NCI RESEARCH AND FUNDING: QUESTIONS AND ANSWERS

GENERAL APPLICATION AND SUBMISSION

- **Where can I find general information on the NIH grants process?**

  NIH Office of Extramural Research provides information on Grant Application Basics and the Grants Process Overview.

  NCI Extramural Funding Opportunities provides links to funding initiatives, applications, grant policies, and research resources.

- **Where do I find information on the electronic grant application process?**

  Go to the NIH Office of Extramural Research web page on the for information on the Electronic Application Process and how find a Funding Opportunity Announcement (FOA) and download an application.

- **Which form do I use to apply for an NIH research grant?**

  For single projects, the SF424 Research and Related (R&R) Grant Application Package is used. Applicants use the "Apply for Grant Electronically" button within their Funding Opportunity Announcement (FOA) to access the Grants.gov download screen (can also be accessed directly via Grants.gov), which lists the available application forms package(s) in the Competition ID field.

  Multi-component applications must use the ASSIST (Application Submission System & Interface for Submission Tracking) system to prepare and submit their multi-project applications. Applicant organizations which use system-to-system solutions will be able to use those services for submitting multi-project applications into Grants.gov if the provider offers that service.

- **How do I submit my electronic application?**

  Grants.gov must successfully receive applications by 5:00 p.m. of the applicant institution's local time on the submission/receipt due date. Follow these steps:

  - Only your business official for Grants.gov -- called an authorized organizational representative/signing official (AOR/SO) -- can submit the application.
  - Your AOR/SO logs in to Grants.gov, then clicks "Submit" in your application package. Corrected applications follow the same process.
  - The AOR/SO should print a copy of the confirmation screen as a record.

  See Electronic Submission page for more information on submitting a single project application.

- **When is my application due?**

  NIH receives R01 and most other investigator-initiated applications three times a year. See Standard Submission/Receipt Due Dates for deadlines. Request for Applications (RFA) and some Program Announcements (PA) have special receipt dates that are provided in the specific Funding Opportunity Announcement (FOA)

See NIH's Standard Submission/Receipt Due Dates for Competing Applications for deadlines for small business awards, fellowships, and other types of applications. If a deadline occurs on a weekend or Federal holiday, it moves to the next business day.

Information on the continuous submission dates for reviewers can be found in NOT-OD-14-028.
This continuous submission process includes:

- Appointed members of chartered standing NIH Study Sections,
- Appointed members of NIH Boards of Scientific Counselors,
- Appointed members of NIH Advisory Boards or Councils,
- Appointed members of NIH Program Advisory Committees, and
- Peer reviewers who have served as regular or temporary members of peer review committees six times in 18 months.

Grants.gov must successfully receive applications by 5:00 p.m. of the applicant institution's local time on the due date.

- **When do I need preapproval from NCI to submit a new or renewal application?**

As stated in NOT-OD-02-004, applicants must seek agreement to accept assignment from Institute/Center staff at least 6 weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year. This policy does not apply to specific initiatives, such as Program Announcement with special receipt, referral and/or review (PAR) or Request for Applications (RFA) that allow budgets in excess of $500,000 for any year. In addition, applicants for conference grants (R13) must seek agreement from the Institute/Center R13 contact at least 6 weeks prior to the receipt date.

- **Should I include a cover letter with my application?**

Yes, Applicants are encouraged to include a cover letter with the application. The cover letter is only for internal use and will not be shared with peer reviewers. The letter should contain any of the following information that applies to the application:

1. Application title.
2. Funding Opportunity (PA or RFA) title of the NIH initiative.
3. Request of an assignment (referral) to a particular Institute/Center or study section within a Center of Scientific Review (CSR) Integrated Review Group.
4. List of individuals (e.g., competitors) who should not review your application and why.
5. Disciplines involved, if multidisciplinary.
6. For late applications, a cover letter is required explaining the reason for the delay (see next question).
7. When submitting a Changed/Corrected Application after the submission date, a cover letter is required explaining the reason for the changed/Corrected Application. If you already submitted a cover letter with a previous submission and are now submitting a Changed/Corrected Application, you must include all previous cover letter text in the revised cover letter attachment.

For electronic applications, attach file under the SF424(R&R) cover form using the Cover Letter Attachment field.

- **May I submit my application late?**

  There is a two week window of consideration after the application due date, during which time NIH might consider accepting a late application . NIH will not consider accepting late applications under the following circumstances:

  - RFAs that must be reviewed on a compressed timeline and that have declared, in the Application Due Date field, “No late applications will be accepted for this Funding Opportunity Announcement”.

  - New Investigator R01 applications resubmitted on special due dates (April 10, August 10, and December 10) as part of the New Investigator Initiative (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-001.html) because the submission deadline for these applications has already been extended by several weeks.

  Examples of Reasons Why Late Applications Might Be Accepted

  - Death of an immediate family member of the PD/PI (or MPI). Sudden acute severe illness of the PD/PI (MPI) or immediate family member.

  - Temporary or ad hoc service by a PD/PI on an NIH advisory group during the two months preceding or the two months following the application due date. Examples of qualifying service include: participation in an NIH study section/special emphasis panel, NIH Board of Scientific Counselors, Program Advisory Committee, or an NIH Advisory Board/Council. Qualifying service does not include participation in NIH activities other than those involved in extramural/intramural peer review or NIH Advisory Council/Board service.

  - Delays due to weather, natural disasters, or other emergency situations, not to exceed the time the applicant organization is closed.

  - For PD/PIs who are eligible for continuous submission (http://grants.nih.gov/grants/peer/continuous_submission.htm), the late application policy applies to activities not covered under the continuous submission policy (i.e., other than R01, R21, and R34 funding opportunities that use standard due dates).

  NOT-OD-15-039 provides more information on late submission.

- **May I send supplementary or missing materials after a receipt date?**

  For electronic applications, the PI and AOR/SO have two full weekdays (Monday - Friday, excluding Federal holidays) to view the application after which the submission process is complete. The only post-submission grant application materials that the NIH will accept after submission are those resulting from unforeseen administrative issues.

  Acceptable post-submission materials include:

  - Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition of equipment)
  - Biographical sketches (e.g., change in senior/key personnel due to the hiring, replacement, or loss of an investigator)

- Letters of support or collaboration resulting from a change in senior/key personnel due to the hiring, replacement, or loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PI moves to another university)
- News of an article accepted for publication (a copy of the article should **not** be sent)
- Video if it meets the guidelines and the intent to submit was included in the original cover letter (see NIH-OD-12-141)

For submissions to Request for Applications (RFA) that have only one due date, updated Specific Aims or Research Strategies pages, late breaking research finding and new letters of support or collaboration are usually accepted. Contact the SRO for more information.

See NIH Policy on Submission of Additional Grant Materials for more information.

- **When will I receive word on my application?**

  Notification that CSR has assigned your application to a scientific review group and Institute should appear in your eRA Commons account within 3 weeks of the submission deadline. If this notification does not appear in this timeframe, please contact the CSR Division of Receipt and Referral at 301 435-0715.

  Your priority score should be available in your Commons account within 3 business days after the peer review meeting, and your summary statement should be available within 30 days. New investigators who submitted R01applications should be able to access their summary statements within 10 days after the review meeting.

- **Is my application confidential?**

  Most grant and contract materials are confidential, including grant applications, progress reports, contract proposals, and proceedings of review meetings. Two exceptions are the grant application's title and abstract, which NIH makes public.

  Reviewers may not take materials from peer review and use them without attribution.

- **Do I need to be a citizen to apply for a grant?**

  You do not need to be a citizen to apply for a research project grant, e.g., an R01, small grant (R03), or exploratory/developmental grant (R21).

  If you are a non-citizen working at a U.S. institution receiving an award, you must remain there long enough to finish your project. If you do not have a permanent visa, state in your application that your visa will allow you to remain in the U.S. long enough for you to be productive on the project. Your institution is responsible for ensuring that you have an appropriate visa.

  Some grant types have a citizenship requirement, including small business and training and career development grants.

- **Will NCI accept applications with multiple PIs?**

  NIH is allowing multiple PIs for most electronic applications, including R01s. For more information, go to Multiple Principal Investigators Web site.

- **How should an application be identified as a "Genome Wide Association Study" (GWAS) application?**

  A cover letter indicating the presence of a GWAS component should accompany all such applications. Staff in the CSR Division of Receipt and Referral will confirm the identification and enter “GW” as a dual assignment whenever appropriate. Program staff in NIH ICs may also recommend that a “GW” dual designation be added or removed. For more information, go to NIH’s Genomic Data Sharing web site.

- **Where do I find information on the NIH policies for research using animals?**

  The Office of Laboratory Animal Welfare (OLAW) oversees policies on use of animal in research. See the Animals in Research website for more information and advice on submitting your grant application.

- **What does CSR do with my application?**

  CSR makes two assignments for your application for two purposes:

  1. **Initial peer review**. CSR assigns your application to either one of its initial review groups or to an institute for review. (For more information, see **Peer Review** section.)
  2. **Administration.** CSR also forwards a copy to the institute that will manage your application and your grant, if it's funded.

  See CSR's The Assignment Process and CSR Study Section Roster Index for more details on review assignment.

- **Where do I find information about funded NIH grants?**

  NCI maintains a searchable NCI Funded Research Portfolio Database for NCI grants. The NIH Research Portfolio Online Reporting Tool (RePORT) site includes a query form for all NIH funded research. In addition, RePORT summaries are provided, including the Research, Condition, and Disease Categorization (RCDC) reports. RCDC is a computerized process the NIH uses at the end of each fiscal year to sort and report the amount it funded in each of 215 historically reported categories of disease, condition, or research area.

- **Where can I find information on paylines and funding policies for NCI?**

  Information on the current payline for R01 applications and funding policies for competing and non-competing applications is available on the NCI Funding Policy web page.

- **Where do I find information about NIH success rates?**

  To find success rate information, go to NIH Success Rates. The NCI Fact Book contains information on how the budget was allocated for a given fiscal year.

- **Where do I find high-priority funding areas?**

  Find all NCI initiatives or Funding Opportunity Announcements on the NCI Funding Announcements List.

NIH publishes most initiatives -- Requests for Applications (RFA) and Program Annouoncements (PA) -- in the *NIH Guide*. For grant types that have transitioned to electronic applications, go to Grants.gov for the Funding Opportunity Announcement package.

Requests for Proposals (RFP) for NCI's contract initiatives are published in FedBizOpps and most do not appear in the *NIH Guide*.

- **How does NCI ensure that the highest priorities are funded?**

NCI pays most grants according to merit (i.e.,, based on the percentile ranking and/or priority score, depending on the type of grant) as assessed by peer review. However, for high-priority areas, NCI funds some applications outside the payline through exception funding. See NCI Funding Policy for RPG Awards .

- **Do I apply for a research supplement the same way as a grant?**

It depends upon the type of research supplement. A revision application or competing research supplement, may be submitted to request support for a significant expansion of the scope of a project or a research protocol. The submission process is similar to the original grant application process; see SF424 instructions for more information.

