The OSP Exchange

Getting to your VPR Compliance Partners: IRB; Research Security, Integrity and Compliance; and an Update of the NIH Other Support and Biosketch format

October 26, 2021

AGENDA

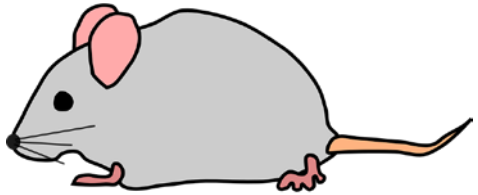
1. Introduction to VPR Directors
2. IRB/IACUC
3. Office of Research Security, Integrity and Compliance
   - Export & Research Security Compliance
4. OSP - NIH Updates
   - NIH Grants Policy Statement
   - Other Support
   - Biosketches

IRB/IACUC

Office for Research Protections - Who Are We?

What does ORP do?

IRB



IACUC

Postdocs

Office philosophy: our job is to make YOUR job easier

IRB: What is it, and why do we have one?

- History of unethical treatment of human subjects in research
  - Nazi experiments in the 40s (biomedical experiments on prisoners in concentration camps)
  - Tuskegee Syphilis Study (1932-1972): subjects were low-income African American sharecroppers in Alabama- treatment withheld even after penicillin became treatment of choice
  - San Antonio Contraception study (1960s-70s): poor Mexican-American women seeking contraceptives were given contraceptives or placebo
- National Advisory Health Council formed to review safeguards for human research, recommended institutional review to ensure rights & welfare of participants.... HHS 45 CFR 46

IRB: Who is on it?

- Chair
- Non-scientist
- Community member
- 2 CSON faculty members
- 1 law faculty member
- 4 LSOEHD faculty members
- 2 Psychology faculty members
- 1 SSW faculty member
- 1 Sociology faculty member
- Prison rep, as needed

Types of Submissions

- Exempt
  - Lowest risk
  - Secondary data analysis, benign surveys, benign behavioral interventions, interviews
  - Fastest turnaround - handled internally
- Expedited
  - No more than minimal risk - collection of blood or bio specimens, audio/visual recording, research on individual/group characteristics or behavior
  - Sent to an IRB member for review - 2+ weeks
- Full board
  - Highest risk (anything more than minimal risk)
  - 5-10 of these per year at BC
  - IRB committee meets once per month, so build this into your timeline!

IRB Application Process

- Take the CITI training
- Check out templates on our website (bc.edu/orp) for consent, recruitment
- Fill out an IRB application at **cyberirb.us/bc**
- After initial internal review, we will send you revisions
- Once we receive your revisions, we will either review internally (exempt) or send to a reviewer (expedited)
- Reviewer may have additional changes they ask you to make
- Once received, your approval will be sent via email
- The vast majority do not expire

What happens after that?

- Amendments
  - Quick turnaround!
  - Any change: adding a site, changing a survey question, etc.
- Continuing Reviews
  - After 2018 flexibility policy, these are rare
  - Currently only for full board, and a handful of expedited
  - Replaced with the Quality Assurance Program
- Adverse Events
  - Must submit to us within 24 hours
  - May or may not be study related

The nitty gritty:
federal grants, collaborators, international research

- Federal grants
  - Federal grants = less flexibility
- Subcontracts
  - Be sure that IRB process is approved for all sites involved
- Authorization Agreements
  - See our website for details!
  - Makes the process more convenient (one single IRB review) - required for federal grants
- International Research Policy
  - See website - local review must be sought if applicable; if not, must submit letter
- Clinical trials: contact me to register

