPRs vary depending on the award type.
- Final RPPRs are due no later than 120 days after the award expiration date.

https://grants.nih.gov/grants/rppr/index.htm

Rebudgeting

- The NIH Grants Policy Statement, in section 8.1, addresses the policies and requirements relating to deviations from the originally approved award budget.
  - The specific guidance for when prior approval is required for rebudgeting is as follows:

"NIH prior approval is not required to rebudget funds for any direct cost item that the applicable cost principles identify as requiring the Federal awarding agency's prior approval, unless the incurrence of costs is associated with or is considered to be a change in scope."

- In section 8.1.2.5, the GPS also offers examples of changes that may be indicators of a change in scope:
  - Significant Rebudgeting, i.e. changing a single category by 25% or more
  - Purchase of a unit of equipment exceeding $25,000

No-Cost Extensions

- A one-time no-cost extension of up to 12 months may be exercised by the grantee institution, provided that:
  - no additional funding is needed;
  - there is no change in scope;
  - the extension is not being exercised solely to spend out a remaining balance; and
  - there are no special terms in the NOA restricting or prohibiting an extension.
- Grantee-approved NCEs may only be submitted during the window extending 90 days back from the end of the final budget period.
- NIH prior approval is required for extensions longer than 12 months, and for NCEs submitted after the end of the final budget period.
- Extension requests requiring prior approval must describe project activities during extension, and include a statement about funds available to support extension.

Effort Commitments

- NIH closely reviews and monitors effort commitments by senior/key personnel throughout both the proposal and award process.
  - In NIH proposals with detailed budgets, senior personnel in section A of the budget cannot have a zero level of effort.
  - At the Just-in-time stage, NIH reviews the PI's effort commitments on the award under review and all current and pending sources of support as detailed in the Other Support document.
  - In the annual RPPRs, the effort committed to the award during the reporting period must be included for the PI and all senior/key personnel.
- Reductions in effort of 25% or more for the PI and any senior/key personnel specifically named in the award document requires prior approval.

Restricted Carryforward

- Each Notice of Award from NIH will indicate if carryforward is automatic (i.e. does not require prior approval).
- In general, the following award types do not have automatic carryforward:
  - Center Awards (P50, P60)
  - U-Series Awards, which are cooperative agreements
  - T-series Institutional Training Grants
- Even on awards that have automatic carryforward, the annual RPPR has a field to indicate if the required carryforward is greater than 25% of the current year's total budget.
  - In cases where the answer to this question is "yes," NIH will review the circumstances, and may request an updated budget.
  - If they determine that the funds are not necessary for the completion of the project, NIH may reduce or offset future funding increments.

Relinquishing Statement

- A Relinquishing Statement is required as part of the Change of Grantee Institution process to transfer an active grant to another institution.
- Relinquishing Statements may be prepared and submitted in the eRA Commons. Required information includes:
  - New institution and administrative contact
  - Estimated remaining balance as of the effective transfer date (direct and indirect costs)
  - Any equipment purchased on the award being transferred which the PI intends to transfer to the new institution.
- The chair or director of the award-owning department must approve the transfer in writing before the Relinquishing Statement is submitted.
- The process can take up to six months or longer, so departments should endeavor to submit relinquishing statements as soon as possible after the decision to transfer the award has been made.

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1.2_prior_approval_requirements.htm#Change3

NIH Controlled-Access Data Sets

- The **National Center for Biotechnology Information**, part of the **National Library of Medicine**, maintains a number of data sets and repositories (for example **db GaP Genotypes and Phenotypes** database) to which investigators and researchers may apply for access.
- Access is granted to individuals through their eRA Commons account, and PIs will have to provide institutional information such as the DUNS number and Signing Official contact information as part of the application.
- If access is granted, the PI and home department are responsible for adherence to the terms of the access agreement, including any data protection/security requirements.

PubMed Central

- The **NIH Public Access Policy** ensures that the public has access to the published results of NIH funded research at **PubMed Central** (or PMC), a free digital archive of full-text biomedical and life sciences journal literature.
- Under the policy NIH-funded investigators are required to submit (or have submitted for them) to PMC an electronic version of the final, peer-reviewed manuscript upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication.
- As part of the RPPR, the PI must report all publications arising from the award. Any publications not compliant with the NIH Public Access Policy will generate a warning message.
  - The PI will still be able to submit the RPPR, but they will get an automatic email indicating that they have two weeks to resolve the non-compliant publications.
  - The institutional signing official (SO) must confirm with the NIH grants management specialist by the end of the two-week period that all publications are complaint.

http://www.pubmedcentral.nih.gov/

Supplemental Topics

Application Due Dates – This website contains the standard deadlines for NIH applications: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

AIDS-Related Due Dates – AIDS-related programs have different deadlines, as shown at this website: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm#AIDS

Review and Award Cycles – NIH has a standard cycle of application review schedules and award start dates, shown here: https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm#review

Clinical Trials – NIH definition of Clinical Trials: 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.

Dr. Francis Collins – Current NIH Director

DHHS – Acronym for the Department of Health and Human Services, the cabinet department under which NIH is managed.

Bethesda, MD – Home to the NIH Headquarters, aka the NIH Campus.

Centers for Disease Control – An institute under DHHS, but not part of NIH, headquartered in Atlanta, GA.

R35 MIRA – "Maximizing Investigators' Research Award," an R-series program within the National Institute of General Medical Sciences, intended to increase the stability in funding for researchers by reducing the number of applications submitted.

S10 Instrumentation Program – NIH's instrumentation grant program to assist NIH-funded researchers with equipment purchases that are typically too expensive to be obtained by an individual investigator with a research project grant.

RePORTER – "Research Portfolio Online Reporting Tools Expenditures and Results," an electronic tool that allows users to search a repository of both intramural and extramural NIH-funded research projects from the past 25 years and access publications since 1980, and patents resulting from NIH funding.

Nobel Laureates - 156 NIH supported researchers have been sole or shared recipients of 92 Nobel Prizes.

Center for Scientific Review – The section of NIH which organizes the peer review groups or study sections that evaluate the majority (75%) of the research grant applications sent to NIH.

Eunice Kennedy Shriver - On December 21, 2007, by act of Congress NICHD (National Institute for Child Health and Human Development) was renamed the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development in honor of Mrs. Shriver's vision and dedication and for her contributions to the founding of the institute.

Embryonic Stem Cells - Primitive (undifferentiated) cells that are derived from preimplantation-stage embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. This site hosts NIH's policies and procedures relating to stem cell research: https://stemcells.nih.gov/.

SBIR/STTR – "Small Business Innovation Research" and "Small Business Technology Transfer," respectively. Programs run by NIH, and other federal sponsors, to allow US-owned and operated small businesses to engage in federal research and development that has a strong potential for commercialization

Catalog of Federal Domestic Assistance (CFDA) – A database which helps the Federal Government track all programs it has domestically funded; NIH's CFDA numbers all begin with "93."

Co-PD/PI - NIH does not recognize the terms "Co-PI" or "Co-PD." One must either do a Multi-PI application, or assign other roles to Co-Investigators.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Letter of Intent - Some ICs request prospective applicants to submit letters of intent prior to the submission of a grant application.

Model Organism - Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Other Significant Contributors - Individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project.

Participant Support Costs – NIH defines participant support costs as "Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects."

Payback Agreement – An agreement required for NRSA postdoctoral fellows stipulating that they must engage in qualified research or teaching activities for a length of time equal to the period of NRSA support received. If the requirement it not met, some or all of the fellowship funds received must be repaid.