An **administrative supplement** provides additional funding to meet increased costs that are within the scope of your approved application, but that were unforeseen when the new or competing renewal application was submitted. If you are contemplating supplemental funding, you should consult in advance with your designated Program Director. Administrative supplements may be submitted electronically: see PA-14-077.

NIH offers administrative supplements to support work by individuals from underrepresented minority groups, disadvantaged backgrounds, or with disabilities on ongoing research projects. For more information, see Research Supplements to Promote Diversity in Health Care Research. NIH also offers Administrative Supplements to Promote Reentry into Biomedical and Behavioral Research Careers. NCI may also publish announcements for administrative supplements in specific research areas such as Activities to Promote Research Collaborations.

Applications for revisions or administrative supplements are **not appropriate** when the sole purpose is to restore awards to the full level recommended by the Scientific Review Group if they were administratively reduced by the funding agency. A revision application **should not be submitted** until after the original application has been awarded and **may not extend beyond the term of the current award period.**

- **What is the NIH Common Fund? How are these initiatives being coordinated and reviewed?**

The NIH Common Fund is an effort to transform the nation's medical research capabilities and speed the movement of research discoveries from the bench to the bedside. The Common Fund supports the series of transformative programs that were established under the NIH Roadmap for Medical Research, as well as other non-Roadmap activities. Programs include the NIH Director's Pioneer awards, New Innovator awards, Early Independence awards, and Transformative R01 Program. For complete information, visit the Common Fund site.

The Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI) is responsible for managing the process by which trans-NIH initiatives are prioritized for consideration and evaluation by both outside advisors and NIH leadership.

FUNDING OPPORTUNITY ANNOUNCEMENTS (FOAs) AND OTHER SPECIAL INITIATIVES

- **What is a Funding Opportunity Announcement or FOA?**

  A Funding Opportunity Announcement (FOA) is an announcement on the Grants.gov web portal of a Federal grant funding opportunity. Grants.gov lets organizations apply for grants sponsored by at least 26 Federal agencies. NIH FOAs can be general "parent" announcements (see below), Program Announcements (PAs) or Requests for Applications (RFAs).

  Each FOA has an application package with forms as well as general instructions that are in the Grant Application Guide. The synopsis of the FOA on Grants.gov links to an *NIH Guide* announcement, which gives you opportunity-specific information and instructions.

- **What is a "parent" announcement?**

  A "parent" announcement is an NIH-wide Funding Opportunity Announcement that enables applicants to submit an investigator-initiated grant application for a single grant mechanism, e.g. R01, R13, using the electronic interface. Others PAs describe specific research an area in Institute is particularly interested in supporting. See the current list of research and training parent announcements available: http://grants1.nih.gov/grants/guide/parent_announcements.htm#more

  PIs must verify that the funding IC(s) most relevant to their research participate in the Parent Announcements to which they plan to submit. Not all ICs participate in all parent FOAs even if they support the grant mechanism through specific PAs or RFAs. For example, NCI does not participate in the NIH R03 and R21 parent announcements. However, the NCI does support R03 and R21 applications through its own omnibus R03 and R21 initiatives and through specific initiatives (See NCI Small Grants (R03) or Exploratory/Developmental Grants (R21) web sites).

- **Are there mechanisms to support pilot projects?**

  Yes. The small grant program (R03) and the exploratory/developmental program (R21) both support pilot or feasibility studies that can be carried out in a short time (2 years or less) with limited resources. Investigators may be a PI on an R03 or R21 grant and still apply for an R01 as a New Investigator.

  The R03 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; and development of research methodology. NCI does not participate in the NIH R03 Parent announcement since the Institute has a specific omnibus FOA for R03 applications with peer review by NCI ad hoc review. A list of active R03 FOAs published by NCI can be found on the R03 web page.

  The R21 mechanism is intended to encourage new, exploratory and developmental research projects by providing support for the early stages of their development. NCI does not participate in the NIH R21 Parent announcement since the Institute has published a specific omnibus FOA for R21 applications with peer review by NCI ad hoc review committees. A list of active R21 FOAs published by NCI can be found on the R01,R21 webpage.

- **What's the best way to find NIH funding opportunities?**

  There are two interconnected options: Grants.gov, the *NIH Guide*. Pre-selected links to all NCI-relevant funding opportunities in the *NIH Guide* can also be found at the NCI Funding Announcements List.

  The *NIH Guide* provides the full announcements for all NIH grant opportunities. The *NIH Guide* announcement includes an "Apply for Grant Electronically" button, which takes you to Grants.gov's application package download page.

- **Should I read the *NIH Guide* announcement or the Grants.gov FOAs?**

  Both. You must find the instructions you need in two places: in the *NIH Guide* RFA and PA announcements and on Grants.gov. NIH Guide announcements include links to the FOAs on Grants.gov.

- **When do I use an NIH Parent Announcement versus an NCI-specific announcement?**

  For a specific grant mechanism (e.g., R01, R03), there may be two types of Funding Opportunity Announcements (FOA)

  - A single NIH-wide Parent Announcement:
    - It allows investigator initiated applications but may be limited to scientific areas of interest to an institute or center (IC).
    - Some ICs may NOT participate in a specific Parent Announcement. For example, NCI does not participate in the R03 and R21 NIH "parent" program announcements but publishes an NCI omnibus solicitation as well as specific FOAs.
  - Specific FOAs
    - The Program Announcements (PA) and Request for Applications (RFA) that the NCI and other ICs have traditionally issued for targeted funding initiatives.
    - Specifies a scientific (or resource) area, special administrative requirements (e.g., special receipt dates and/or review requirements), or both.
    - May be issued by a single NIH IC or jointly by several ICs.

- **Where do I find high-priority funding areas?**

  Find all NCI Funding Opportunity Announcement (FOA) on the NCI Extramural Funding Opportunities page under NCI Sponsored Research Initiatives.

  NIH publishes most initiatives -- Request for Applications (RFAs) and Program Announcements (PA) -- in the *NIH Guide*. For funding mechanisms that have been transitioned to electronic applications, you may access the application package (i.e., form and instructions) from the FOA in the NIH Guide or by going directly to the FOA in Grants.gov.

  Requests for Proposals (RFP) for NCI's contract initiatives are published in FedBizOpps, and most do not appear in the *NIH Guide*. NCI lists the current RFPs on the NCI Request for Proposals List.

• **May I submit in response to an RFA an application that is largely identical to a previously submitted application?**

Yes. NIH will accept an application in response to a Request for Applications (RFA) that is the same as a new, revised, or renewal application as long as the overlapping applications are not review at the same time. See "Evaluation of Overlapping Applications".

• **My application submitted in response to an RFA was not funded. May I resubmit the application as an investigator-initiated application?**

Yes. However, you must submit it as a new application and you cannot include an introduction describing any changes that you may have made to your previous submission.

This rule allows you to benefit fully from the NIH policy that allows only one resubmission.

PEER REVIEW OF APPLICATIONS

- **Where can I find basic information about peer review?**

  See Grant Application Basics and the Peer Review Process for information.

  The Center for Scientific Review also provides Applicant Resources including a video of a study section meeting, tips for applicants, and information on peer review.

- **What is peer reviewed at NCI?**

  NCI reviews the following:

  - Investigator-initiated applications using for the following mechanisms - program projects, conference, training, and career development. In addition, applications submitted in response to some PARs are reviewed at NCI such as small grant PARs.
  - All applications for center grants (e.g., P20, P30, P50) and cooperative agreements, and all applications received in response to Request for Applications (RFA).
  - Research and development contract proposals received in response to Requests for Proposals.

- **How do I find grants or contracts staff to discuss my application prior to submission?**

  Go to NCI Contacts for Applicants for program staff working with grants, contracts, and small business and research training awards.

- **Whom do I contact at NCI before the initial review of my application?**

  Call the Scientific Review Officer (SRO) of the scientific review group reviewing your application. The SRO's name is available in your eRA Commons account.

- **How and when can I obtain information about the status of my application?**

  Notification that CSR has assigned your application to an IC and to a scientific review group should be available in your eRA Commons account within 3 weeks of the submission deadline. If this notification does not appear in this timeframe, please contact the CSR Division of Receipt and Referral (Ph: 301-435-0715).

  Your scores should appear in your Commons account within 3 business days, and your summary statement within 30 days after the review. New Investigators who submitted R01 applications should be able to access their summary statement within 10 days after the review meeting.

- **Whom do I contact at NCI after the review of my application?**

  Call the program director or official listed on your summary statement.

- **If I forget something, may I send it after the due date?**

  The only post-submission grant application materials that the NIH will accept are those resulting from unforeseen administrative issues. This option is to be used when an unexpected event such as the departure of a participant, natural disaster, etc. has occurred, not to correct oversights/errors discovered after submission of the application. For RFAs with one receipt date, contact the SRO to determine if there are any exceptions.

See NIH Policy on Submission of Additional Grant Materials for more information.

- **How will Data Sharing Plans and sharing plans for Genome Wide Association Studies (GWAS) and Model Organisms be reviewed?**

  Peer reviewers will evaluate data sharing plans for consistency with the NIH policies and will provide comments on them in the Administrative Remarks section of summary statements. Program staff are responsible for assessing the appropriateness and adequacy of proposed data sharing plans. Program concerns regarding data sharing plans must be resolved prior to making awards.

  See NIH Data Sharing policy, GWAS policy, and Model Organism Sharing policy for more information.

- **Will compliance with the NIH Public Access Policy affect the outcome of the application review?**

  Compliance with the NIH Public Access Policy is not a factor in the scientific and technical merit evaluation of grant applications. Non-compliance will be addressed administratively, and may delay or prevent awarding of funds.

- **How does NCI handle conflict of interest in review?**

  NCI follows standard NIH procedures to prevent program staff, project officers, peer reviewers, or National Cancer Advisory Board members who may have a real or apparent conflict of interest with an applicant from participating in a peer review. See the Conflict of Interest in Peer Review .

- **Will most reviewers on the review committee be experts in my specific field?**

  For chartered study sections, there will generally be several experts in each of the broad fields included in the topics of the study section. The reviewer roster as a whole will cover many overlapping areas in the broader field. However, there may not be an expert in your specific subfield on the roster. You may suggest areas of expertise that should be included in the review of your application in your cover letter or contact the scientific review administrator (SRO). The SRO may recruit one or more ad hoc reviewers to participate in the review, if needed. You should also make sure that your application explains the significance and approach of your research in language that can be understood by experts in the general field of your research.

- **How does NIH ensure that peer review panels have the appropriate expertise and experience and how can I ensure that my application gets an appropriate review?**

  Peer review is generally conducted by established panels composed of reviewers who have broad and overlapping areas of expertise. These panels may also include some ad hoc review members who have expertise in specific areas of science needed for one or more specific applications.

  However, it is impossible to have experts in each grant application's specific research area on study sections that review up to 120 applications. If you feel the assigned study section does not have the appropriate expertise, contact the SRO to discuss the general areas of expertise needed. You may also include this information in your cover letter.