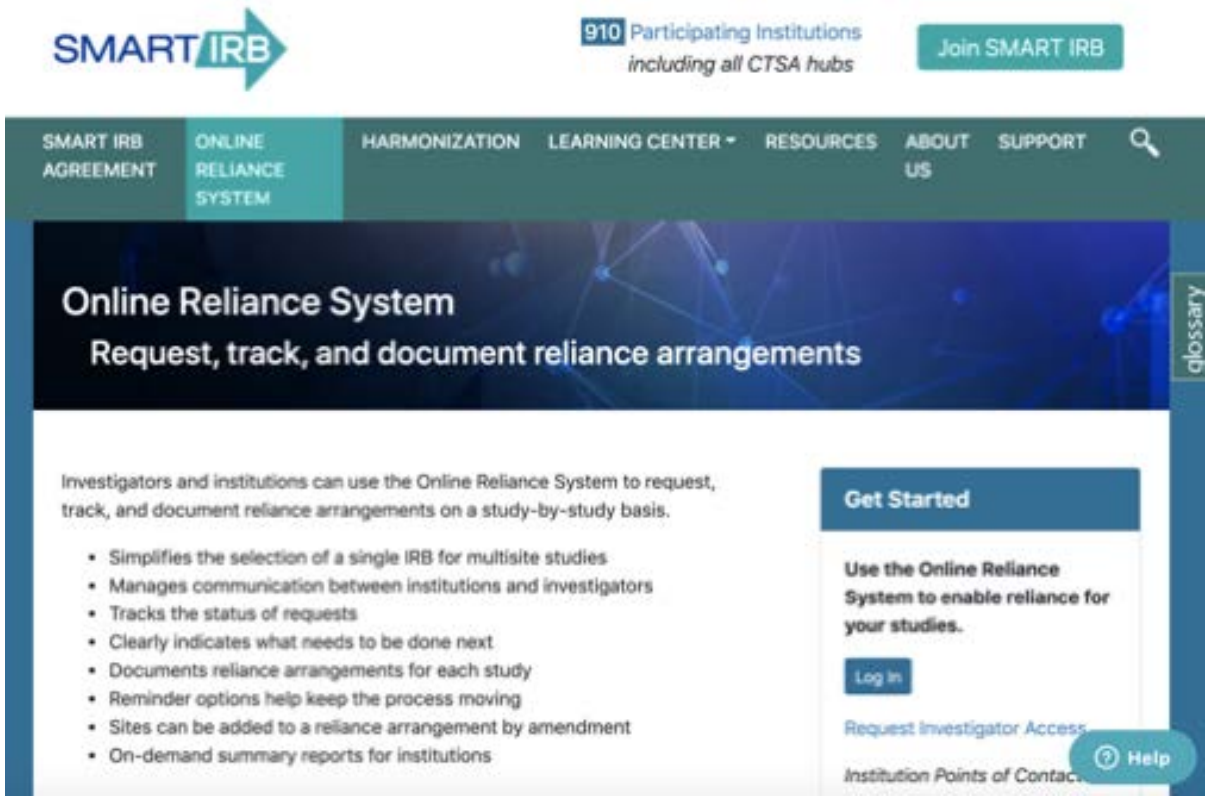
Your Role

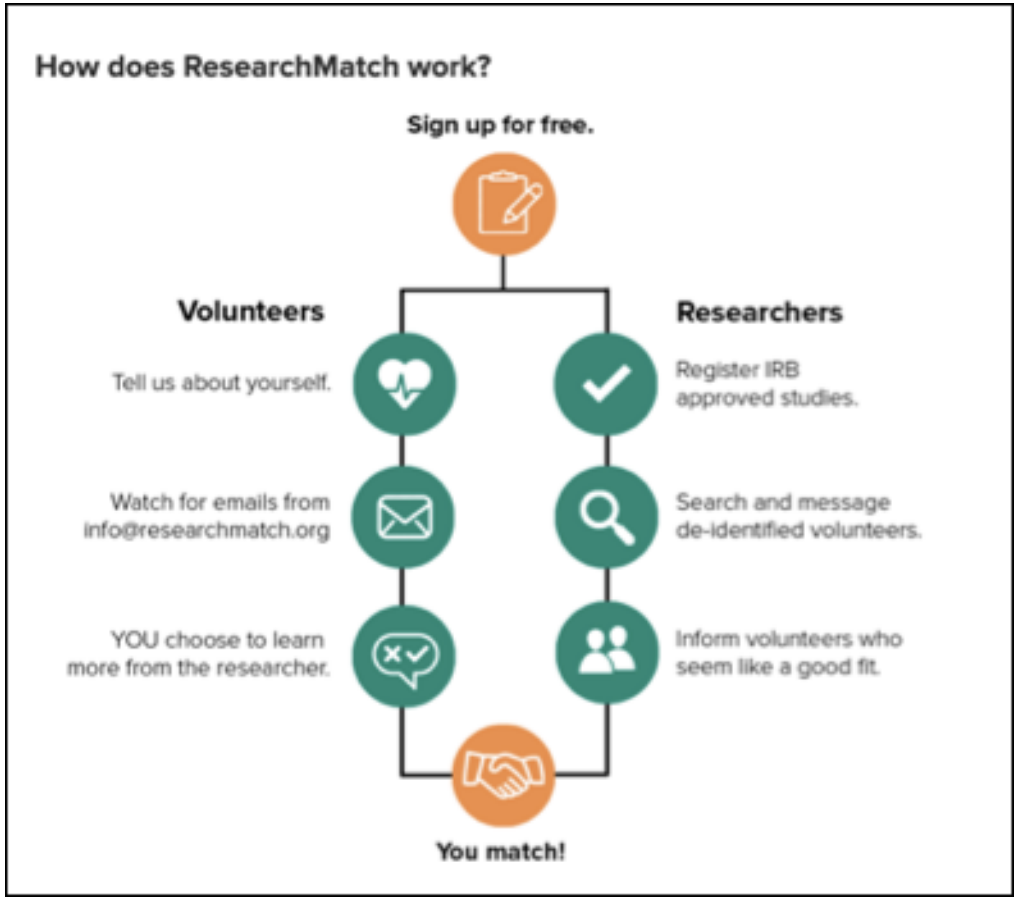
- Faculty member
  - Electronically sign your students' protocols through Cyber IRB
  - Please discuss/review with students before they submit
  - Can assign a doc student or staff member to manage IRBs if needed
- OSP staff and DRAs
  - Check in - is IRB required/approved?
  - Subcontracts involved?
- Department chairs
  - Will be notified (but no need to sign) when faculty protocols are submitted

