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THE INVESTIGATOR'S GUIDE TO GRANTS AND CONTRACTS

v.1.2, 5/19/2017

Table of Contents

Investigator Guide. UIC Department of Pediatrics, v.1.2, 5/19/2017

5 | P a g e

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Chapter 1
Pre award: preparation and submission of proposals

By Hélène Gussin

In collaboration with Susanne Feret

SCOPE

This chapter will guide investigators to navigate the pre-award period, from project conceptualization to proposal submission.

1. Overview

Note: New investigators MUST request an eRA commons account from NIH, through the UIC Office of Research Services, at least 6 weeks prior to submission deadline:
http://research.uic.edu/sponsored_programs/nih_commons_account_request

Time to sponsor deadline	Activity
4-12 months before deadline	Identify funding opportunity Identify collaborating partners Conduct literature review Develop draft research question and aims
2-4 months before deadline	Review FOA for specific instructions Gather and analyze supportive data Finalize aims Finalize collaborators list Finalize SOW for collaborators Request biosketches and LOS from collaborators Draft research strategy outline Draft facilities and resources document Draft budget and budget justification
4-6 weeks before deadline	For NIH proposals with direct costs ≥$500,000 in any year of project, obtain approval from Center/Institute. Develop elements of research strategy document: significance, innovation, approach and project timeline (e.g. Gant chart) Finalize facilities and resources (if applicable) Finalize equipment, resource sharing, multi PI plan (if applicable) Develop vertebrate animals section (if applicable) Develop human subjects, clinical trial sections (if applicable) Develop authentication of key biological and/or chemical resources (if appropriate) Finalize budgets for/with outside collaborating partners (consortium). Budget, BJ, SOWs, draft LOI for subsites routed to collaborating institutions for approval and endorsement
3-4 weeks before deadline	Finalize abstract, narrative, bibliography Assemble LOS Near-final research strategy
2-3 weeks before deadline	All financial documents completed PAF finalized and routed for signature
10 days before deadline	All documents finalized. Final review
7 days before deadline	ORS submission deadline. Note that final material must be submitted to ORS at least 5 business days prior to sponsor deadline to ensure timely review and submission. If this timeline is not followed, timely submission will NOT be guaranteed.
D0 (sponsor deadline)	ORS submits proposal

Abbreviations: **BJ**: budget justification; **FOA**: Funding Opportunity Announcement; **LOI**: letter of intent (a.k.a. consortium letter); **LOS**: letter of support; **ORS**: Office of Research Services; **PAF**: Proposal Approval Form; **SOW**: scope of work.

2. Submission material

2.1.   Considerations for trainees and junior investigators

Your training period offers the opportunity for you to develop your skills as an independent. A few tips to keep in mind as you get started:

- ✓ If you are applying as a PI and you have not previously registered in eRA, you MUST request an eRA commons account from NIH, through the UIC Office of Research Services, at least 6 weeks prior to submission deadline:
  http://research.uic.edu/sponsored_programs/nih_commons_account_request

- ✓ Mentorship is available for development of your grant! Please contact Dr. Marian Fitzgibbon (312-996-0146, mlf@uic.edu) or Dr. Molly Martin (mollyma@uic.edu) for guidance on conceptualization, development of research plan, or other scientific assistance.

- ✓ Business office personnel can assist you in the development of a customized timeline and checklist for your application. Please contact Dr. Hélène Gussin (312-355-5166, hgussin@uic.edu), or Ms. Susanne Feret (312-996-7568, sferet1@uic.edu) for guidance on budget, administrative topics, logistics and submission mechanics.

2.2.   Considerations on pre-applications, letters of intent, limited competitions

2.2.1.   Pre-Selection process by Sponsor/Funder

The application process for some funding opportunities consists in 2 main steps:

Step 1: Pre-application (also called "initial application", "letter of intent", "pre-selection"). Submission of a letter of intent may be optional for some opportunities, and mandatory for others. PI must review application guidelines to determine if an LOI/pre-application is preferred, required, or not requested.

Pre-application/LOI may be competitive process, i.e., only some of the applicants who submitted an LOI will be invited to submit a full application. Alternatively, some sponsors/funders will accept full applications from all applicants who submitted a letter of intent.

Pre-application requirements commonly include specific aims or a brief summary of the project and list of proposed collaborators. Requested content varies widely based on sponsor.
Classically, the pre-application is submitted directly by the PI (no involvement of the Pediatrics business Office or University ORS).

Exceptions include pre-applications that request **budget/financial information**, and those that necessitate **official endorsement**; such applications must be routed through the Pediatrics business Office and obtain institutional approval.

Step 2: Full application.

Limited competition: If pre-application is considered responsive, sponsor will invite PI to submit a full application. Invitation letter must be submitted with the project PAF.

2.2.2. "One submission per institution": the OVCR pre-selection process

Some other sponsors state that institutions may submit one proposal. Accordingly, interested candidates should work through OVCR in obtaining the appropriate approval from the institution.

As soon as opportunity is identified, investigators should contact OVCR (Mr. Tony Halford, ahalford@uic.edu; and /Ms. Heather Schuster, hschust@uic.edu) to let them know of their intention to apply. If more than one investigators from the institution declares their intention to apply, OVCR will oversee a rapid peer reviewed selection process. OVCR will let the PI what information is required or this selection process.

Principal Investigator of the selected application will receive an email from OVCR authorizing submission of application to sponsor. A copy of this message must be enclosed with PAF documentation.

2.3. Checklist: Internal routing: Proposal Approval Form "PAF" (2-3 weeks before deadline)

All full applications (e.g. federal and non federal sponsored application, foundation applications, bids) must be routed through the Pediatrics business Office and obtain institutional approval *prior* to submission to sponsor/funder.

No application, regardless of amount of funding requested, should be submitted without approval.

Documentation needed for routing of PAF must be provided to Pediatrics business Office 2-3 weeks prior to sponsor deadline. Required material:
- □ PAF form, prepared by Pediatrics business office. Name, UIN and department affiliation of all internal investigators are required. Signature from all UIC investigators and their Department Heads (or College Dean, if Department Head is an investigator named in proposal).
- □ Project title
- □ Project dates
- □ Abstract or specific aims
- □ Budget
- □ Budget justification; if NIH project with direct costs ≥$500,000 in any year, attach NIH approval.
- □ (If appropriate) Waiver form for F&A deviations or cost-sharing. If sponsor-mandated deviation (e.g., cap on indirect costs): copy of sponsor material highlighting this requirement, such as application guidelines.
- □ (For projects which include external collaborators): site-approved site-specific budgets, BJ, SOW, endorsed LOI, COI certification.
- □ (For limited competitions): invitation letter from sponsor or OCVR (see considerations above, section 2.2).