- **What is being done to recruit senior and experienced peer reviewers?**

  Scientific Review Officer (SRO) strive to recruit senior and experienced peer reviewers whenever possible. The majority of reviewers serving on CSR study sections are successful peer reviewed investigators at the Associate Professor level or above. See NIH Notice regarding the expectation that principal investigators of NIH supported grants and contracts serve on NIH peer review groups. Training committees or ad hoc committees organized to review specific initiatives, such as RFAs, may have junior investigators if the scientific area is a narrow research field and many of the senior experts have applied. A description of "How Scientists are Selected for Study Section Service" is provided on the CSR web site.

  NIH is striving to recruit experienced reviewers and improve reviewer retention by providing reviewers more flexibility regarding their tour of duty, and by instituting a continuous R01 applications submission process for appointed members of chartered NIH study sections (NOT-OD-08-026) and reviewers with recent substantial service (NOT-OD-11-093).

- **Is there a way to shorten the review process so that investigators can receive the review outcome and resubmit more rapidly?**

  Beginning with the September/October 2007 study section meetings, New Investigators now have the option of submitting a resubmission/amended R01 application for consecutive review cycles, saving four months. The summary statements for qualifying applications will have an explicit note indicating eligibility for next cycle submission. See NOT-OD-12-001 for more information.

- **There is concern that innovation in research is not adequately emphasized in peer review.**

  The NCI Provocative Questions Project is intended to assemble a list of important but non-obvious questions that will stimulate the NCI's research communities to use laboratory, clinical, and population sciences in especially effective and imaginative ways. Recommendations and collaborations through this project are expected to influence the direction of NCI research in the future.

  The NIH Commons Fund has created new high risk research programs to encourage innovation such as the NIH Director's Pioneer Award, NIH Director's New Innovator Award, and the Transformative R01 Program.

  Many of the recommendations of the NIH report on Enhancing Peer Review at NIH encourage reviewers to emphasize innovation rather than methodology in their reviews. Enhanced review criteria have been adopted (see NOT-OD-09-025) to emphasize innovation and a new scoring system has been developed (see NOT-OD-09-024). Application forms have been restructured to be better aligned with review criteria. A Research Strategy section has three components: Significance, Innovation, and Approach (see NOT-OD-09-149).

- **Where do I find rosters and review dates for CSR study sections?**
  On the NIH Center for Scientific Review (CSR) Web site, go to CSR Study Section Roster Index.

- **Where do I find rosters and review dates for NCI review committees?**

  Find them on NCI's Advisory Boards and Groups page. Chartered Initial Review Group (IRG) subcommittees review training, career development, cancer centers, and the clinical trials cooperative groups. NCI Special Emphasis Panels review program projects, conference grants, RFAs, contracts, and PAs assigned to NCI for review.

- **How do SROs select reviewers and how can I volunteer to serve on a review committee?**

  The SRO contacts senior or NIH funded investigators who have been successful at obtaining funding in the past and have an understanding of the grant and peer review process. For CSR study sections, reviewers with broad expertise in the scientific field of interest are sought. For special initiatives, reviewers with special expertise in the given field are selected. A description of "How Scientists are Selected for Study Section Service" is provided on the CSR web site.

  Contact the Director, Division of Extramural Activities, NCI, if you are interested in volunteering for NCI review committees or councils. For CSR peer review committees, go to "How to Become a CSR Reviewer" for information on reviewer qualifications and CSR nomination process.

- **How do patient advocates participate in NCI's research activities and programs?**

  The NCI has established the Consumer Advocates in Research and Related Activities (CARRA) program within the Office of Advocacy Relations (OAR). The CARRA program was created to integrate the perspective of people affected by cancer into a wide range of NCI's programs and activities, including peer review of clinical research. See CARRA web page for more information.

REFERRAL AND ASSIGNMENT

- **Where do I find rosters of study sections managed by the NIH Center for Scientific Review (CSR)?**

  On the NIH Center for Scientific Review (CSR) Web site, go to CSR Study Section Roster Index.

- **Should I request assignment to a specific study section(s) and/or an IC (NIH Institute or Center) in the cover letter with my application?**

  It is a good idea to request assignment provided you are familiar with all the potential study sections and the Institutes and Centers (ICs). Most applicants will request a study section, and let CSR determine the appropriate IC. However, if you do not request a study section, the CSR will assign your application to an appropriate study section. For descriptions of the CSR Integrated Review Groups and study sections and a tool for searching study section descriptions, go to http://public.csr.nih.gov/StudySections/Standing/Pages/default.aspx .

- **What should I do if I do not like the scientific review group (i.e., the study section) assigned to my application by the CSR?**

  If you are not happy with the assignment made by the CSR, you can call the Scientific Review Officer (SRO) for the assigned study section and/or the SRO of another desired/possible study section to discuss an alternate assignment.

- **The study section I requested was not assigned to my application. What should I do?**

  Contact the CSR Referral Office (Ph: 301-435-0715) to discuss the issue. It is possible the requested study section did not have the appropriate expertise, or there was a potential conflict, or it was just an oversight.

- **What should I do if I do not like the IC (NIH Institute or Center) or IC program office assigned to my application?**

  If you think your application has not been assigned to the correct NIH IC, you may call the CSR Referral Office (Ph: 301-435-0715) to ask that consideration be given to change the IC assignment or to request a dual assignment with another IC.

  If you think your application has not been assigned to the correct program office within the NCI, you may call the NCI Referral Office (Ph: 240-276-6449) and speak to a Referral Officer about a possible program reassignment.

- **Should I check the roster of peer reviewers for the assigned review group?**

  Yes. Make sure that there are no conflicts in the roster and that the roster includes members who have an understanding of your research area. Contact the Scientific Review Officer if you have concerns.

- **What applications are peer reviewed through NCI-managed review groups and why?**

  NCI oversees initial peer review of applications with Institute-specific requirements to ensure that peer reviewers with the appropriate expertise and experience evaluate the scientific and other merits of the proposed projects.

NCI manages the peer review of the following:

- All program projects, center grants, training (except F awards), and career development;
- All grant and cooperative agreement applications received in response to NCI-issued Request for Applications (RFA);
- Certain grant and cooperative agreement applications received in response to some Program Announcements (PA), such as specialized centers (P50), cooperative agreements (U01) and the omnibus small grants (R03) and exploratory grants (R21) initiatives;
- Research and development contract proposals received in response to Requests for Proposals (RFP) and Loan Repayment Program (LRP) proposals (L30, L40); and
- Conference grant (R13) applications.

The NIH Center for Scientific Review oversees peer review of investigator-initiated applications for all other award types.

- **Where do I find rosters of NCI-managed review committees?**

  Find them on NCI's Advisory Boards and Groups page. Chartered Initial Review Group (IRG) subcommittees review training, career development, cancer centers, and the clinical trials cooperative groups. NCI Special Emphasis Panels review program projects, conference grants, RFAs, contracts, and PAs assigned to NCI for review.

- **Where can I find the name of the Scientific Review Administrator (SRO) who is assigned to manage the peer review of my grant or cooperative agreement application?**

  The name of the SRO is provided with the information about your (successfully submitted) application in your eRA Commons account.

- **How and when can I obtain information about the status of my application?**

  Notification that CSR has assigned your application to an IC and to a scientific review group should be available in your eRA Commons account within 3 weeks of the submission deadline. If this notification does not appear in this timeframe, please contact the CSR Division of Receipt and Referral (Ph: 301-435-0715).

  Your scores should appear in your Commons account within 3 business days, and your summary statement within 30 days after the review. New Investigators who submitted R01 applications should be able to access their summary statements within 10 days after the review meeting.

RESUBMISSIONS AND RENEWALS

See also "Questions and Answers on Resubmissions of NIH Research Grant Applications" (http://grants.nih.gov/grants/policy/resubmission_q&a.htm)

- **NIH and Grants.gov seem to use different terminology for application types. What is a "resubmission" and what is a "revision" application?**

  A "resubmission" now refers to an application previously reviewed (formerly called revised or amended), whereas a "revision" now refers to a request for a supplement to an existing grant (previously called a competing or administrative supplement).

- **What is the current policy on resubmissions?**

  NIH permits one resubmission of an unfunded application (see NOT-OD-09-016). For **all** application due dates after April 16, 2014, following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate new application due date (see NOT-OD-14-074).

  Resubmissions (A1) must be submitted within 37 months of the new (A0) application (see NOT-OD-10-140). For more details on the Resubmission Policy, visit the Resubmissions webpage.

- **What is the success rate for resubmitted applications versus original applications?**

  The success rates for resubmitted applications are two to three times higher than that for original applications, depending whether the application is a new submission versus a competitive continuation. Success rates for all NIH competing research project grants by submission number can be found on the NIH Research Portfolio Online Reporting Tools (RePORT) web site. For example in FY2014, 10.6% of new R01 applications were funded versus 34.5% of resubmitted new R01 applications.

- **My resubmission application was not funded. May I now submit it as a new application?**

  Yes. Investigators should take into account the scores of the previous application, the reviewer comments, and advice from NIH program staff when deciding whether to submit the application as new. Should you decide to submit the application as new, take advantage of the comments from reviewers to reshape your application, but remember, you should not directly reference the previous review in the new application. Work from the prior funding period should be presented as preliminary data and/or rationale for the proposed research. Publications from the prior work may be cited in the reference list, as applicable, and/or listed in the biosketches of the investigators.

  Go to "Questions and Answers on Resubmissions of NIH Research Grant Applications" (http://grants.nih.gov/grants/policy/resubmission_q&a.htm) and discuss with the program director of your previous grant submission.

- **Where can I find information on paylines and funding policies for NCI?**

  Information on the current payline for R01 applications and funding policies for competing and non-competing applications is available on the NCI Funding Policy web page. The NCI Fact Book provides information on historical funding and success rates.

- **What are renewals and where can I find basic information about them?**

  Grant renewals are awards that extend grants whose project periods are over. To continue research on the same topic after your grant ends, you must again recompete for NIH support and the application must undergo peer review. This application is referred to as a competitive renewal. Alternatively, you may submit a new application to continue your research.

- **Do appointed members of chartered NIH study sections have different receipt dates for their applications?**

  NIH has implemented policy and procedures to allow appointed members of NIH review and Advisory Groups, and peer reviewers with recent substantial service (six times in 18 months), to submit their research grant applications (R01, R21, or R34) on a continuous basis and to have those applications undergo initial peer review in a timely manner. Continuous submission is **NOT** available for other types of applications or applications submitted for special receipt dates and initiatives (RFAs, some PARs). See http://grants.nih.gov/grants/peer/continuous_submission.htm for more information.

- **How should I time the preparation of my competitive renewal application?**

  Success for a competitive renewal depends heavily on the progress made during the initial funding period as well as the significance and approach of the work proposed in the renewal. If the previous aims have been completed and there is strong data to support the new research plan, submitting the renewal application earlier than needed to maintain continuity of funding gives you time to revise and resubmit if you do not get a fundable score the first time.

  Note: Your competitive renewal cannot begin before the end date of your previous award no matter when you submit your application. If your application would normally be considered for funding in the Fiscal Year prior to your current grant end date, funding will not be considered until the next Fiscal Year and will be subject to the new Fiscal Year paylines. See NIH's Review and Award Cycles table, part of Standard Due Dates for Competing Applications, for receipt and funding dates.