IACUC

- ACF is located in Higgins Hall
- Small number of PIs from Biology and Psychology
- Email iacuc@bc.edu to request forms
- ACF training is available through iLab

New(ish) Resources for Researchers





Training for faculty, PhD students, postdocs

- Research Scholarship and Integrity Program - based on requirements from NIH and NSF in responsible conduct of research
- PhD students and postdocs must complete the program in their first two years
  - Require: two general sessions, plus four seminars
- Sample topics: difficult conversations with mentors, copyright, authorship disputes, IRB, teaching and ethics, data acquisition and management, misconduct
- Faculty may register as needed (and please volunteer for a panel!)
- Check out other training opportunities at citiprogram.org

So you want to hire a postdoc...

- Items to email to me:
  - Offer letter (contact our office for template if needed) with start date
  - CV
  - Export Controls form (to be reviewed by LA)
- HR will then communicate directly with the candidate
- NIH salary minimums
- Postdoc will be required to complete the RSI program in their first two years
- Please note - BC's first ever postdoc grants - deadline is 11/1!

How to Find Us

- bc.edu/orp
- Office hours: 2nd Tuesday of the month 10-12, 3rd Monday of the month 2-4
- Zoom IRB clinics in your school or department
- Twitter: BC_ORP

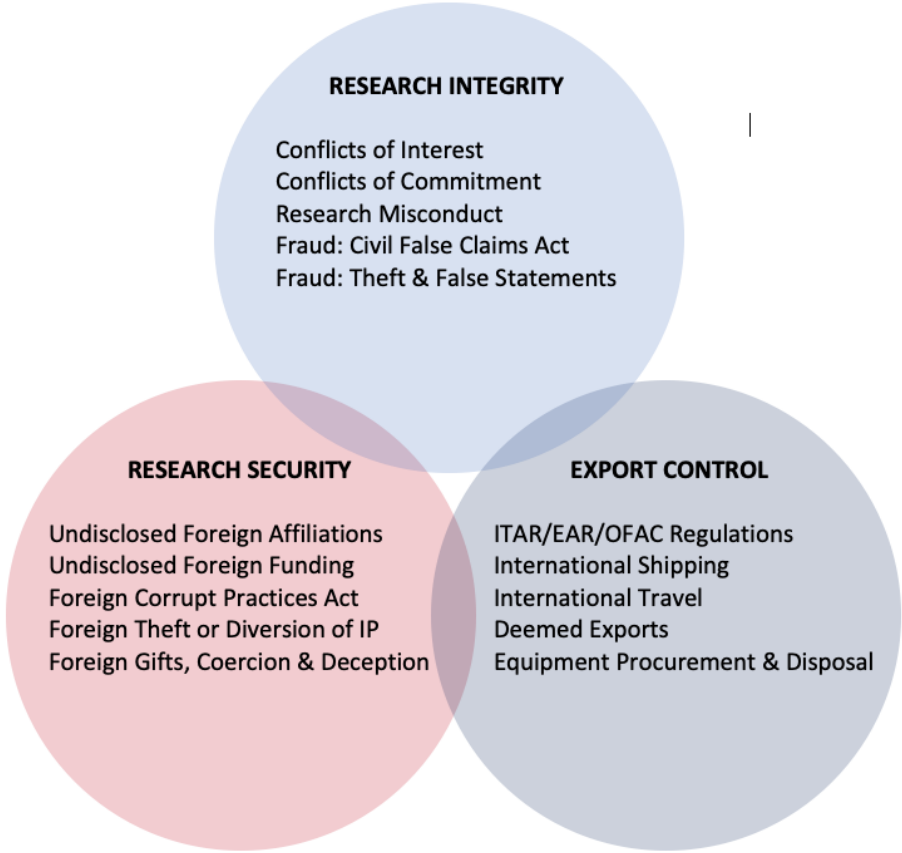
Office of Research Security, Integrity and Compliance