2.4. Checklist: NIH standard application (7-10 days before deadline)

- For Pediatrics business office:
  - Project dates
  - List of PI and other research personnel. Must include full name (first, middle, last), organization name, address with zip + 4, phone number, fax number, email address, eRA Commons username, project role. All listed individuals will have to provide biosketch.

- Attachments
  Note: documents must be formatted with margin of at least ½ inch on all sides, for all pages; font size 11 points or larger; fonts Arial, Helvetica, Palatino linotype, Georgia; no more than 6 lines/inch

Document	Max. Limit	Sections, if applicable / comments
(if applicable) Cover letter		Do not include assignment or review request information (use PHS assignment request form instead) For NIH project with direct costs ≥$500,000 in any year, attach NIH approval in cover letter.
Abstract	30 lines	
Narrative	3 sentences	
Bibliography/References		
Specific Aims	1 page	
Facilities and resources		
Research strategy	RO1: 12 pages RO3, R21, R36: 6 pages Other, per FOA (e.g. may be 25-30 pages for some K awards)	✓ Significance (scientific premises) ✓ Innovation ✓ Approach (as of May 2016, must include sections on scientific premises, rigor and transparency, consideration of sex and other biological variables) ✓ Project timeline (e.g. Gant chart)
Authentication of key biological and/or chemical resources	1 page	
Biosketches of all key personnel	5 pages/each	
Budget		Prime and subawards, if applicable
Budget justification		Prime and subawards, if applicable
LOS	Required for R36 applications	
Equipment		
(if applicable) Appendix	10 attachments	
(if applicable) resource sharing: for applications requesting ≥$500,000 direct costs in any budget year.		

(if applicable) multiple PD/PI leadership plan, required if more than 1 PD/PI		
(if applicable) vertebrate animals, required if Vertebrate Animals is "yes" on cover form		
(if applicable) protection of human subjects, required if Human subjects is "yes" on cover form		
(if applicable) inclusion of women and minorities, required if Human subjects is "yes" on cover form, and exemption number is not 4		
(if applicable) inclusion of children, required if Human subjects is "yes" on cover form, and exemption number is not 4		
(if applicable) clinical trial enrollment form, required if Clinical Trials is "yes" on cover form	PHS inclusion Enrollment Report	New form (FORMS-D)
(if applicable) Data Safety Monitoring Plan, required if Clinical Trials is "yes" on cover form		
(optional in most applications) PHS assignment form		New form (FORMS-D)
(resubmission and revision) Introduction to application	1 page	
(if applicable) Other attachments, as requested by FOA		

2.5.   NIH application - -Special considerations:

2.5.1.   Vertebrate animals euthanized by method NOT consistent with American Veterinary Association guidelines: describe method and provide justification (1,000 characters max.)

2.5.2.   Program income: If program income is anticipated during the periods for which grant support is requested, please provide the following information:
   (1) Budget period   (2) Anticipated amount ($)   (3) Source(s)

2.5.3.   Involvement of human embryonic stem cells: If project involves human embryonic stem cells, list registration number of the specific cell line(s) from http://stemcells.nih.gov/research/registry. If specific cell line(s) cannot be referenced at time of application, check box indicating that one from the registry will be used.

2.5.4.   Renewals only: Inventions and Patents (yes/no)? If yes, previously reported (yes/no)

2.5.5.   Impact on environment: If project has impact (positive or negative) on environment, explanations will be required. Please contact business office for guidance.

2.5.6.   International activities/partnerships: If project involves activities outside of the US, or partnership with international collaborators, countries must be identified. Explanations are optional.

2.5.7.   Budget over $500,000 in direct costs in any budget year: If the direct costs in any budget year reach or exceed $500,000:
   - *Advance NIH approval* is required prior to submission for some Institutes/Centers. Contact the awarding component to determine whether you must obtain prior approval at least six weeks prior to the anticipated submission. If the requested dollars are significantly greater than $500,000, then approval should be sought even earlier. Some NIH Institutes/Centers (IC) do not require prior approval. It is recommended that you include the official communication from an NIH official approving your application that requests $500,000 or more, as part of your cover letter attachment.
   - A "*resource sharing*" section must be included in application packet

3. Standard NIH dates

Note: Make sure that proposed project start date is consistent with "Earliest Project Start Date" presented in Table 3.3 below. Proposal, budget (internal and submitted to sponsor) and PAF will need to have matching dates.

Source: http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm (accessed 6/6/2016)

- If the FOA says "standard dates apply", refer to the table below using the activity code specified in the title of the FOA.
- Note that renewal/resubmission/revision applications may have different due dates than new applications. Read the table carefully.
- The AIDS and AIDS-related dates apply to all activity codes.

3.1.   Application Due Dates

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
P Series *All - new, renewal, resubmission, revision*s P01P20P30P40P41 P42 P50P51P60PL1 PN1PN2P2CPM1	**Program Project Grants and Center Grants P01** NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept P series applications for all three receipt/review/award cycles.	January 25	May 25	September 25
R18, U18 R25 *All - new, renewal, resubmission, revision*	**Research Demonstration Education Projects**	January 25	May 25	September 25
T Series D Series	***Institutional* National Research Service Awards Other Training Grants**	January 25	May 25	September 25