- **Should I submit a competitive renewal application on time even if I do not have enough data?**

  If you do not have enough data, don't resubmit until you do. It is better to come in a round late with a successful application, than to waste a submission on an application that has obvious deficiencies. No matter when your application arrives, reviewers expect to see data indicating progress.

- **What is the funding cap for competitive renewal applications?**

  As part of its financial management plan, NCI limits the budget increases that investigators can request in their competitive renewal applications for R01, U01, and P01 grants. In May 2008, this cap was set at 10 percent more than the direct costs of the last year of the preceding award (see Guide Notice).

  Additional budget reductions may be required based on the financial management plan for a specific year. See NCI Funding Policy for more information.

- **How does NCI calculate the 10 percent budget cap?**

  For nonmodular awards, NCI considers the direct costs of the expiring award minus facilities and administrative costs for all subawards. Increase that amount by 10 percent and include facilities and administrative costs for subawards. You may apply the permissible NIH inflationary adjustment (currently 3%) to each of the years after the first year. Awardees operating within a modular budget format may round up their request to the next higher module in the first competing year after increasing by 10 percent, with no subsequent future year increases. See Guide Notice for more information.

- **The budget for my first R01 was low; how much can I request for my new budget?**

  Investigators submitting their first renewal are also limited to a 10% increase over the previous year's budget. Please discuss with your program director whether an exemption to this policy can be considered.

  If your research has evolved in scope, you may want to apply with a new grant. In that case, change the title and abstract to include your new specific aims, so the focus of the application reflects the new scale of your research.

- **If I ask for the modular budget cap amount for my first year, can I make a bigger request for subsequent years?**

  No. All budgets are based on the first year budget. Modular Grants typically get the same number of modules each year. Nonmodular grants may get a small percentage increase for inflation or a decrease, depending on NCI's financial management plan for that year.

- **Must I keep the title of the grant unchanged when applying for a renewal?**

  No. While it is often best to keep the same title, use a different title if it's a better fit. If you do, check the box indicating that your application is a competitive renewal on the checklist (the last page) of the grant application, and enter your grant number. That way, NIH will know that the title is new, but the application is a competitive renewal.

- **What format should I use for the Research Plan section of an R01 renewal?**

  A Research Plan follows the same format and page limits for a renewal application as a new application, but there are a few differences.

  Instead of preliminary studies, you'll include a Progress Report. You should also add a Progress Report Publication List and, if you're conducting human subjects research, an Inclusion Enrollment Report.

  Check the Grant Application Guide of the R01 Funding Opportunity Announcement for further details.

- **If my grant will be ending and I want to renew it, do I have to apply as a renewal, or can I apply as a new grant application?**

  The science should drive your decision. Apply as a renewal if you are continuing along the same research path. Applying as a renewal gives you some advantage because you are continuing an existing research project and your progress report provides support for your specific aims. In addition, you may qualify for interim support or exception funding if your application is beyond but close to the payline.

Apply as a new application if you want to change or expand the scope of your research, or increase your budget. A new application does not include a progress report. Be sure to use a new title.

For NIH success rates for new and competing continuation applications, go to: http://report.nih.gov/success_rates/index.aspx.

- **Is there a window of time that a PI can submit an application as a renewal?**

  The NIH will not accept a resubmission that is submitted later than thirty-seven months after the date of receipt ("receipt date") of the initial New, Renewal, or Revision application. See NOT-OD-10-140 for more information.

  If a significant amount of time has elapsed, indicate what you have done in the interim. Highlight any preliminary data you may have obtained and show that your planned research is current with the latest science.

- **When does NCI require pre-approval to submit a renewal application?**

  As stated in NOT-OD-02-004, applicants must seek agreement to accept assignment from NIH Institute/Center staff at least 6 weeks prior to the anticipated submission of any application requesting $500,000 or more in direct costs for any year. This policy does not apply to specific initiatives, such as PARs or RFAs that allow budgets in excess of $500,000 for any year.

  In addition, applicants for conference grants (R13) must seek agreement (i.e., obtain clearance) for application submission from the Institute/Center R13 contact at least 6 weeks prior to the receipt date.

TRAINING AND RESEARCH CAREER AWARDS

- **Where can I find more information about fellowships and training and career awards?**

  Go to the NCI Training Career Development and Education page or the Diversity Training Branch (DTB), Center to Reduce Cancer Health Disparities (CRCHD) for information on training and career development initiatives.

  To identify the appropriate Program Contact for your area of interest, see the Cancer Training Branch's Program Contact List, the DTB, CRCHD Program Contact List, or contact the program director identified in the Program Announcement.

- **How do I identify the correct training award mechanism for my research career?**

  The Cancer Training Branch and the CRCHD Training web sites list the different NCI supported research training and career development awards according to career stage (i.e., high school, undergraduate, predoctoral, post-doctoral, junior faculty, etc).

  The NIH Career Award Wizard may also assist you in identifying the correct career award. In addition, see the NIH K Kiosk for information on career development awards.

- **What training opportunities does the NCI support for students and investigators from diverse groups, disadvantaged backgrounds, or with disabilities?**

  Information on training and career development for individuals from racially and ethnically diverse and medically underserved populations, including eligibility, is available on the CRCHD Training web site.

  Administrative supplements to existing grants can be provided to investigators who are seeking to support the training of individuals from underrepresented diverse groups, disadvantaged backgrounds, or with disabilities. For more information, see Research Supplements to Promote Diversity in Health Care Research.

- **Does the NCI support any pre-doctoral training awards?**

  Yes. The CRCHD uses the NIH F31 grant mechanism to help ensure that diverse pools of highly trained scientists will be available in appropriate research areas to carry out the Nation's biomedical, behavioral, health services, and clinical research agendas.

  The NCI Cancer Training Branch supports Ruth L. Kirschstein National Research Service Award Institutional Training Grants (T32) that provide training opportunities for predoctoral as well as postdoctoral individuals in biomedical and behavioral research. Candidates must determine if their institution has a T32 program focused on providing a training experience in the research area of their interest and then apply for a position or slot in the program. Here is a list of the currently active T32 grants. The CRCHD provides supplements to these grants to train individuals from under-represented diverse groups, disadvantaged backgrounds, or with disabilities.

- **What post-doctoral training awards does the NCI support for investigators from diverse backgrounds?**

  The CRCHD Diversity Training Branch supports four distinct types of Career Development Award or K awards: Mentored Research Scientist Career Development Award (K01) , Career Transition Awards (K22), Mentored Clinical Scientist Research Career Development Award (K08), and Mentored Patient-Oriented Research Award (K23)

  The Research Supplements to Promote Diversity in Health Care Research and the Supplements to Promote Reentry into Biomedical and Behavioral Research Careers also support post-doctoral training.

- **What is the NIH Director's Early Independence Award?**

  NIH Director's Early Independence Award is a new funding mechanism that provides an opportunity for exceptional junior scientists to "skip the post-doc", and start an independent research career at a supportive Institution directly following the completion of their graduate degree. The proposed research may be in any scientific area relevant to the mission of NIH (biological, behavioral, clinical, social, physical, chemical, computational, engineering, and mathematical sciences).

- **What is the Pathway to Independence Award?**

  The Pathway to Independence (PI) Award assists post-doctoral investigators pursuing a research career in the biomedical sciences in transitioning from a mentored postdoctoral position to a stable independent research position with independent NIH or other independent research support at an earlier stage than is currently the norm.

  The NIH Pathway to Independence Award uses the NIH K99 grant mechanism to provide 1 - 2 years of mentored support and uses the NIH R00 grant mechanism to provide 1 - 3 years of independent research support after an independent research position is secured. The NCI restricts eligibility for this award to researchers conducting basic science research in human cancer systems.

- **What NCI Career Development Awards exist for physician scientists interested in conducting patient oriented or clinical research?**

  For the purpose of this question, the term "physician scientists" includes clinicians pursuing careers in laboratory-based basic science as well as patient-oriented research. Additionally, the term "clinical research" is research in which the identity of the patients or the identity of the patients from whom cells or tissues under study are obtained is known. Finally, patient-oriented research is research conducted with human subjects (or on material of human origin) for which an investigator (or colleague) interacts directly with human subjects.

  The NIH Mentored Patient-Oriented Research Career Development Award and the NCI Mentored Patient-Oriented Research Career Development Award to Promote Diversity use the K23 grant mechanism to support the career development of clinically trained professionals who have made a commitment to focus on patient oriented research.

The NIH Mentored Clinical Scientist Development Award and NCI Mentored Clinical Scientist Award to Promote Diversity Award use the NIH K08 grant mechanism to support individuals with clinical doctoral degrees who have made a commitment to focus on laboratory-based basic science, biomedical, behavioral, and/ or translational research.

The NCI Mentored Career Development Award to Promote Diversity uses the NIH K01 grant mechanism to support the career development of applicants with a doctoral degree in the fields of cancer biology, etiology, pathogenesis, prevention, diagnosis, and/or treatment. Applicants for this award are limited to individuals from racial and ethnic minority groups; or with disabilities; or from disadvantaged backgrounds.

The NCI Transition Career Development Award and the NCI Transition Career Development Award to Promote Diversity use the NIH K22 grant mechanism to support protected time for newly independent physician scientists who are pursuing basic science or patient oriented research careers to develop their first independent research program.

The NIH Mid-career Award in Patient-Oriented Research uses the NIH K24 grant mechanism to provide mid-career clinical investigators with protected time (1) for patient-oriented research and (2) to act as mentors for junior clinical investigators.

The NCI Paul Calabresi Career Development Award For Clinical Oncology used the K12 grant mechanism to support a research career development experience for medical doctors and basic science researchers in the design, development, and implementation of hypothesis-based therapeutic cancer clinical trials.

- **What NCI Career Development Awards exist for investigators interested in conducting cancer prevention, control, behavioral, and population science research?**

  The NCI Cancer Prevention, Control, Behavioral and Population Sciences Career Development Award (K07) uses the development component of the NIH K07 grant mechanism to support the career development of postdoctoral fellows and junior faculty members who are pursuing careers in cancer prevention, control, behavioral, and the population sciences.

  The NCI Mentored Career Development Award to Promote Diversity (K01) supports the career development of individuals from racially and ethnically diverse and medically underserved populations in the fields of cancer biology, etiology, pathogenesis, prevention, diagnosis, and/or treatment.

  The NCI Transition Career Development Award and the NCI Transition Career Development Award to Promote Diversity uses the K22 grant mechanism to support protected time for newly independent investigators (e.g., Ph.D.s, DPHs, MD.s) to develop and receive support for their initial cancer-research programs in cancer prevention, control, behavioral, and the population sciences.

  Specific funding initiatives are provided under Funding Opportunities on the Division of Cancer Control and Population Sciences and Division of Cancer Prevention pages.

- **What opportunities are available for oncology fellows to pursue in basic science or translational cancer research careers?**

  The Ruth L. Kirschstein Individual National Research Service Award (NRSA) uses the F32 grant mechanism to support individuals with a doctoral degree (e.g., M.D., Ph.D., D.P.H.) for a three-year period of supervised research in cancer. The Ruth L. Kirschstein National Research Service Award Institutional Training Grant for T32 programs is also available.