Office Overview

- In August 2021, the VPR merged the Office of Research Security and Export Compliance with the Office of Research Integrity and Compliance, creating the Office of Research Security, Integrity and Compliance.
- The VPR established the office in response to the rapidly changing compliance environment faced by research universities, faculty and staff, including increased oversight and enforcement of highly complex federal regulations and policies.
- Current Staff:
  - Leigh-Alistair Barzey, Director of Research Security, Integrity & Compliance
  - Michael Curry, Assistant Director of Export Compliance

Area of Responsibility

- Provides support and guidance to BC faculty and staff with matters involving:
  - **Export Controls**
  - **Research Security**
    - Improper Foreign Influence
    - IP Theft/Economic Espionage
  - **Research Integrity**
    - Research Misconduct
    - Conflicts of Interest
    - Conflicts of Commitment
    - Grant Fraud



Overview of Export Controls

- Export control laws are a complex set of federal regulations designed to protect U.S. national security; advance U.S. foreign policy; and maintain U.S. economic competitiveness.
- The U.S. Government restricts the export of defense articles; dual-use goods and technology; certain nuclear materials and technology; and items that would assist in the development of nuclear, chemical, and biological weapons.
- Violations of federal export control laws can result in severe criminal, civil and administrative sanctions and penalties for BC, and its faculty, staff and students.

Federal Export Regulations

- The U.S. export control regulations are administered by multiple federal agencies, including:
  - **Export Administration Regulations (EAR):** Exports of dual-use goods and technologies, as well as some military items, are licensed by the Commerce Department.
  - **International Traffic in Arms Regulations (ITAR):** Exports of defense articles, services and technology are licensed by the State Department.
  - **Office of Foreign Assets Control (OFAC):** Restrictions on exports based on U.S. sanctions are administered by the Treasury Department.

“Export” Defined

- The federal government defines an “export” as any item that is sent from the U.S. to a foreign destination.
- For the purposes of export control, the term “item” includes, but is not limited to:
  - software or technology
  - materials
  - circuit boards
  - blueprints
  - design plans
  - technical information

Methods of Exporting

- **The method of exporting technology outside of the U.S. does not matter.**
- An export-controlled item or technology can be “exported”:
  - by mail, shipment, courier, or hand-carried on an airplane
  - uploaded to, or downloaded from, an Internet site
  - transmitted via email, fax, telephone or an in-person conversation

Deemed Exports

- **Deemed Export:** The dissemination or transmission of export-controlled information or technology to a Foreign Person who is located in the U.S. The U.S. Government "deems" that release of export-controlled technology as an export to the Foreign Person's country.
- **Deemed Export Scenarios:**
  - Conducting tours of research labs and facilities by Foreign Persons
  - Working with Foreign Postdocs and Students
  - Sponsoring Foreign Visiting Scholars

U.S. Person vs. Foreign Person

- **U.S. Person:** A U.S. citizen, a U.S. entity, a U.S. permanent resident (Green Card Holder), or a person lawfully in the U.S. under certain refugee or asylum designations.
- **Foreign Person:** Anyone who is not a U.S. Person.
  - Under the EAR, the Commerce Department considers the individual's most recent citizenship and their permanent residence.
  - Under the ITAR, the State Department considers the individual's country of origin/birth and all current citizenships.