		January	May	September
All - new, renewal, resubmission, revision T14T15T32T34T35T37T90TL1 TU2T01T02T09T42TL4 D43D71DP1DP2DP3DP4DP5DP7	NOTE: Applicants should check with the relevant Institute or Center (IC), since some do not accept T series applications for all three receipt/review/award cycles. Applicants should refer to the IC Table of Contacts for information for each IC's scientific/research contact for the NRSA T32 program.			
C06/UC6 *All - new, renewal, resubmission, revision*	**Construction Grants**	January 25	May 25	September 25
G07, G08, G11, G12, G13, G20, R24, S06, S11, S21, S22, SC1, SC2, SC3, UG1, U10, U19, U24, U2C, U41, U42, U45, U54, U56 *All - new, renewal, resubmission, revision*	**Other Activity Codes**	January 25	May 25	September 25
R01 *new*	**Research Grants**	February 5	June 5	October 5
U01 *new*	**Research Grants - Cooperative Agreements**	February 5	June 5	October 5
K series *new* K01K02 K05K06K07K08K12K14K18 K22K23K24K25 K26K30K99KL1 KL2 KD1KM1K21K43K76K00	**Research Career Development**	February 12	June 12	October 12
R03, R21, R33, R21/R33, R34, R36, UH2, UH3, UH2/UH3 *new*	**Other Research Grants and Cooperative Agreements**	February 16 See NOT-OD-15-057	June 16	October 16
R15 *All - new, renewal, resubmission, revision*	**Academic Research Enhancement Award (AREA)**	February 25	June 25	October 25

R01 *renewal, resubmission, revision*	**Research Grants**	March 5	July 5	November 5
U01 *renewal, resubmission, revision*	**Research Grants - Cooperative Agreements**	March 5	July 5	November 5
K series *renewal, resubmission, revision* K01K02 K05K06K07K08K12K14K18 K22K23K24K25 K26K30K99KL1 KL2 KD1KM1K21K43K76K00	**Research Career Development**	March 12	July 12	November 12
R03, R21, R33, R21/R33, R34, R36, UH2, UH3, UH2/UH3 *renewal, resubmission, revision*	**Other Research Grants and Cooperative Agreements**	March 16	July 16	November 16
F Series Fellowships (except F31 Diversity) *new, renewal, resubmission* F05F30F31F32F33F37F38FI2F99	***Individual* National Research Service Awards (Standard)** (see NRSA Training Page)	April 8	August 8	December 8
R13, U13 *All - new, renewal, resubmission, revision*	**Conference Grants and Conference Cooperative Agreements**	April 12	August 12	December 12
F31 Diversity Fellowships *new, renewal, resubmission*	***Individual* Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research** (see NRSA Training Page)	April 13	August 13	December 13
R41, R42 R43, R44, U43, U44, *All - new, renewal, resubmission, revision, AIDS and AIDS-related* SB1, UB1	**Small Business Technology Transfer (STTR)* Small Business Innovation Research (SBIR)* Commercialization Readiness Pilot (CRP) Program***	September 5	January 5	April 5

3.2. AIDS and AIDS-Related Applications

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
All Activity Codes Cited Above *new, renewal, resubmission, revision*	**AIDS and AIDS-Related Applications** *Effective. Sept 5, 2015 - N/A for SBIR/STTR Applications using Standard Due Dates NOTE: See Key Dates section of funding opportunity announcement to determine if AIDS dates apply.	May 7	September 7	January 7

3.3. Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

4. Useful links

4.1.   Funders and sponsors

4.1.1. National Institutes of Health (NIH)

NIH offers funding for many types of grants, contracts, and even programs that help repay loans for researchers. NIH advertises availability of grant support through funding opportunity announcements (FOAs). Search for an FOA specific to your area of interest, or apply to one of our generic parent announcements.

Note: Use the link in the FOA to access the specific forms required to submit an application. There is no generic application form to use from the website. Application forms are associated with each FOA. Read the FOA carefully. Use the instructions in the announcement in conjunction with the application guide to prepare your application. If instructions conflict, follow the FOA.

Links:

- Funding opportunities: http://grants.nih.gov/funding/index.htm, or http://www.grants.gov/
- NIH application guide: http://grants.nih.gov/grants/how-to-apply-application-guide.htm

4.1.2. Patient-Centered Outcomes Research Institute (PCORI)

PCORI funds projects that answer patient-centered questions about health and health care. By highlighting comparisons and outcomes that matter, PCORI expects research findings to inform decisions by patients, caregivers, clinicians, and other healthcare stakeholders.

PCORI is looking for projects that assess the benefits and harms of interventions related to preventive, diagnostic, therapeutic, or palliative care or the healthcare delivery system. In most research projects funded by PCORI, researchers partner with patients and other stakeholders from the planning stages through the final dissemination of findings (but recognize that in some highly technical and methodological projects, patients may not make appropriate partners.)

Note: Applications requirements vary based on funding announcement. Please review application guidelines related to PFA you are applying to. Some PCORI opportunities are limited competitions that require submission of an LOI (see "Special considerations related to limited competitions" above).

Links:

- PCORI funding center: http://www.pcori.org/funding-opportunities
- PCORI applicant training: http://www.pcori.org/funding-opportunities/applicant-training

4.1.3. Department Of Defense (DOD)

The Department of Defense – Congressionally Directed Medical Research Programs (DoD-CDMRP) issues solicitations as Program Announcements (PA) and Broad Agency Announcements (BAA). Their mission is "Transforming healthcare through innovative and impactful research".

Note: Application is a 3-step process:

- ✓ step 1 (either non competitive LOI, or preproposal followed by invitation to submit) submitted in eBRAP by PI (https://ebrap.org)
- ✓ step 2 (full application) submitted in grants.gov by ORS
- ✓ step 3 (application verification) completed in eBRAP by PI.

Links:

- Available DoD funding opportunities: http://cdmrp.army.mil/funding/default.shtml
- Application guide: http://cdmrp.army.mil/funding/apply.shtml

4.1.4. Other funding sources: IDPH, Foundations, pharmaceutical firms, …

Funding is available from a multiplicity of sources at the local, regional, national, and even international level. When applying for funding from any source, investigators must carefully review guidelines to ensure compliance with deadlines, budget/allowable costs (including F&A), required material, etc.

> **All submissions and pre-submissions that involve budget information or require institutional endorsement must be routed to the ORS through the Department Business Office.**

5. Templates and guidance

5.1. Budget and justification

5.1.1. Categories

Personnel: Salaries and fringe benefits

Budgets should include a salary category, which includes the names, role, % effort devoted to project, and base salary of all individuals who will be involved in the project. For multi-year projects, and depending on sponsor/funder's limitations, an inflation rate of 2-3% on base salaries may be applied.

Note: Some funders/sponsors have specific salary caps (see "Expense caps" section below).