The Mentored Clinical Scientist Development Award and Mentored Clinical Scientist Award to Promote Diversity use the NIH K08 grant mechanism to support individuals with a clinical doctoral degree for an intensive, supervised research career development experience in the fields of basic science, biomedical, behavioral, and/or translational research.

The Pathway to Independence Award (K99/R00) assists post-doctoral investigators pursuing a research career in the biomedical sciences in transitioning from a mentored postdoctoral position to a stable independent research position.

The NCI Transition Career Development Award and the NCI Transition Career Development Award to Promote Diversity uses the K22 grant mechanism to support protected time for clinicians, or equivalent, who are pursuing careers in basic science or in patient oriented research.

- **What type of support is available to transition from postdoctoral positions to independent investigators?**

  The NCI Transition Career Development Award and the NCI Transition Career Development Award to Promote Diversity use the K22 grant mechanism to support "protected time" for newly independent investigators to develop and receive support for their initial cancer-research programs. . This award is intended to facilitate the transition of investigators from the mentored to the independent stage of their careers. It applies to clinical and research fellows who are pursuing careers in all areas of cancer research.

  The Pathway to Independence Award (K99/R00) provides up to five years of support, divided into two phases. Phase I provides one to two years of mentored support under a K99 mechanism. Phase II provides up to three years of independent research support under an R00 mechanism.

- **Does the K08 grant mechanism support human subjects research?**

  Yes, the K08 grant mechanism can be used to support human subject research. However, clinicians interested in patient-oriented research, should consider the NIH Mentored Patient-Oriented Research Career Development (K23) Award or the NCI Mentored Patient-Oriented Research Career Development (K23) Award to Promote Diversity.

- **What NCI Career Development Awards exist for investigators with quantitative scientific and engineering backgrounds?**

- **Does NCI provide support for cancer education?**

  Yes. The NCI Cancer Education Grant Program (R25E) provide funding for the development of cancer education programs and cancer research dissemination projects that can be completed within five years.

- **Are all training mechanisms restricted to U.S. citizens or VISA holders?**

  Yes, with one exception: the Pathway to Independence Award (K99/R00). Otherwise, you must be a U.S. citizen, a non-citizen national, or a permanent resident with a valid Alien Registration Receipt Card (a "green card") at the time of award.

- **Can K award recipients apply for and receive R01/ R21/ R03 grant funding?**

  Yes, K award recipients can apply for and simultaneously hold a K award and an R01, R21, and/ or R03 award; and can additionally have been or be the PI of an R03 or R21 grant at the time of application for a K-award. If they receive an R01 award, they can no longer apply or accept a K-award.

- **Can K award recipients draw research support from the R01/ R21/ R03 grants?**

  Yes. K award recipients can draw research support from both their own and others' R01, R03, and R21 grants. However, the maximum level of R-grant research support will be determined by the effort commitment requirements of the K-award.

- **Can K award recipients draw salary support from their own R01/ R21/ R03 grants?**

  Yes, but only during the last 2 years of their K award and if they are the PI of the R01/R21/R03 grant at the time of review. See the April 10, 2008, Guide announcement.

- **What NCI Career Development Awards exist for experienced scientists who wish to make major changes in the direction of their research careers?**

  The NIH NRSA For Senior Fellows uses the F33 grant mechanism to support experienced scientists who wish to make major changes in the direction of their research careers or who wish to broaden their scientific background by acquiring new research capabilities as independent investigators in cancer research.

- **Does NCI have Loan Repayment Programs for investigators?**

  Yes. NCI participates in the NIH Loan Repayment Programs. In exchange for a two year research commitment, NIH will repay up to $35,000 per year of your qualified education debt and the taxes incurred on that income. Research areas include clinical research, pediatric research, and health disparities research.

- **Does NCI have a training office I can call for advice?**

  Yes. The Cancer Training Branch and the Diversity Training Branch provides information regarding both training and career development. To identify the appropriate program contact for your area of interest, see the Cancer Training Branch's Program Contact List, the Diversity Training Branch's Program Contact List, or contact the program director identified in the Program Announcement.

NEW INVESTIGATORS

- **As a new applicant, where can I look for advice?**

  NIH offers Resources for New Investigators. In addition, you should contact an NCI Program Director in your research area to discuss your research application and seek advice if you are submitting an investigator initiated R01 application. Contact the NCI Program Director listed in the Funding Opportunity Announcement (FOA) if you are responding to a specific Program Announcement (PA) or Request for Applications (RFA)

  Contact the NCI Cancer Training Branch if you are interested in training or career development awards.

- **What kinds of fellowships and career awards does NCI support?**

  NCI supports training awards, fellowships, and career development awards. For more information, see the NCI Training Career Development and Education web page.

- **How do I know if I qualify as a New or First-Time Principal Investigator?**

  In general, a Program Director/Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a significant NIH independent research award. Specifically, a PD/PI is identified as a New Investigator if he/she has **not** previously competed successfully for an NIH-supported research project **other than** the following small or early stage research awards:

  - Pathway to Independence Award-Research Phase (R00)
  - Small Grant (R03)
  - Academic Research Enhancement Award (R15)
  - Exploratory/Developmental Grant (R21)
  - Clinical Trial Planning Grant (R34)
  - Dissertation Award (R36)
  - Small Business Technology Transfer Grant-Phase I (R41)
  - Small Business Innovation Research Grant-Phase I (R43)
  - Shannon Award (R55)
  - NIH High Priority, Short-Term Project Award (R56)
  - Competitive Research Pilot Projects (SC2, SC3)
  - Resource Access Award (X01)

  Additionally, the PD/PI is not excluded from consideration as a “New Investigator” if he/she has received an award from any of the following classes of awards:

  Training-Related and Mentored Career Awards

  - All Fellowships (F awards)
  - All career awards (K awards)
  - Loan repayment contracts (L30, L32, L40, L50, L60)
  - All training grants (T32, T34, T35, T90, D43)

Instrumentation, Construction, Education, Health Disparity Endowment Grants, or Meeting Awards

- G07, G08, G11, G13, G20
- R13
- S10, S15, S21, S22

- **What are the qualifications for an "Early Stage Investigator"?**

  An individual who is classified as a New or First-Time Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI). Applications from ESIs and New Investigators will be identified to reviewers so that appropriate consideration of their career stage can be applied during review. More information on ESI designation is available at: http://grants1.nih.gov/grants/guide/notice-files/not-od-08-121.html

  In some cases, there may have been one or more lapse in the period of research or research training after the terminal degree or the completion of medical residency. NOT-09-034 describes the procedures for requesting an extension of the ESI period and the conditions under which such extensions will be considered.

- **How does NIH know if an applicant is a New Investigator or ESI ?**

  There will no longer be a New Investigator checkbox on the SF 424 and PHS 398 applications starting in February, 2009. Investigators will be identified by modifying the data collection related to degree dates and medical residency within the personal profile of the eRA Commons. PD/PIs must update their personal profile in the eRA Commons to provide information on degree and residency completion dates in order to be considered for the New Investigator or ESI classification.

- **For a multiple PI application, what constitutes a new investigator?**

  To qualify as a New Investigator application, all PIs on a multiple PI application must meet NIH's definition of a New Investigator.

- **If I am a project leader on a program project grant (P01), can I qualify as a new PI for an R01 application?**

  Yes. As a project leader on a program project, you are not a PI, so you are still eligible to be a New Investigator

- **If I received a grant from the National Science Foundation, am I still considered new for NIH?**

  Yes. Only PHS grants affect your status as a New Investigator for NIH.

- **Are there special initiatives for new investigators and ESIs?**

  The NIH Director's Early Independence Award Program (DP5) established in 2011 provides a mechanism for exceptional early career scientists to move rapidly into independent research positions at U.S. institutions by essentially omitting the traditional post-doctoral training period. To be eligible, candidates must be within one year (before or after) of completion of their terminal degree or clinical residency at the time of application. Moreover, since each institution may submit only up to two applications, candidates must be chosen by the institution through an internal institutional selection process.

The NIH Director's New Innovator Award Program was launched in 2007 to support a small number of ESIs of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact on broad, important problems in biomedical and behavioral research. In addition, see the NCI Training Career Development and Education available to New Investigators.

- **What type of investigator initiated award should I apply for?**

  If you have sufficient preliminary data, you should apply for an R01. R01s give you a solid level and duration of support, whereas smaller types may not provide enough money or time to complete a major project.

  If you don't have preliminary data, check for Program Announcements for one of the following smaller awards, an R03 or R21 grant, to pay for time and resources to collect the data needed for an R01 application. See current list of R03 Program Announcements and R21 Program Announcements for more information.

- **Are reviewers less critical of new investigators and ESIs?**

  Yes. The Center for Scientific Review provides special instructions to reviewers for the review of R01 applications from new investigators that emphasize training and research potential rather than track record and publications. In addition, the NIH will, wherever possible, cluster applications from New Investigators for discussion during initial peer review.

- **Should I avoid collaborators to demonstrate my independence and show I can do it all?**

  No. You can impress reviewers by bringing in collaborators to fill gaps in your expertise and resources. It helps to choose a mentor or collaborator who is well known and respected; reviewers may recognize their name.

- **Is there a way to shorten the review process so that investigators can receive the review outcome and resubmit more rapidly?**

  New Investigators now have the option of submitting a resubmission/amended R01 application for consecutive review cycles,saving four months. The summary statements for qualifying applications will have an explicit note indicating eligibility for next cycle submission. See NOT-OD-11-057 for more information.

SMALL BUSINESS AWARDS

- **What is the Small Business Innovation Research Program?**

  The Small Business Innovation Research (SBIR) program is a set-aside program (2.5% of an agency's extramural budget) for domestic small business concerns to engage in Research/Research and Development (R/R&D) that has the potential for commercialization and public benefit.

  The Small Business Technology Transfer Program (STTR) was established in 1992 with as setaside program of 0.3% of the agency's extramural budget. The unique feature of the STTR program is the requirement for the small business concern applicant organization to formally collaborate with a research institution in Phase I and Phase II.

- **Where can I find basic information on small business awards?**

  Basic information on SBIR and STTR awards is located on the NCI Small Business Grants page, which includes videos from recent SBIR and STTR forums and News and Events. Additional information including information on upcoming SBIR/STTR conferences is available on the NIH Small Business Research Funding Opportunities page.

- **How do I apply for a small business award?**

  SBIR and STTR applications are now submitted electronically through Grants.gov by scrolling down the SBIR or STTR Funding Opportunity Announcement and selecting the button that says "Apply for Grants Electronically." Remember to read the full announcement and before beginning your application. Examples of applications are provided on the NCI Small Business Resource Center site.

- **What constitutes a small business?**

  A small business is independently owned and operated and not dominant in its field. It has no more than 500 employees and it controls the facilities in which it conducts a major part of NIH-supported research. See Eligibility Criteria for more information.

- **Can a foreign business own an SBIR-funded company?**

  No. According to the Omnibus Solicitation for SBIR/STTR Grant Applications, a company or subsidiary must have majority ownership by U.S. citizens and a principal place of business in the U.S.. It must also conduct all grant-funded research in the U.S.