International Travel & Export Controls

- Any international trip can involve U.S. export control and sanctions regulations.
- To avoid unintended export violations, prior to traveling internationally, the following questions should always be answered:
  - Where are you going? **(Destination)**
  - What are you taking with you? **(Technology and Equipment)**
  - What are you doing on the trip? **(Purpose and Activities)**
  - Who are you meeting/working with while abroad? **(People and Entities)**

Technology Control Plans

- A Technology Control Plan (TCP) outlines security measures implemented to prevent unlicensed deemed exports of export-controlled technology. TCPs are usually utilized in the research enterprise; however, any university activity where export-controlled information is exchanged may be subject to a TCP.
- TCP security measures vary by project or activity, but can include the following:
  - Identifying individuals authorized to participate in the project.
  - Identifying secured areas where research activities may take place.
  - Protecting electronic files.
  - Marking materials as subject to export controls.

Fundamental Research Exclusion

- **Fundamental Research:** The "basic and applied research in science and engineering, the results of which are ordinarily published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development... the results of which ordinarily are restricted for proprietary or national security reasons."
- The results of Fundamental Research are exempt from export control, but the application of the exemption is limited:
  - The exemption can be nullified by restrictions on publication or participation.
  - The conduct of Fundamental Research can be export-controlled if the research uses equipment, technology or software that is export-controlled.

Publicly Available/Public Domain Exclusion

- **EAR:** Publicly available technology and non-encryption software is not subject to the EAR. (15 CFR § 734.3)
  - This includes information that is the subject of an open patent application, published in a book or periodical, released at an open conference anywhere, available on a website accessible by the public with no access controls, or information that will be published.
- **ITAR:** Information which is already published and generally accessible to the public is not subject to ITAR. (22 CFR § 120.11)
  - Information that is available through books, periodicals, patents, open conferences in the U.S., websites accessible to the public with no access controls, or other public release authorized by the U.S. government, is considered in the public domain.

Educational Information Exclusion

- **EAR:** Information "released by instruction in a catalog course or associated teaching laboratory of an academic institution," is not subject to the EAR. (15 CFR § 734.3(b)(iii))
- **ITAR:** "Information concerning general scientific, mathematical, or engineering principles commonly taught in schools, colleges, and universities," is not subject to the ITAR. (22 CFR § 120.10(b))

Assistance with Export Control Issues

- Please contact the Office of Research Security, Integrity and Compliance for assistance with any of the following Export Control issues:
  - **International Shipments**
  - **International Travel**
  - **“Deemed” Exports**
  - **Export Control “Exclusions”**
  - **Procurement of scientific instruments or equipment**
  - **Technology Control Plans**
- Office Email: exportcontrol@bc.edu
- MJ Curry, Asst. Director, Export Compliance: 617-552-2068, curryma@bc.edu

Increased Federal Focus on Funded Research

- The U.S. Government is increasingly focused on “research security” and threats to the integrity of America’s research enterprise, including:
  - **Improper foreign influence in federally-funded research**
  - **Researchers’ failure to disclose foreign affiliations, Conflicts of Interest (COI) and Conflicts of Commitment (COC) to funding agencies and universities**
  - **Intellectual property theft and economic/academic espionage**
- National Security Presidential Memorandum (NSPM)-33, issued on 1/14/2021.
- The White House Office of Science and Technology Policy (OSTP) subsequently issued a report “Recommended Practices for Strengthening the Security and Integrity of America’s Science and Technology Research Enterprise.”

OSTP Definitions of COI & COC

- **COI:** "a situation in which an individual, or the individual's spouse or dependent children, has a financial interest or relationship that could directly and significantly affect the design, conduct, reporting, or funding of research."

- **COC:** "a situation in which an individual accepts or incurs conflicting obligations between or among multiple employers or other entities."