Fringe benefits apply to project personnel's salary, and should be included in the budget as direct costs. Current fringe benefit rates are available at https://www.obfs.uillinois.edu/government-costing/rate-schedules/chicago/. For multi-year projects, and depending on sponsor/funder's limitations, an inflation rate of 2-5% on fringe benefit rate may be applied.

IMPORTANT: Departmental Policy of investigator's effort

In an effort to assist investigators preparing budgets for sponsored studies, to ensure fair use of departmental resources, and to help balance department budget by minimizing cost-sharing, the Department of Pediatrics is putting forth a policy regarding investigators' effort for sponsored programs. This policy is to be followed for all projects with PI(s) or investigators affiliated with the UIC Department of Pediatrics.

Policy: When budget for a program or project is being prepared, actual effort and corresponding salary/fringes projected for the investigators must be included. Effort that is expanded by investigator, but is not reimbursed by sponsor, is considered cost-sharing and uses department resources. Cost-sharing is to be minimized as much as possible and requires departmental approval. Unless not allowed by sponsor guidelines, minimum level of effort budgeted for PI/co-PI should be as follow:
- NIH, NSF, DoD, PCORI, etc: 15-20% minimum.
- Industry-sponsored trials: 5-10% minimum.

Make sure to include time for administrative tasks (i.e., supervision of study, communication with sponsor) and for performance of study (such as conducting physical examinations for research, writing research notes)

Level of effort listed on budget for an investigator (co-I) must reflect actual involvement and effort in the project. The following minima are recommended and may vary based on investigator's role in project:
- NIH, NSF, DoD, PCORI, etc: 5-10%
- Industry-sponsored trials: 3-5%

Note that very small levels of effort (1-2%) correspond to approximately 20-40 hours per year and must be reserved for studies in which investigators have minimal involvement (e.g., assist with design/analysis/interpretation of results, conduct of a few, well-defined procedures, etc.).

Waivers: Waivers for deviation from above-stated policy will have to be thoroughly justified. Waiver requests will be reviewed by grant office and Director of Administrative Operations and allowed/not allowed on a case by case basis.
Prior to requesting waiver, level of effort will have to be discussed with grant office and with Director of Administrative Operations, to ensure availability and proper allocation of resources. Effort level will have to be justified on budget justification and detailed list of activities to be performed (with estimate of time) will have to be provided.

For industry-sponsored studies (e.g., pharmaceutical trials), please consult the Departmental Guidelines on budgeting and invoicing for industry-sponsored studies available on Pediatrics website.

Non-personnel costs

- **Consultants:** Includes professional services performed by non-UIC employees an hourly basis. Base cost per hour, and expected number of hours/budget period should be noted. If applicable, reimbursement for members of Data Safety Monitoring Board (DSMB), External Advisory Committee (EAC), or other advisory groups can be included under the consultant category.
   Notes:
   o Current or former University employees may not be paid as consultants. Such individuals should be included in personnel category, and payments to current or former University employees will be paid through the University payroll system.
   o Participant/patient stipends should not be included in the consultant category.

- **Supplies**: Includes consumable materials specifically and exclusively related to the project.

- **Equipment**: Includes items with an acquisition cost of $5,000 or more, including components for fabrication of equipment which cost $5,000 or more, or lease purchase agreements for equipment costing $5,000 or more. Classically, computers are not included in the "equipment" category.

- **Travel**: Includes scientific travel (i.e., related to the performance of the project, such as mileage/ parking reimbursement for visits to patients, travel to investigator meetings, etc) and programmatic travel (such as travel to conferences). Travel should be reasonable, allowable and consistent with sponsor/funder's guidelines and University policy.

- **Patient care costs**: Includes costs related to research patient care, either as inpatient or outpatient.

- **Other expenses**: Includes costs specifically related to project that are not included in other categories. Examples include publication costs, participant stipend, cage fees for research animals, IRB costs for industry-sponsored trials, etc.
   Note: Tuition remission is considered a direct cost and is included in the "Other" category. Tuition remission is assessed on graduate assistant salary reimbursement when they meet the applicable campus/department requirements.

- **Consortium/ Subawards**: Includes other institutions that will perform work on project under leadership of UIC investigators. Direct and indirect subaward costs are classically considered direct costs on UIC's budget.
  Notes:
    o Subawardees must submit to UIC a formal proposal including site-approved site-specific budgets, budget justification and scope of work, letter of intent/commitment endorsed by subawardee's institution and including provisions on conflict of interest (if applicable).
    o It is permissible for a subawardee to have their own subawardee(s). Costs for "sub-subawardee" must be reflected in the subawardee's budget and justification.

5.1.2. Indirect costs (F&A)

Indirect costs (also known as IDC, Facilities and Administration, and F&A) are costs that are not directly accountable to a cost object (such as a particular project, facility, function or product). They cover expenses associated with building space, heating, lighting, administrative, etc.

How to calculate F&A costs using full rate

The rates are negotiated by the University's Office of Grants and Contracts with the Office of Naval Research (cognizant federal audit agency). The agreement provides rates for organized research, sponsored instruction, and other sponsored activities. Rates for FY 18 are found in table below; current rates may be found at http://research.uic.edu/sponsored_programs/preparing-proposal/developing-budget/rates

Finalized negotiated FY 17 rate per agreement	Rate
Organized research	59.9% of MTDC
Instruction	42.4% of MTDC
Other sponsored activities	36.0% of MTDC
Off-campus activities	26.0% of MTDC
Other F&A rates	
Industry clinical trials	**25.0%** of TDC
Tuition remission	**42.0%**

When using the negotiated rates, F&A is calculated as a percentage of the Modified Total Direct Cost (MTDC). The MTCD includes salaries and wages, fringe benefits, materials and supplies, services, travel, and subawards up to the first $25,000. It *excludes* the following:

- Capital Expenditures
- Equipment (i.e., items that cost $5,000 or more)
- Tuition remission
- Patient care charges
- Rental costs
- Scholarships and fellowships
- The portion of each subgrant/subcontract in excess of $25,000

Using F&A lower that full rate

Some sponsors/funders only allow F&A rates lower than the federally negotiated rate. If a non-federally negotiated indirect cost (less than full) rate is employed, F&A is calculated as a percentage of the Total Direct Cost (TDC).

Total direct cost includes all direct costs (personnel, fringe, tuition, equipment, supplies, travel, other, etc.) charged to a sponsored program. *Exception*: IRB fees for industry-sponsored clinical trials are not included in TDC.