- **What's the difference between an SBIR and an STTR?**

  Under SBIR Program, the Principal Investigator must have his/her primary employment with the small business concern at the time of award and for the duration of the project period; however, under the STTR Program, primary employment is not stipulated. The STTR Program requires research partners at universities and other non-profit research institutions to have a formal collaborative relationship with the small business concern. At least 40 percent of the STTR research project is to be conducted by the small business concern and at least 30 percent of the work is to be conducted by the single, "partnering" research institution.

- **What is the difference between a small business grant and contract?**

  Small business concerns are invited to submit Phase I grant applications in any area within the NCI mission identified in the SBIR/STTR Omnibus Solicitation. Contract proposals are accepted only if they respond specifically to a research topic within the Contract Solicitation. The topics are not the same as those in a grant solicitation. They are much more focused and specific. Contracts are only solicited one time each year versus three receipt dates per year for grants.

- **Are there other funding opportunities besides NIH Omnibus Solicitation for SBIR/STTR Grant Applications?**

  Search the NCI Funding Announcement List for additionalProgram Announcements and Requests for Applications open to small business concerns. Links to SBIR/STTR Funding Opportunity Announcements provided on the SBIR/STTR Funding Opportunities page, including the Innovative Molecular Analysis Technologies initiatives. Note that you will face strong competition with funding opportunities that are open to large companies and academic investigators.

- **Should I apply for a small business award if my goal is to patent a product?**

  Yes. You can pay for patent costs out of a fee that you request for your SBIR or STTR grant.

- **Do I own the intellectual property from my STTR award?**

  In general, grantees own the rights to data and inventions resulting from any grant-supported project. Read the NIH Grants Policy Statement (10/13) for more information on intellectual property rights.

- **Does NIH often use its march-in rights to take away intellectual property?**

  No. NIH may use march-in rights only if an awardee fails to achieve practical application of an invention. Furthermore, NIH has never exercised this right because of the lengthy administrative process. For more information, see Appendix D of the June 4, 1998, Report of the NIH Working Group on Research Tools.

- **How much of my small business research project may I outsource?**

  You may outsource up to 33 percent of your project for a phase I SBIR award or 50 percent for a phase II SBIR. For an STTR award, you may outsource no more than 60 percent of your project.

  While you may have some leeway with this requirement in an SBIR grant, the maximum outsource level for STTR grants is not negotiable.

- **Even though the normal phase I for STTRs is six months, can I ask for 12 months of funding?**

  You can, and it is recommended that you do.

- **What is a Fast Track application?**

  The SBIR Fast Track process requires phase I and phase II proposals in the initial application. In contrast, a normal SBIR application includes only a phase I proposal,

and an applicant sends a phase II proposal only if a phase I award is made. The success rate of Fast Track applications is lower than phase I applications. Contact NCI SBIR/STTR program staff to discuss further.

- **Are reviewers more likely to find problems with bigger applications?**

  The more you expand the research goals of your application, the more likely you are to include specific aims that are subject to criticism. Your best strategy is to limit your phase I goals to those necessary to support your phase II application. For more advice, contact the NCI SBIR/STTR program staff.

- **Can small business award funds be spent on research in a foreign country?**

  No. Although funds can not be spent directly, in your application, you can request and justify a fee of up to 7 percent of your total grant. The fee belongs to the company, so you may use it to pay for costs outside the U.S.

- **Can I use small business award funding to analyze patient-derived samples collected in a foreign country?**

  You may use SBIR/STTR funding to analyze samples from a foreign country, but the analysis must be performed in the U.S.

- **Are there special programs to assist small business awardees in commercialization of their research project?**

  To help NIH SBIR phase I and phase II awardees move their products into the marketplace, NIH has developed a "menu" of technical assistance programs (see below) that will provide technical and/or commercialization assistance specific to the companies' individual needs. Programs are pilot tested prior to offering to all SBIR awardees.

  Niche Assessment Program (NAP): Assesses if there are other applications or niches for the SBIR-developed technology and evaluates the market opportunities, needs and concerns of the end-users, and helps to discover new markets for possible entry.

  Commercialization Assistance Program (CAP): Provides assistance with developing and implementing an appropriate business strategy that will help commercialize the products that have resulted from federally funded SBIR research projects.

  Manufacturing Assistance Program (MAP): In partnership with the NIST Manufacturing Extension Partnership (MEP) program, participants will have access to MEP's nationwide network of non-profit manufacturing centers.

- **Are there any funding opportunities to bridge the gap between the completion of the phase II award and commercialization?**

  The SBIR Phase II Bridge Award is intended to augment previously funded NIH-wide SBIR Phase II projects that require additional funding in order to achieve key technical and regulatory milestones along the path toward commercialization. This funding opportunity focuses on the continued development of cancer therapies and cancer imaging technologies, which require clinical evaluation and approval by a Federal regulatory agency.

INTERNATIONAL AWARDS

- **Does NCI support international research?**

  Yes. The NCI Center for Global Health coordinates the Institute's worldwide including coordination of cancer research activities under agreements between the US and other countries; planning and implementation of international scientist exchange programs; and sponsorship of international workshops. Go to International Funding Opportunities for additional information.

  Foreign institutions and international organizations are also eligible to apply for research project grants, with the exception of Kirschstein-NRSA institutional research training grants, program project grants, center grants, resource grants, SBIR/STTR grants, or construction grants.

- **Do I need U.S. affiliation or citizenship to be a grantee or PI?**

  No. You don't need U.S. affiliation or citizenship to become a grantee or PI. If you are working at a U.S. institution that is receiving the award, you have to remain there long enough to finish your project.

  - If you do not have a permanent visa, state in your application that your visa will allow you to remain in the U.S. long enough for you to be productive on the project.

  - Your institution ensures that you have an appropriate visa.

- **Do I need U.S. affiliation or citizenship to be a trainee on a training grant or receive a career award or fellowship?**

  Yes, with one exception: the Pathway to Independence Award (K99/R00). For all other career development and training awards, you must be a U.S. citizen, a noncitizen national, or a permanent resident with a valid green card at the time of award.

- **Are all grant mechanisms available to foreign organizations?**

  In general, foreign institutions and international organizations are eligible to apply for research project grants. Foreign institutions and international organizations are not eligible to apply for Kirschstein-NRSA institutional research grants, program project grants, center grants, resource grants, SBIR/STTR grants, or construction grants. However, some mechanisms, such as program project grants, may support projects awarded to a domestic institution with a foreign component. Check the eligibility requirements in the Funding Opportunity Announcement to verify eligibility. See Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components for more information.

- **Do foreign organizations have an additional step for electronic applications?**

  Yes. Foreign organizations must obtain a NATO Commercial and Government Entity code in addition to an Employer ID Number (EIN) and a DUNS number. For more information on registering, see Grants.gov Registration Instructions for Domestic and Foreign Organizations.

- **If I'm applying from a foreign institution, do I need to indicate this on the application?**

  Yes. Both paper and electronic applications have a checkbox for foreign institutions and domestic institutions with a foreign component.

- **Are foreign companies eligible for Small Business Innovation Research grants?**

  No. To be eligible for an SBIR grant, a company must have majority ownership by U.S. citizens or permanent resident aliens, and conduct all the research funded by the grant in the U.S. This condition makes subsidiaries of foreign companies ineligible unless they are majority owned by U.S. citizens. For more information on small business grants, see the NCI SBIR and STTR Program.

- **What is different about the review of foreign applications?**

  In addition to standard review criteria, peer reviewers assess the following:

  - Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.
  - Whether the proposed project has specific relevance to the mission and objectives of the NIH and has the potential for significantly advancing health sciences in the United States.

  This requirement does not apply to applications from U.S. organizations containing a foreign component.

  For second-level review, NCI must present foreign applications as special issues to the National Cancer Advisory Board (NCAB). The NCAB reviews whether comparable work is being conducted in the U.S.

- **Are there special budget requirements for applications from foreign institutions?**

  Yes. NIH announced a requirement for detailed budgets in August 23, 2006, *Guide* notice.

  Foreign institutions may use an F&A rate of up to 8 percent. See Grants to Foreign Institutions, International Organizations, and Domestic Grants with Foreign Components for more information.

- **Will NIH funding support foreign postdoctoral fellows?**

  Foreign postdoctoral fellows may work on NIH-funded research grants, but they may not work on a National Research Service Award fellowship or training grant.

  According to the NIH Grants Policy Statement, PIs and others supported by NIH research grants are usually not required to be U.S. citizens, though some programs have citizenship requirements. Check the program announcement or request for applications to be sure.

- **If I move to a foreign institution, may I take my grant with me?**

  Yes, if your grantee organization agrees and the grant mechanism is open to foreign organizations. Contact your program director for more information on obtaining approval from the NCI and concurrence from the National Cancer Advisory Board.

- **If I relocate to a new country, can I take NIH-funded equipment with me?**

  Yes. If your grantee organization agrees, you may take the equipment to a new site. Your organization needs to submit an Official Statement Relinquishing Interests and Rights in a Public Health Service Grant form (PHS 3734) for approval.

CONTRACT AWARDS

- **Does NCI have a contracting Web site?**

  Yes. Go to the NCI Office of Acquisitions (OA) web site.

- **Is there a resource for general information on NCI contracts?**

  For general information on contracts on the NCI acquisition process, see "Understand NCI Contracts, A Guide for Principal Investigators and Project Directors" at:http://ncioa.cancer.gov/oa-internet/reference/PI-Handbook-508.pdf.

- **What percentage of the NIH and NCI budgets are spent on contracts?**

  In FY 2012, 7.7% of the NIH extramural award budget, $1.85 billion, went to R&D contracts. About 11.6% percent of the NCI extramural budget, $589 million, went to R&D contracts.

- **Where are the current Requests for Proposals (RFPs) solicitations published?**

  You can find NCI's current RFPs on the NCI Request for Proposals List. In addition, all Federal Government RFPs are required to be published on the Federal Business Opportunities (FedBizOpps) web site.

- **Is the list of current and past NCI contract awards available?**

  Yes. A searchable database of contracts awarded by the NCI Office of Acquisitions is available on the NCI OA Internet site under Reference Materials/OA References, *NCI Contract Awards* at: http://rcb.cancer.gov/rcb-internet/award.htm .

- **How does NCI decide to award a contract instead of a grant?**

  Contracts are used procure research, supporting services and products for the direct benefit or use of the Federal Government. All contracts have a Statement of Work, which specifies the Government's requirement. A grant is an assistance mechanism used to stimulate research when the Government does not anticipate being substantially involved in the project, thus allowing a grantee considerable flexibility in determining the research direction. No fixed service or product is expected.

- **Are requirements and administrative processes more stringent for contracts?**

  Yes. Contracts describe in detail the report(s), product(s) and/or service(s) the Contractor must deliver to satisfy the contractual requirement identified in the Statement of Work. The contract document stipulates exactly what is to be delivered, how it is to be delivered and when it is to be delivered. In addition to technical deliverables, contracts also require terms and conditions mandated by the Federal Acquisition Regulation (FAR), the submission of financial and administrative reports, i.e. invoices, invention reporting, and documentation to close out the contract. See Section III of Understand NCI Contracts for more information.