- The OSTP report stated that although "[m]any organizational policies define [COC] as conflicting commitments of time... *obligations to share information improperly with, or to withhold information from, an employer or funding agency, can also threaten research security and integrity, and are an element of a broader concept of conflicts of commitment.*"

OSTP Report on Research Security & Integrity

- The OSTP report stated that “research security and the integrity of the research enterprise are inexorably linked” and provided the following examples of “research integrity” breaches due to researchers’ failure to disclose:
  - **Funding and research subsidies**
  - **Parallel laboratories**
  - **Outside employment**
  - **Affiliations or appointments with foreign research organizations**
  - **Participation in foreign talent plans**
  - **Conflicting financial interests**
  - **Ownership of private companies**

Pending Federal Guidance and Legislation

- On August 12, 2021, the OSTP advised that President Biden was committed to implementing NSPM-33 in a consistent and coordinated manner that preserves core values of America's scientific research enterprise.
- The OSTP further advised that by November 2021, it would issue NSPM-33 implementation guidance to funding agencies and universities that would address three key areas:
  - **Disclosure Policies**
  - **Oversight & Enforcement**
  - **Research Security Programs**
- In the past few months several bills addressing research security and integrity compliance were passed in the House and Senate with bipartisan support. If the legislation is successfully conferenced by the Congress, it will likely be signed into law by the President.

Assistance with Research Security Issues

- Please contact the Office of Research Security, Integrity and Compliance for assistance with any of the following Research Security or Integrity issues:
  - **International Collaborations**
  - **International Travel**
  - **International Research**
  - **Hosting Foreign National Visitors on Campus**
  - **Foreign Talent Plans**
- Leigh-Alistair Barzey, Director, Research Security, Integrity and Compliance: 617-552-1144, barzeyl@bc.edu

OSP Federal Compliance
NIH Updates

October 2021

Science & Security

What is driving some of the changes at federal agencies with respect to grant applications, other support and foreign involvement?

Transparency: Federal Agency Initiatives, Announcements and Clarifications

- **Funding agency concerns:**
  - Failure to disclose resources for research at non-U.S. universities
  - Conflicts of commitment ("conflicting obligations … among multiple employers or other entities")
  - Diversion of intellectual property and know-how developed with federal funding
  - Breach of confidentiality of peer review
- **Concerns also voiced by members of Congress from both parties**
- **Ongoing investigations and prosecutions linked to failure to disclose and other issues**

NIH Notices on Other Support, Foreign Components, Biosketch

Number	Date	Title	Highlights
NOT-OD-19-114	7/10/19	Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components	• ***Remind*** to report foreign activities in other support, foreign components, and financial conflict of interest • ***All*** resources made available to a researcher in support of and/or related to *all* of their research endeavors • All positions, scientific appointments, domestic and foreign held by SKP relevant to application incl. affil. foreign entities or govt. • Foreign component: existence of any "significant scientific element or segment of a project" outside of the United States
NOT-OD-21-073	3/12/21	Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021	• ***Align Biosketch, Other Support format and Application*** with OSTP and other guidance • Updated forms required after 5/25/21 • 'Positions and Honors' now 'Positions, Scientific Appointments, and Honors' • Other support page reorganized to separate funded support from ***in-kind*** • **Signature block on OS** • **Supporting documentation** for contracts, grants or agreements for foreign appts./employ. • **Immediate notice of undisclosed other support**
NOT-OD-21-110	4/28/21	Implementation of Changes to the Biographical Sketch and Other Support Format Page	• NIH ***expects*** updated biosketch, OS format for applications, JIT, and RPPR as of May 25, 2021; require by 1/25/22 • Responsible for ***disclosing all*** research endeavors ***regardless of the forms used***; must still capture all the necessary information
Extramural Nexus	5/5/21	Updated Biographical Sketch and Other Support Format Pages Available Now and Required January 2022	• Use of the new format pages is ***preferred*** immediately and required for due dates and submissions on or after January 25, 2022 • Applicants and recipients **remain responsible for disclosing all research endeavors regardless of the version of the forms** used including supporting documentation and immediate notification of undisclosed OS

Other Support

How is other support used?
What is other support?
When?

What is Other Support?

Other Support is to report support other than the application or award on which you are reporting. “Neither the application under consideration nor the current PHS award for this project should be listed as Other Support.”

Sometimes referred to as “current and pending support”

Other Support includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution

How is “other” or “current and pending” support information used?