5.1.3. Allowable costs

When developing budget, investigators must answer the following questions:

1. Are costs allowed by funder/sponsor? For example, some sponsors will not allow PI's effort to be budgeted; others will not allow food or travel; others will not allow the purchase of equipment; others do not allow indirect costs.
2. Is budget at/below maximum allowed by sponsor? Most sponsors will not allow the submission of proposals with budgets exceeding the maximum award published in funding announcement.
3. Is the allowed award amount inclusive of direct costs only, or is it total award (direct + indirect costs)? For example, maximum awards published in NIH and PCORI's funding announcements reflect only the direct costs. Those published by IDPH include direct AND indirect costs. As an illustration, a $200,000 award means the following for different funders:

Funder:	Published award amount	Direct costs	Indirect costs (Example rate: 59.9%)	Total requested in application
NIH	$200,000	$200,000	$119,800	$319,800
IDPH	$200,000	$125,078	$74,922	$200,000

5.1.4. Expense caps

Salary cap

Federal agencies (e.g., NIH) have a cap on the maximum <u>base</u> salary allowed for personnel listed on the proposal. As of January 8, 2017, NIH salary cap is set at $187,000. When preparing your budget, please verify cap at http://grants.nih.gov/grants/policy/salcap_summary.htm. Note that, for Department of Defense funding announcements, salary cap varies based on application. Program guidelines must be reviewed.

<u>Example</u>: Dr. Jane Doe's base salary is $215,000/year. She will devote 10% effort to proposal. Her effort for a NIH-sponsored will be budgeted as follows:

Name	Role	Base salary	% effort	Requested salary	Fringes (*Example*: 40.23%)	Total

| Jane Doe, MD* | PI | $187,000 | 10 | $18,700 *Calculate using cap salary: $187,000 x 10%* | $7,523 *Calculate using requested salary: $18,700 x 40.23%* | $26,223 |

* Salary above agency cap

Other funders (e.g., PCORI) have different salary caps. As of June 2016, PCORI salary cap is $200,000. Please verify cap in PAF application guidelines. Budget for Dr. Doe's participation in a PCORI-funded project will be budgeted as follows:

Name	Role	Base salary	% effort	Requested salary	Fringes (*Example*: 40.23%)	Total
Jane Doe, MD*	PI	$200,000	10	$20,000 *Calculate using cap salary: $200,000 x 10%*	$8,046 *Calculate using requested salary: $20,000 x 40.23%*	$28,046

* Salary above cap

Caps on indirect costs

Other funders may limit the indirect cost rate. For example, PCORI caps the amount of indirect to 40%. If the F&A rate used in the proposal is not the UIC federally negotiated rate:

- This rate is applied to the Total Direct Cost (i.e., no exclusions will be taken before applying the F&A).
- Investigator must provide published sponsor documentation (i.e., application guidelines highlighting the rate cap), and an F&A waiver form.

Caps on other categories

Some funders will limit the amount that may be allocated to a certain category. For example, PCORI caps the amount allocated to scientific travel (such as travel to conferences) to $10,000 for the totality of the award (i.e., cumulative for all investigators and personnel, including consortium, and for whole duration of the award).

> **Review guidelines closely and be aware of sponsor/funder's specific caps, as budgeting over these may cause your application to be rejected, or your award to be decreased.**

5.2.   Facilities and Resources

Facilities and resources section must be <u>tailored to the proposed studies</u> and indicate how the institution, research, and/or clinical environment will contribute to the success of the project. Below is some template language that may be used and adapted for specific projects.

5.2.1. University of Illinois at Chicago

[adapted from www.uic.edu]

The University of Illinois at Chicago is an acclaimed research institution with 15 colleges dedicated to the discovery and distribution of knowledge. A Public Research University, with an annual operating budget over $ 2 billion, and more than $360 million spent annually on research, UIC provides the broadest access to the highest levels of intellectual excellence. UIC's mission is:

- To create knowledge that transforms our views of the world and, through sharing and application, transforms the world.
- To provide a wide range of students with the educational opportunity only a leading research university can offer.
- To address the challenges and opportunities facing not only Chicago but all Great Cities of the 21st century, as expressed by our Great Cities Commitment.
- To foster scholarship and practices that reflect and respond to the increasing diversity of the U.S. in a rapidly globalizing world.
- To train professionals in a wide range of public service disciplines, serving Illinois as the principal educator of health science professionals and as a major health care provider to underserved communities.

UIC is among the top five most diverse campuses in the nation and a national leader among urban, public higher education institutions in providing access to underrepresented students. UIC is focused on eliminating disparities in health, education and economic opportunity. Community engagement is a centerpiece of UIC's urban mission. Faculty, students and staff in every college work with neighborhood, foundation and government partners on a wide range of projects to improve the quality of life in metropolitan areas around the world.

A remarkable feature of UIC is the presence of seven health colleges within a single campus, ensuring a holistic approach to health and healthcare, and a global understanding of the needs of the communities we serve. Through multiple projects and programs led by the colleges of Medicine, Nursing, Pharmacy, Dentistry, Allied Health, Public Health, and Social Work, students and faculty are involved in cutting-edge research that helps redefine healthcare and reduce health disparities in our communities and around the world.

5.2.2. University of Illinois Hospital & Health Sciences System (UI Health)

[adapted from www.uic.edu]

The University of Illinois Hospital & Health Sciences System is UIC's academic medical center and the state's major public hospital. Located in the heart of the Illinois Medical District, UI Health is made up of a 495-bed hospital, Children's Hospital University of Illinois, an outpatient care center, and 13 Mile Square Health Centers located in neighborhoods throughout Chicago. Students have the opportunity to gain hands-on clinical experience in a broad range of medical specialties by caring for UI Health's diverse patient population and engaging in translational research that can help improve the lives of patients in Illinois and beyond.

5.2.3. College of Medicine

[adapted from www.medicine.uic.edu]

Recognized as one of the country's best medical schools, the University of Illinois College of Medicine is also its largest and attracts some of the best students and faculty in the country. The mission of the College of Medicine is to produce new knowledge in the medical sciences, develop best practices in health care delivery, and educate the next generation of physicians and biomedical scientists committed to serving the needs of Illinois and the nation.