- **Do academic scientists generally apply for NIH R&D contracts?**

  Yes. Principal Investigators and research scientists from academic institutions, non-profit organizations and businesses "propose on" NIH R&D contracts requirements.

- **Does NCI support R&D contracts for small business concerns similar to the Small Business Innovative Research (SBIR) grants?**

  Yes. Every fall, NCI participates in the NIH/CDC Solicitation for SBIR Contract Proposals. Current and past research topics can be accessed at NCI's SBIR & STTR web site at: http://sbir.cancer.gov/funding/contracts/

- **Do contracts undergo a rigorous peer review?**

  Yes. For details on the process, go to "Proposal Submission and Evaluation Process" of Understand NCI Contracts for more information on the proposal submission and evaluation process.

- **Are contract proposals reviewed by the National Cancer Advisory Board?**

  No. R&D Contract proposals are peer reviewed by a Technical Evaluation Panel. The technical evaluation will be conducted solely on the basis of the evaluation criteria set forth in the Request for Proposal.

- **Is merit the primary criterion for awarding contracts?**

  Yes. NCI makes awards based on technical merit, though cost and past performance may also be factors in funding decisions.

- **Do offerors in the competitive range answer scientific and other questions?**

  Yes. NCI's Office of Acquisitions conducts written and oral negotiations simultaneously with all offerors in the competitive range. During negotiations, offerors may provide written responses or clarifications to business and technical concerns from the review.

- **What is source selection?**

  After negotiations, the Office of Acquisitions holds a source selection meeting to review all revised proposals and select a contractor. Offerors are notified after the review.

- **Can I request a debriefing after a competition is over?**

  Yes. Each offeror is entitled to one debriefing. Offerors must request a debriefing in writing within three days after receiving notification of the contract award. At this "post award" debriefing you will receive information about your proposal's strengths and weaknesses as well as some information about the ward process, i.e. overall ranking of offerors and a summary of the rationale for award.

  Offerors may also choose to request a debriefing prior to the award of the contract. Offerors must request a debriefing, in writing within three days after receiving a notification of exclusion from the competition. Offerors must also specify whether the request is for a "pre" or "post" award debriefing. At a "pre award" debriefing only information about the offeror's proposal will be discussed. Because the competition is ongoing, no information about the award process will be provided.

- **When can I get more information on the competition?**

  Much of the information for a competition is confidential, including the identity of offerors. After a contract is awarded, all offerors are informed of the number of proposals submitted, name of the successful offeror, and dollars and period awarded. Award notices are posted on the FedBizOpps website as well.

- **How do I find NCI contracting staff?**

  Go to Mission and Structure in the NCI Office of Acquisitions. For RFP-specific questions, see the contact(s) listed in the individual RFP located under "Current Request for Proposals."

CLINICAL RESEARCH

- **Is there a source for information on the preparation of clinical research grant applications?**

  The Center for Scientific Review (CSR) has developed a web site for Advice to Investigators Submitting Clinical Research Applications. The web site also contains links to policies and institute contacts.

  See Conducting Clinical Trials for links to NCI clinical trial resources.

- **Are there special initiatives to support clinical trials research?**

  Yes. See NCI Extramural Funding Opportunities for all initiatives. Specific initiatives to support clinical trials include Early Phase Clinical Trials in Imaging and Image Guided Interventions (R21) and Validation of Molecular Diagnostics to Predict Patient Outcomes Using Specimens from Multi-Site Clinical Trials (R01).

- **Does NCI support investigator initiatied grants for phase III clinical trials?**

  No. In 2013, Notice CA-13-012 was issued informing potential applicants that the NCI will no longer use the R01 and P01 activity codes to support investigator-initiated Phase III clinical trials for cancer-related medical interventions and/or cancer imaging modalities.

- **Where can I find information on the policies applicable to human subjects research?**

  See Research Involving Human Subjects for information on the HHS and NIH requirements and resources for the extramural community involved in human subjects research.

  In addition, see link to Inclusion of Women and Minorities as Participants in Research Involving Human Subjects.

- **Where can I find information on the requirements for data and safety monitoring plans on NCI funded grants?**

  The essential elements required for a data safety and monitoring plan funded by the NCI can be found at the NCI Data Safety and Monitoring Guidelines link. In addition, examples of cancer center monitoring plans are provided.

- **What resources and programs are available to assist clinicians in carrying out clinical research ?**

  The Cancer Therapy Evaluation Program (CTEP) provides access to a wide variety of resources, including Clinical Investigator forms and electronic applications for the standardization of trial data collection and reporting, including common toxicity criteria and common data elements. The Investigator's Handbook provides information on the policies and procedures for participants in clinical trials of investigational agents sponsored by NCI. The Clinical Trials Support Unit (CTSU) allows physicians who are not affiliated with a cooperative group to enroll patients on NCI sponsored clinical trials.

Information on industry collaborations is provided including guidelines for collaborations and a list of CTEP sponsored agents. The NCI and the Life Sciences Consortium of the CEO Roundtable on Cancer jointly developed a set of common clauses, or START (Standard Terms of Agreement for Research Trial) Clauses, that are accessible for any party to use when initiating a trial.

The NCI Experimental Therapeutics (NExT) pipeline is designed to assist translation to the clinic of novel therapeutic interventions, either synthetic, natural product, or biologic, arising from cademic, private, or government entities. *NExT is not a grant mechanism.* Approved proposals gain access to drug discovery and development resources through the NExT Program.

Contact the Division of Cancer Prevention for information on prevention clinical trials. Contact the Division of Cancer Control and Population Sciences for information on behavior, clinical epidemiology and genetics, survivorship, and outcomes research.

Visit the NCI Clinical Trials and Programs web site for a description of all of the clinical trials activities.

- **How can a physician not affiliated with a cooperative group participate in NCI phase III clinical trials?**

  The Clinical Trials Support Unit (CTSU) is a project sponsored by the NCI for the support of a national network of physicians to participate in NCI-sponsored Phase III cancer treatment trials. More information is provided on https://www.ctsu.org/.

- **How can primary care physicians become involved in primary and secondary prevention studies?**

  The National Community Oncology Research Program (NCORP) is a new integrated national network to: 1) design and conduct cancer prevention, control, and screening clinical trials; 2) design and conduct cancer care delivery research; 3) enhance patient and provider access to treatment and imaging clinical trials conducted under the reorganized National Clinical Trials Network (NCTN); and 4) Integrate disparity research questions into clinical trials and cancer care delivery research. Primary care physicians are encouraged to become involved with their local NCORP program.

- **Since physicians are not aware of many clinical trials, are there marketing tools to assist physicians and patients?**

  The NCI Clinical Trials web site provides information on clinical trials, trial results, and education materials. The PDQ (Physician Data Query) is NCI's comprehensive cancer database on active clinical trials and includes peer-reviewed summaries. Clinical trials information on all NIH sponsored clinical trials can be accessed through the web site, clinicaltrials.gov.

  The Cancer Information Service (CIS) educates the public about cancer prevention, risk factors, symptoms, diagnosis, treatment, and research. Fact Sheets are available at the CIS web site and cancer information specialists will answer questions at 1-800-4-CANCER. See the NCI Publications Locator to view and order NCI publications.

  The Clinical Trial Education Series (CTES) is a group of thirteen different educational materials (books, booklets, slides, videos) to target education and outreach for health professionals and patients.

- **Are NCI supported human specimen banks available to investigators?**

  Yes. The Specimen Resource Locator is a database to help researchers locate human specimens (tissue, serum, DNA/RNA, other specimens) for cancer research. It includes tissue banks and tissue procurement systems with access to normal, benign precancerous and cancerous human tissue from a variety of organs.
  In addition, the Biorepositories and Biospecimen Research Branch (BBRB) was established to guide, coordinate, and develop the NCI's biospecimen resources and capabilities. BBRB activities include the Biospecimen Research Database, development of NCI Best Practices for Biospecimen Resources, and sponsoring a series of Biospecimen Best Practices Forums.

- **Can NIH help me protect the confidentiality of my research subjects?**

  Yes, with a certificate of confidentiality. See NIH's Certificates of Confidentiality Kiosk for details and follow instructions on applying for the certificate.

- **Can NCI help pay for costs related to the privacy rule?**

  Yes. You can discuss privacy rule issues in the Research Plan of your grant application and budget (for grants or cooperative agreements) or technical and business proposal (for contracts).

- **Do NIH grantees and contractors have ethical requirements for human subjects?**

  Yes. See the Regulations, Policies & Guidance Ethical Guidelines & Regulations for ethical guidelines and federal regulations on the protection of human subjects. In addition, see guidance on Research Involving Vulnerable Populations.

- **When is a clinical trial required to be registered on ClinicalTrials.gov?**

  Public Law 110-85 (also known as the FDA Amendments Act), includes a requirement that if an "applicable clinical trial" is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, any grant or progress report shall include a certification that the responsible party has made all required submissions for the applicable trial to ClinicalTrials.gov. Under the statute, the "applicable clinical trials" trials generally include:

  (1) Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;

  (2) Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

  See Clinical Trials Registration in Clinicaltrials.gov for more information on the requirements and process.

- **What are NCI's future plans in the area of clinical trials and translational research?**

  The Clinical Trials Working Group (CTWG) was established in January, 2004, to advise NCI on issues concerning NCI-supported cancer clinical trials. An extramural advisory committee, the Clinical Trials Advisory Committee (CTAC), oversees the implementation of the recommendations of the CTWG. Contact Coordinating Center for Clinical Trials (CCCT) for more information.

The Translational Research Working Group (TRWG) was established in 2005 to develop recommendations about how the NCI can best organize its investment to further "translational research." Go to TRWG web site.

NCI asked the Institute of Medicine (IOM) of the National Academies to review the NCI Clinical Trials Cooperative Group Program in order to gather independent and expert perspectives on the state of cancer clinical trials and to obtain advice about improvements in the NCI Cooperative Group Program. The IOM report was issued in April 2010 and is available at http://transformingtrials.cancer.gov/initiatives/cooperative-groups/iom-report and NCI and the cooperative groups are working to response to the recommendations. In 2012, NCI published a series of RFAs soliciting cooperative agreements for the reorganization of the cooperative groups into the National Clinical Trials Network.

- **How do patient advocates participate in NCI's research activities and programs?**

The NCI has established the Consumer Advocates in Research and Related Activities (CARRA) program within the Office of Advocacy Relations (OAR). The CARRA program was created to integrate the perspective of people affected by cancer into a wide range of NCI's programs and activities, including peer review of clinical research. See CARRA web page for more information.

- **How do I locate NCI staff involved in clinical research?**

For treatment trials, go to the Cancer Therapy Evaluation Program for therapeutic trials, Radiation Research Program for radiation trials, and Cancer Imaging Program for imaging trials.
For cancer prevention trials, go to National Community Oncology Research Program (NCORP).

For cancer control and population research, including behavioral and outcomes research, go to the Division of Cancer Control and Population Sciences.