Understand resources available to researchers in support of their research endeavors (including grants and contracts, and externally supported personnel, lab space, materials and other resources)

Identify and avoid potential scientific and budgetary overlap with the proposed research, domestic and foreign

Investigator and staff commitment, and the potential for over-commitment (effort greater than 100%)

- Applicable regardless of resource location and whether the support is monetary or “in-kind” and/or direct to the researcher

Any foreign resources that meet the definition of a foreign component have received appropriate **prior approval**.

When is Other Support Disclosed?

Proposal	Just-in-Time	RPPR Other Support & Personnel	During Project/Prior Approval
• All appointments, domestic/foreign, FT/PT, honorary, etc (Biosketch) • Foreign component	• All sources of support • In-kind including visiting scholars funded by foreign sources • Foreign contracts for appointments/employment of SKP	• New appointments • New support • New in-kind • New collaborators • New visitors	• New Foreign Component • Previously undisclosed other support (immediate disclosure as soon as known)

NIH Other Support: Who??

- **Senior/key personnel—those devoting measurable effort to a project**

Who Not?

*Not for Program Directors, training faculty, and other individuals involved in the oversight of training grants since applicable information is collected in other sections of a training grant application.

*Not for individuals categorized as Other Significant Contributors.

Other Support: What?

- **All current projects and activities**, even if only in-kind (e.g. office/laboratory space, equipment, supplies, employees).
- **All research resources including, but not limited to, foreign financial support**, research or laboratory personnel, lab space, scientific materials, selection to a foreign "talents" or similar-type program, or other foreign or domestic support must be reported.
- **Total award amount for the entire award period covered** (including facilities and administrative costs), as well as the number of person-months (or partial person-months) per year to be devoted to the project by the senior/key personnel involved.

NIH Other Support: What?

- All positions and scientific appointments domestic and foreign including affiliations with foreign entities or governments
- All resources made available to a researcher in support of and/or related to all of ***their research endeavors***, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes but is not limited to:
  - foreign and domestic entities
  - financial support for laboratory personnel
  - high-value materials not freely available
  - Consulting agreements, ***when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities***. Non-research consulting activities are not Other Support.
  - In-kind contributions supported by an outside source.

NIH Other Support: What Not?

- **Training awards, prizes, or gifts***
- **Institutional resources**, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources
- **Start-up packages from the institution****
- **F&A reimbursement**
- **In-kind contributions** such as technology, chemicals, etc. if intended for use on the project being proposed to NIH in the application, the information must be included as part of the Facilities and Other Resources or Equipment section of the application and does not need to be replicated on Other Support

***Gifts are resources provided where there is no expectation of anything (e.g. time, services, specific research activities, money, etc.) in return. An item or service given with the expectation of an associated time commitment is not a gift and is instead an in-kind contribution and must be reported as Other Support.

****Start-up from outside organizations should be disclosed

Effective May 25, 2021, NIH requires the following:

- **Supporting documentation**, which includes copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If the contracts, grants or other agreements are not in English, recipients must provide translated copies.

- **Immediate notification of undisclosed Other Support**. When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

Other Support FAQ:
What should be used for dollar amounts for listing awards?

7. Should the dollar amounts reflected on the Other Support document reflect annual total cost or annual direct cost only?

- Other Support submissions should provide the total award amount, direct and indirect, for the entire project period (e.g. competitive segment for NIH grants), not just the annual budget period.

18. When a researcher works on a subaward to an NIH grant that is awarded to another institution, how should that information be included in Other Support?

- The researcher should provide the project number, PD/PI name for the prime award. All other information, including the total award amount and person months, should be specific the subaward.

23. When providing the total award amount for an NIH funded grant project, should the researcher provide what was requested in the initial application, or the amount of funding listed on the current Notice of Award?

- Researcher's should list the total award amount, direct and indirect, for the entire project period, based on the most recent Notice of Award specific to that project.

Updated NIH Biosketch

Required by January 2022

Recommended Tips: SciENcv

PIs are strongly encouraged to set up their biosketches and current and pending in **Sciencv.** This tool is endorsed by the NIH and NSF and is updated to reflect any changes to the agencies' biosketch and C&P policies. It generates nicely formatted documents.

https://www.ncbi.nlm.nih.gov/sciencv/

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

SciENcv Background

Science Experts Network Curriculum Vitae (SciENcv) is a new electronic system that helps researchers assemble the professional information needed for participation in federally funded research. SciENcv gathers and compiles information on expertise, employment, education and professional accomplishments. Researchers can use SciENcv to create and maintain biosketches that are submitted with grant applications and annual reports. SciENcv allows researchers to describe and highlight their scientific contributions in their own words.