One of four campuses that make up the University of Illinois College of Medicine, the Chicago campus is located in the heart of the world's largest medical district, just one mile west of the city's business center. The UIC College of Medicine is guided by the following values:
- Excellence everywhere - in research, education and clinical work.
- Collaboration with all who can advance our mission at UIC and UIUC, the medical district and other institutions world-wide.
- Diversity- in all its forms from students, to areas of research to collaborative partners- as a means to a higher quality of health care for all.
- Innovation and Translation of new knowledge and new approaches to disease and health care delivery.
- Integrity and Commitment to the people we work with as patients, research subjects, communities and our own students, faculty and staff.
- The Promise of Hope for our patients and supporters by striving toward cures for diseases that have plagued humankind for millennia.

The College of Medicine's research goals are broad and ambitious, as are the needs and hopes of our patients. We aim to advance treatment now, and health in the future, by pursuing both fundamental insights and their application to the practice of medicine. Investigators across the College of Medicine are doing cutting-edge research in clinical medicine, in basic biomedical science, and in the translation of basic findings into clinical practice and societal health. Focus areas include cancer, women's health, neurosciences, cardiac and vascular medicine, infectious disease, and obesity and diabetes.

Resources available to UIC researchers include 10 dedicated Research Centers with different focuses: Center for Alcohol Research in Epigenetics, Center for Magnetic Resonance Research, Center for Magnetic Resonance Research-3T Program, Center for Cardiovascular Research, Center for Clinical and Translational Science, Center for Structural Biology, Center for Research on Women and Gender, University of Illinois Cancer Center, Institute for Minority Health Research, and Research Resource Center.

Note: Investigators using the Research Centers are encouraged to include specific details on how these resources will contribute to the success of the proposed studies. Researchers planning on using the CCTS are encouraged to visit www.ccts.uic.edu, which provides details on their services, facilities, expertise, and resources.

5.2.4. Department of Pediatrics
[Adapted from www.chicago.medicine.uic.edu/departments___programs/departments/uic_pediatrics/]
Children's Hospital University of Illinois (CHUI) is home to an extraordinarily committed and talented group of physicians, scientists, educators, and administrators dedicated to advancing the field of

pediatric medicine. We have made remarkable progress in fulfilling our three-pronged mission: to provide comprehensive and compassionate care to all children, especially the underserved; be an acclaimed leader in moving pediatrics forward through research; and educate medical professionals and health care workers in all aspects of our field.

With over 80 physicians and investigators, the UIC Department of Pediatrics is leading the charge to advance the health and well-being of children in Chicago through outstanding healthcare and innovative programs. Our specialized pediatric divisions provide unparalleled attention to children and their families and expert care in areas including adolescent medicine, allergy/ immunology/ pulmonary and sleep, cardiology, critical care, development biology, education, endocrinology, general and developmental pediatrics, genetics, hematology/oncology, infectious diseases, neonatal-perinatal medicine, nephrology, neurology, and rheumatology.

Department of Pediatrics' physicians and investigators have been recognized and received support for their ground-breaking initiatives. In one such example, the University of Illinois Pediatrics recently received a $19.6 million federal grant to test a medical care model that focuses on poor children and young adults with chronic conditions such as asthma and diabetes. The program, called University of Illinois Check, would establish and build a "medical neighborhood" model to address the lack of access to care in medically underserved areas on the West and South sides of Chicago.

Note: **This section is intended to show how the institution, research, and/or clinical environment will contribute to the success of the project.**

It is recommended to include additional text <u>specific to proposed studies</u> and list resources expressly available to PI and co-investigators, such as information on laboratory (e.g., personnel, resources, expertise), access to patients (e.g., clinics, clinical research center), etc, as appropriate.

5.3.   Biosketch

Biosketches are the way reviewers will evaluate the qualification and expertise of the team, in the context of the project. Biosketches are required for all individuals listed in co-investigators/key personnel section of the application. NIH biosketch format was revised in 2014; template is available at http://grants.nih.gov/grants/forms/biosketch.htm. Investigators must ensure latest format is used, and that document does not exceed 5 pages, or their application may be rejected on administrative grounds (NIH screens for format compliance!).

Biosketches are divided into four sections:

A. **Personal statement:** This is an introduction of personnel to reviewing committee, it must explain why an individual is well suited for his/her role on the proposed project (training, skills, expertise, unique resources, experience). It must be customized for each proposal, and focus on the link between the individual's experience/expertise and the project. It *may* include up to 4 publications.

B. **Positions and Honors**: List of previous positions in chronological order, concluding with most recent. List honors, including membership on any Federal Government public advisory committee.

C. **Contribution to science**: This section is new to the 2014 revised biosketch. Investigators may include up to 5 separate contributions to science, each listing up to 4 publications. Research contributions may include new findings that advance field, work contributing to policies/regulations (e.g., role in committees), etc. It's OK to include non-traditional publications (e.g., articles in lay press, policies, websites, etc). Manuscripts "in press" may be listed, but work in progress (or not published) should not be included in this section. When available, include DOI, PMID, and PMCID numbers to each citation.
For investigators whose list of published work is not completely covered in this section, a link to a complete bibliography is expected. This list must be established using MyBibliography trough MyNCBI (PubMed), or SciENcv (www.ncbi.nlm.nih.gov/sciencv). Other platforms (e.g., Google Scholar) are not recommended.

D. **Research Support**: Ongoing and completed research projects. Federal and non-federal funding (including foundation grants and internal funding) may be listed.

Helpful examples of biosketches can be found at:
http://grants.nih.gov/grants/policy/faq_biosketches.htm

5.4.   NIH Form "Authentication of Key Biological and/or Chemical Resources"

(source: https://www.urmc.rochester.edu/ctsi/research-help/documents/RigorandReproducibility_final.pdf)

"Authentication of Key Biological and/or Chemical Resources" is a new form (FORMS-D) that is required for all applications that involve key biological and/or chemical resources. 1 page recommended.

Scope: Briefly describe methods to ensure the identity and validity of key biological and chemical reagents used in the proposed studies.