BUDGET PROCESS

- **What is the NCI Bypass Budget?**

  Each year, as mandated by the National Cancer Act of 1971 (P.L. 92-218), the NCI prepares the NCI Bypass Budget which describes continuing and new activities that take advantage of new discoveries and opportunities and maximize the use of NCI resources. This annual plan and budget proposal is provided directly to the President of the United States for formulating the budget request to Congress.

- **How are funding decisions made?**

  NCI no longer publishes RPG paylines. Individual consideration of a broad range of competing applications will be the hallmark of NCI's selection process. Peer review evaluation of scientific merit will remain the primary consideration in these funding decisions, which will be made by NCI Scientific Program Leaders (SPL) following discussions with Program Staff. The NCI SPL will give special consideration to applications that fill a significant gap in the cancer research portfolio or propose an especially novel or promising scientific approach. Although there are no guaranteed paylines, the SPL does identify a percentile cutoff for R01s and R21s, then discusses additional applications for funding above the percentile. NCI has a strong commitment to New Investigators , including early stage investigators, and establishes a higher percentile cutoff for these R01 applications. More information is available at NCI Funding Policy. Funding decisions for Request for Applications (RFA) are determined by the set aside of funds available and the quality of the grant applications.

- **Where is information available on the funding level in specific disease or research areas?**

  NCI reports how appropriated funds are spent in a number of different categories or classifications including specific cancer sites, cancer types, and diseases related to cancer, as well as types of research mechanisms. See the NCI Fact Book for information on funding of disease categories as well as funding and success rates for grant mechanisms.

  The NCI Funded Research Portfolio provides access to various NCI budget reports associated with research funding by research categories. It also provides the ability to search the database in various ways including a text search of the project abstract and a search of the NIH research categories that are assigned to the projects by extramural and intramural groups.

  The NIH report, Estimates of Funding for Various Diseases, Conditions and Research Areas, includes funding levels for grants and contracts across NIH by fiscal year.

- **Where can I find information on paylines and funding policies for NCI?**

  Information on the current payline for R01 applications and funding policies for competing and non-competing applications is available on the NCI Funding Policy web page.

- **Where is information available on funding and success rates?**

  See the NCI Fact Book for information on funding of disease categories as well as funding and success rates for grant mechanisms. NIH Success Rates are also available by institute and grant mechanism on the NIH Research Portfolio Online Reporting Tool (RePORT).

- **Where is information available on funding and success rates for new investigators?**

  Information on NIH first-time Principal Investigator (PI) success rates and the average age of PIs can be found in the NIH Data Book on the RePORT web site.

ADVISORY BOARDS

- **Where can I find information about National Cancer Institute advisory boards, committees, etc.?**

  Find basic information at the main NCI Advisory Boards and Groups web page, including charters, members, meeting agendas and dates, and meeting minutes and slide presentations.

- **What is the National Cancer Advisory Board?**

  The National Cancer Advisory Board (NCAB) is a chartered advisory committee that provides a diverse perspective on science, health, and the human impact of disease. The NCAB is responsible for advising NCI on policy, making recommendations on future directions, and performing the second level of review for grant applications. For more information, see the NCAB web page and NCAB Orientation Book.

- **Do all NIH institutes have an advisory council?**

  Yes. By law, each institute at NIH must have an advisory council. To read the law, go to the Federal Advisory Committee Act (FACA) of 1992 (P.L. 92-463). NCI has the only presidentially appointed advisory group which is termed a "board" and not "council".

- **Who is on the National Cancer Advisory Board?**

  The NCAB has 18 voting members, including 12 health or science experts and six lay members, all of whom usually serve overlapping terms of four years. The NCAB also includes twelve nonvoting *ex officio* members who provide liaison with higher level organizations. Find the list of current members at NCAB Membership.

- **When does the NCAB meet?**

  The NCAB is mandated to meet four times annually. Meetings are generally held in February, June, September, and December for two days. Meetings in February, June, and September are for second level review and December for review of the intramural programs. For meeting dates, go to Agenda and Future Meetings web site.

- **What takes place during a NCAB meeting?**

  Meetings consist of open sessions for special presentations, subcommittee reports, and remarks by NCI Director. Closed sessions include the full second-level review of applications, including review of grant applications needing special consideration. The NCAB open sessions may be viewed on http://videocast.nih.gov/.

- **What does the NCAB look at during second level review?**

  The NCAB reviews all grant applications with reference to the needs of the institute and the priorities of the National Cancer Program. During the second level review, the Special Actions Subcommittee is informed of applications for which reviewers expressed concern about any biohazard, human subjects, animal, child, gender, or minority welfare concern. Applications from foreign institutions are brought to the attention of the NCAB and reviewed for concurrence with the NIH policy on foreign grants. R01 applications from PIs with current NIH awards in excess of $1million in direct costs are reviewed for concurrence. Appeal letters are reviewed and staff

recommendations to concur or request a variance from recommendations of study sections are considered. Council does not look at the scientific merit of an application and does not repeat the initial peer review.

- **How does the appeals process actually function?**

  NIH has a formal process to resolve disagreements between applicants and NIH review committees and/or NIH staff concerning the referral (assignment) and review of applications. Note that disagreements are not necessarily grounds for appeal. Each institute has an assigned appeals officer. The NIH appeals policy and process is described in the *NIH Guide for Grants and Contracts*.

  Before beginning the appeals process, the applicant is strongly advised to speak with the NCI program director responsible for the application. The program director can explain the options and consequences and is often in a position to help the applicant understand the study section's recommendation. Appeal letters should be submitted to the NCI program director. NCI will make the appeal letter together with the staff recommendation available to the National Cancer Advisory Board for its consideration during the closed session. If an appeal of initial peer review is pending on the original application, the NIH will not review a resubmission application (A1 version) until the appeal is resolved.

- **Do all applications need NCAB's recommendation before funding?**

  By law, applications must be approved by an outside body, or the NCAB, before they can be funded with the exception of Individual National Research Service Award (NRSA) applications.

- **What is expedited Council review?**

  The NCI has implemented a procedure to streamline the second-level review to expedite Institute funding of specific mechanisms. The expedited NCAB approval process is used for percentile R01s reviewed by CSR and for all R21s, except for those applications submitted in response to a set-aside (RFA or PA with a set-aside). Qualifying applications must have received an initial peer review, rank within the payline, and have no special concerns such as human subjects or animal concerns.

- **Does Council recommend applications before human, animal, and other issues are resolved?**

  Yes. If the application is selected to pay, program or grants management staff will contact the PI to resolve any issues and seek the appropriate NIH and NCI approval.

- **What is the Board of Scientific Advisors?**

  The Board of Scientific Advisors (BSA) is a chartered advisory group that provides scientific advice on a wide variety of matters concerning scientific program policy, progress and future direction of the NCI's extramural research programs, and concept review of extramural program initiatives. Information on membership and agendas is provided on the BSA web site.

- **What is concept clearance and the BSA's role in it?**

  Concept clearance is a review of each new program initiative and reissuance proposed --

Request for Applications (RFA) or Request for Proposals.. Concept clearance is a mandatory step before NCI can develop and publish an initiative. Go to the NCI Extramural Funding Opportunities for a list of active initiatives.

- **Who is the point of contact for nominations for Boards or review committees?**

  Contact the Director, Division of Extramural Activities, NCI, if you are interested in volunteering for NCI review committees or boards, committees, etc.

PRIVACY, CONDUCT, AND CONFLICT OF INTEREST

FOIA and Privacy

- **Is my application confidential?**

  Most grant and contract materials are confidential, including grant applications, progress reports, contract proposals, and proceedings of review meetings. Two exceptions are the grant application's title and abstract, which NIH makes public.

  Reviewers may not take materials from peer review and use them without attribution.

- **Can my grant be released to a third party through a Freedom of Information Act request?**

  Yes. Yes. NIH can release funded applications and research data in response to a FOIA request. NIH will notify the grantee before releasing information. The investigator will have the opportunity to identify any patentable information and information that is of commercial or financial nature. If the investigator wishes for certain portions of their grant application to be withheld prior to release, they will need to demonstrate that release of that information will reveal a trade secret or will result in substantial competitive harm. Personal information is also removed from the application prior to release under FOIA.

  See Notice of Amendment of A-110 for guidance on access to research data.

- **What information does an applicant have the right to obtain about the review?**

  You have access to the summary statement available through eRA Commons. The summary statement consists of minimally edited critiques from each reviewer and a summary of the discussion at the review meeting. If the application is triaged, there is no discussion or summary.

Grantee and Contractor Conduct

- **What constitutes research misconduct?**

  The Office of Research Integrity (ORI, DHHS) handles allegations of research misconduct that involve PHS-supported research. Misconduct in research means fabrication, falsification, plagiarism, or any significant departure from accepted practices of the research community for proposing, performing, reviewing research or reporting research results. It does not include honest error or differences of opinion about interpretation of data. (a)Fabrication is making up data or results and recording or reporting them; (b)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; (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

- **If I encounter research misconduct, should I notify my program director?**

  No. The established procedure is to check with your institution for policies and procedure concerning allegations of possible research misconduct and they will direct you to the institutional Research Integrity Officer (RIO). They will contact the NCI RIO, who will then initiate contact as required with the NIH Agency Extramural Research Integrity Officer (AERIO) and the DHHS Office of Research Integrity, ORI, Division of Investigative Oversight (DIO). The ORI webistge is http://ori.dhhs.gov

- **Do NIH grantees and contractors have ethical requirements?**

  Yes. Grantees are subject to the regulations in the NIH Grants Policy Statement on Ethical and Safe Conduct in Science and Organizational Operations. Contractors must meet Contractor Qualifications.

  Investigators involved in human subjects' research must obtain education in protecting research participants. NCI offers an online Human Participant Protections Education for Research Teams course to meet the requirement.

- **What are the conflict of interest requirements for grantees?**

  Each institution receiving PHS funds must have written policy guidelines on conflict of interest and avoidance thereof. These guidelines should reflect state and local laws and must cover financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery. These rules must also indicate how outside activities, relationships, and financial interests are reviewed by the responsible and objective institution official(s). See Conflict of Interest web site for more information.

  The NIH has developed a web-based Tutorial on Financial Conflict of Interest which reviews the requirements of, and the Institutional and Investigator responsibilities for compliance with, the regulation. The tutorial is designed for use by Institutional officials responsible for managing NIH funded projects and for individuals who are responsible for the design, conduct or reporting of NIH-supported research.

- **Do financial conflicts of interest need to be reported?**

  Yes. For awarded grants and cooperative agreements, Institutions must submit all FCOI reports to the NIH through the electronic Research Administration (eRA) Commons FCOI Module. See *NIH Guide for Grants and Contracts*, Notice No. NOT-OD-09-072. Refer to the FCOI Module User Guide for additional information.

Peer Review Conflict of Interest

- **Can reviewers review applications for which they have a conflict of interest?**

  No. Members of peer review committees must leave the room during discussions of grant applications in which they or close associates have an interest that could bias their evaluations. See revised policy for managing conflict of interest in the initial peer review of NIH grant and cooperative agreement applications (NIH-OD-13-010).

  If reviewers are in conflict with one contract proposal, they should not participate in the review of any proposals in response to the specific RFP.