What SciENcv does:

- Eliminates the need to repeatedly enter biosketch information
- Reduces the administrative burden associated with federal grant submission and reporting requirements
- Provides access to a researcher-claimed data repository with information on expertise, employment, education, and professional accomplishments
- Allow researchers to describe their scientific contributions in their own language

Updated NIH Biosketch

- Per 3/12/2021, 4/28/21 Notices and Blog 5/5/21
- Use of the updated format pages will be required for applications and Research Performance Progress Reports (RPPRs) submitted for due dates on or after January 2022
- During the transition to the new Biosketch format, NIH will not withdraw applications that include the previous Biosketch format
- Beginning with applications submitted on or after January 25, 2022, failure to follow the appropriate Biosketch format may cause NIH to withdraw your application from consideration.

Specific Changes to Biosketch Instructions - Updates

- **Instructions for a Biographical Sketch**

- **Personal Statement updated to read:**

  - *Briefly describe why you are well-suited for your role(s) in this project. Relevant factors may include: aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and/or your past performance in this or related fields, including ongoing and completed research projects from the past three years that you want to draw attention to (previously known as research support).*

- **Positions, *Scientific Appointments*, and Honors updated to read:**
  - *List in reverse chronological order all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). High school students and undergraduates may include any previous positions. For individuals who are not currently located at the applicant organization, include the expected position at the applicant organization and the expected start date.*

- **D. Scholastic Performance updated to remove 'Research Support'**. Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support, only Scholastic Performance.

Reminder: Interim Progress Reports

- **8.6.2 Final Research Performance Progress Report**

- A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, the recipient must submit an Interim-RPPR while their renewal application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim RPPR will be treated by NIH staff as the institution's Final RPPR.

- A Final RPPR should be prepared in accordance with the requirements in the RPPR Instructions found on the **NIH RPPR** website and any specific requirements set forth in the terms and conditions of the award.

- **Final RPPR Instructions for SBIR/STTR Phase II Reports are in Section 7.3. of the RPPR Instructions.**

8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA

- **The recipient is required to submit a prior approval request to the GMO if:**

There is a significant change in the status of the PD/PI or other Senior/Key Personnel specifically named in the NoA including but not limited to withdrawing from the project entirely, being absent from the project during any continuous period of 3 months or more, or reducing time devoted to the project by 25 percent or more from the level that was approved at the time of initial competing year award. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting Yes in the RPPR constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.

- There is a change from a multiple PD/PI model to a single PD/PI model.
- There is a change from a single PD/PI model to a multiple PD/PI model.
- There is a change in the number or makeup of the PD/PIs on a multiple PD/PI award.

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

8.1.2.7 Change of Recipient Organization

- **https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1.2_prior_approval_requirements.htm**
- A request for change of recipient organization should include mention as to whether the change in recipient institution is related to concerns about safety and/or work environments (e.g. due to concerns about harassment, bullying, retaliation, or hostile working conditions) involving the PD/PI. NIH will in turn be better positioned to enable informed grant-stewardship decisions regarding matters including, but not limited to, substitute personnel and institutional management and oversight.
- The NIH expects both the relinquishing and applicant organizations to disclose whether a Change of Recipient Organization is occurring within the context of an ongoing or recent investigation of misconduct of any kind, including but not limited to professional misconduct or **research misconduct.**

Recap- Publication of Revised NIH Grants Policy Statement Notice Number: NOT-OD-21-107

- Applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2020
- Section 2.3.7.12 Biographical Sketches (Biosketches) Consolidated all existing requirements on Biosketch into a single section
- Section 2.3.9.3 Modified Submission Policy for Appointed Members of NIH Review and Advisory Group and Reviewers with Recent Substantial Service
- Section 2.5.1 Just In Time Procedures Updated application instructions for Other Support per NOT-OD-21-073
- Section 8.1.2.6 Change in Status, Including Absence of PD/PI and Other Senior/Key Personnel Named in the NoA
- Section 8.1.2.7 Change of Recipient Organization

THANK YOU!

Questions?