- What is a key biological resource?
  - Resources that might differ from lab to lab over time
  - Have qualities or qualifications that could influence the results
  - Are integral to the proposed research
  - These include, but are not limited to cell lines, specialty chemicals, antibodies and other biologics
- Briefly describe the methods you will use to authenticate your key resources.
- Information in this section must focus only on authentication/validation of key resources used in the study; all other methods and preliminary data must be included within the page limits of the research strategy

- Researchers should transparently report on what they have done to authenticate key resources, so that NIH can develop understanding of consensus approaches.
- You can use one description for multiple different resources in the same category (example: authenticating cell lines)
- Actual data demonstrating that authenticated resources exist is not necessary
- If a key resource is being made as part of the project or is under development, that should be in your research strategy, not this document.

6. Other pre-award considerations

6.1. Just in time (JIT)

All PI with NIH grant applications that received a score of 40 or less (regardless of institute's funding threshold) receive a standard request for "Just-in-Time (JIT) Information". If you have any additional questions, please contact the assigned **Grants Management Specialist** (*not* the Program Officer). Contact information for these individuals can be found in Commons (Status section).

JIT information usually requested includes:

- **Other support** information for PI, other investigators, and key personnel, as appropriate. There is no form to complete; however, following format must be followed:

NAME OF INDIVIDUAL
ACTIVE/PENDING

Project Number (Principal Investigator)	Dates of Approved/Proposed	Person Months
Source (i.e., Sponsor/Funder)	Project	(Cal/Academic/
Title of Project *(or Subproject)*	Annual Direct Costs	Summer)

The major goals of this project are…

OVERLAP *(summarized for each individual)*

- **Certifications:**
  - o IRB approval: If the proposed project involves human subjects research, the certification date of IRB review and approval must be submitted.
  - o IACUC approval: If the proposed project involves research with live vertebrate animals, the verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted.
  - o Human Subjects Education: If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted.
  - o Human Embryonic Stem Cells (hESCs): If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) should be included.
  - o SBIR Funding Agreement: For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: http://grants.nih.gov/grants/forms.htm#sbir. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.
  - o STTR Funding Agreement: For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: http://grants.nih.gov/grants/forms.htm#sbir. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

- **Other Information Requested by the Awarding IC**: NIH IC's may also request additional Just-in-Time information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animal sections of the application. These changes should be submitted as an "Other Upload" file in the eRA Commons Just-In-Time module.

Notes:
   - ✓ PIs are responsible for uploading information into eRA Commons.
   - ✓ All of the information must be submitted electronically using the Just-In-Time feature of the eRA Commons found in the Commons Status section, using the JIT box/hyperlink corresponding to application for which JIT information is being submitted.
   - ✓ All documents must be in pdf format.
   - ✓ After all information is uploaded, click Save at bottom of screen".
   - ✓ Once all information is uploaded, PI must contact ORS (awards@uic.edu), and send following information:
       - □ Subject line: JIT documents ready in commons for application # (NIH application # or UIC IP #)
       - □ Body of text: This is to notify you that the JIT documents for (NIH application #) are ready to be submitted to the NIH commons
         IRB protocol # (if applicable)
         ACC protocol # (if applicable)
       - □ Signature: PI name and contact information
   - ✓ ORS will review information, approve, and route to NIH. An automatically-generated email receipt will be sent from NOH to ORS and PI.

6.2.   Other documents that must be routed through ORS with a Proposal Approval Form (PAF)

Some other documents must be submitted to the ORS using a PAF form, even if no money is involved.

- Non-disclosure and Confidentiality agreements
- Material transfer agreements
- Memorandum of Understanding (MOU)
- Data Use Agreement
- Changes in contract involving budget
- Research Performance Progress Report (RPPR); see Chapter 2, section 4.2.2 for additional details.

Chapter 2
Post-award: implementing the proposal

By Hélène Gussin

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SCOPE

This chapter will guide investigators to navigate the post-award period, from notification of award to project close-out.

1. Overview

Congratulations! You heard from sponsor that your proposal was awarded.

During the project lifetime, a series of activities must be conducted, as summarized in Table below.

Table of events, from sponsor notification to project close-out

Phase	Activities
Awards announced	Awards announced Notification of ORS Notification of Department administrator
Award acceptance	Final negotiation Contract/agreement execution
Award set-up	Set up: • Recurring charges • Standing orders • Payroll • P-cards • Subcontracts
Research conduct	Perform research activities Administrative management (interim reports, compliance and compliance renewals, approvals) Re-budgeting (if necessary) No-cost extension (if necessary)
Close-out	Administrative and financial close-out Final progress report

Note:

Investigators may access fund activity on sponsored research awards via the PI portal link:

https://myresearch.uillinois.edu/piPortal/

2. Award announcement, negotiation, and acceptance

> **Investigators should NOT contact sponsor/funder directly to negotiate and accept award.**
>
> **All awards including amendments must be routed to ORS for processing.**
>
> **Only the Board of Trustees of the University of Illinois by the University Comptroller, Walter K. Knorr, is authorized to accept/execute agreements on behalf of UIC.**

2.1. Notification of ORS

Investigators should let Department Administrators know of award. All material announcing award (letter, fax, or email) will be forwarded to the ORS, for review. A Request for Action Form ("RFA"), stating PAF#, amount of award, and deadline, will accompany the material.

2.2. Negotiation

Following review of notification of award material, ORS will assign a negotiator to the award. Investigators will receive a notice from ORS indicating the name and contact information for their award's negotiator.

Negotiator will communicate directly with sponsor. If necessary, negotiator may request material from the investigators (e.g., conflict of interest certification, IRB approval, etc). Negotiation may also involve the legal department, especially for contracts/grants containing specific clauses regarding indemnification, confidentiality, or intellectual property.

Notes:

- Terms of agreement may be modified during the negotiation process.
- All agreements are individually tailored to a specific award.

2.3. Award acceptance

When terms of agreements are approved by the University and by sponsor/funder representatives, agreements will be routed for signature by Board of Trustees.

Agreement will be executed only when signed by the University Comptroller, Walter K. Knorr, and by sponsor/funder representatives. Signature of Principal Investigator *may* also be required.

Negotiator will notify PI when agreement is executed. A copy of executed agreement and related material will be placed in the PI portal link: https://myresearch.uillinois.edu/piPortal/.

Note:
Most sponsors/funders will <u>not</u> execute contract until they receive notice that protocol has been

approved by the Institutional review Board (IRB) for projects that involve human subjects, or by the Animal are Committee (ACC) for projects involving use of animals. Investigators should start the review and approval process early, so as not to delay award.

If protocol is not ready (e.g., instruments or outcomes not finalized, etc), investigators may seek IRB approval of the study through a "protocol development" process. Note that a complete protocol, with all pertinent forms and material (i.e., all instruments, consents, etc) will have to be submitted and approved by the IRB prior to conducting any research activities, including focus groups.

3. Award set-up

3.1. NOA

As described above, after awards are announced, contract and budget material are reviewed by a contract negotiator. Upon execution, contracts get routed to OBFS, which will generate a "Notice of Banner Codes Assignment". This notice ("NOA") is sent to the PI and to the department grant administrator, and includes:

- KC Award Number   (e.g., 012345)
- KC Proposal Number and PAF Number)   (e.g., PAF# 2016-04321, IP# 00102030)
- Short Title and Project Title
- Dates of projects and budget
- Principal Investigator
- Department Name
- Banner Grant Code (e.g., G3456)
- Fund Code (e.g., 554433)
- Organization Code: 905000 (for Pediatrics)
- Program Code (e.g., 191100)
- Index Code (e.g., G34561)
- Award amounts: Direct Cost, Indirect (F&A) Cost (rate and $), Tuition Remission (rate and $), Total
- Additional Notes, if appropriate
- Name and phone number of Assigned Specialist

3.2. Anticipation account

If there is a lag in contract execution, generation of a NOA, or if activities must start prior to the establishment of an account (e.g., a check is received and we need to make a deposit), an anticipation account may need to be open.

Department administrator will apply for establishment of an anticipation account. Principal Investigator will receive a confirmation and request for approval.

When anticipation account is established, PI and Department Administrator will receive an Anticipation NOA, containing element described above.

Note
When a permanent account is established, the temporary anticipation account will automatically roll into it; Banner codes will remain unchanged.

3.3.   Allocation of expenses

After account is established, expenses will have to be allocated to correct FOAPAL.

PI must make sure to only make charges that are included in approved budget.

3.3.1.   Payroll encumbrances

Salary distribution will be set-up by Department administrators and HR office.

PI are encouraged to review the funded budget, and confirm name, function, % effort, $ amount, and service dates for all project personnel. Make sure to let Department administrators know of any changes.

3.3.2.   Supplies and other non-personnel expenses

PIs should charge supplies/other non-personnel expenses to the appropriate FOAPAL, as budgeted. Note that some sponsors are very strict about matching expenses and budget (e.g., PCORI), and will require formal contract modification if expected and actual expenses differ.

P-cards

"Purchase cards" or "P-cards" are set up for a specific award, for small dollar purchases of supplies and small equipment (limit: $4,999/transaction; maximum monthly cycle limit: $25,000). It is a University paid, University liability Mastercard™.

They are delivered through accounting to PI and a limited number of project staff. Small purchases made for the related award may be charged to the P-card. It is strictly prohibited to place a P-Card account number on file with any vendor.

Notes

- Several expenses are not allowed, such as travel expenses, cash advances, some chemicals, drugs and pharmaceuticals, animals, and uniforms (including safety shoes) (full list available in Department's grant office and Section 7.6 of the OBFS BFPP).
- The University of Illinois is granted a governmental exemption from sales and use taxes on purchases for University use. When placing orders, cardholder should always inform the vendor the purchase is made on behalf of the University of Illinois, which has a tax-exempt status. Tax Exemption Forms may be required and can be found on Section 18.12 of the OBFS BFPP.
- Purchases are tracked by accessing the P-Card Web Solution™ (https://pcards.apps.uillinois.edu). Cardholders or a delegate must obtain an original, itemized receipt for each purchase and enter the detailed purchase information in an order log. The University business purpose of each purchase must be documented.
- The Reconciler for the unit will match the information on the original receipt with the order log and with the transaction the Bank submits electronically into the software. This process allows units to monitor purchases, keep records, and create reports. The purchase information is

posted in Banner for accounting purposes. Reconcilers must process (reconcile) transactions within 7 days of receiving the bank records and must ensure receipts are filed as directed by the department's business office and retained for five years plus current fiscal year.

Standing/purchase orders

Standing/purchase orders will be set-up through accounting.

For purchases over $4,999.99, P-cards cannot be used, and a purchase order must be processed via iBuy (set-up through accounting). iBuy is an online marketplace for purchasing goods and services at the University of Illinois. Banner must be used for any non-conforming purchases. Non-conforming purchases arise when there is no formal agreement (Purchase Order, Contract) prior to the goods or services being provided.

Recurring charges

Recurring charges (e.g., BRL, telecommunications) will be set-up by division administrator through accounting.

Travel expenses

P-Cards may not be used for employee travel expenses. Such travel expenses must be reimbursed on an Employee Travel/Miscellaneous Reimbursement Form available at: https://www.obfs.uillinois.edu/.

If available, a University Travel card ("T-card") may also be used for travel expenses, such as plane tickets, hotel lodging, taxi cabs (but not meal purchases, except if hosting an allowable business meal, as specified in https://www.obfs.uillinois.edu/bfpp/section-8-payments-reimbursements/determine-allowability-business-meals-refreshments). If the T-card holder is not going to be traveling, holder needs to pre-arrange use of T-card with hotel (ask hotel for a "credit card pre-authorization"). Note that only room + taxes may be charged (i.e., no room service, minibar, movies, etc.).

Travel arrangements may be made through Corporate Travel Planners and its iTravel Online booking tool (registration at https://www.concursolutions.com/registration/register_form.asp?regcode=UIL156718).

Per diem is a daily allowance for meal expenses while in travel status that includes an overnight stay. Per diem is not given for same day travel. Receipts are not required to receive this per diem allowance. Per-diem reimbursement have the following limitations:

1. May not exceed per-diem allowances for in-state or out-of-state travel ($28 and $32 per day, respectively, as of July 2016). Updated allowances can be found at https://www.obfs.uillinois.edu/travel/reimbursement-rates/meal-per-diem-reimbursement-domestic-travel/.
2. Covers meals during travel status only, expressed as quarters (for each day, quarter 1: 12:01 am to 6am; quarter 2: 6am-12pm, quarter 2: 12:01pm-6pm; quarter 4: 6:01pm-12midnight)

3. If a meal is provided or otherwise expensed (e.g., meal provided during a conference, business meal, etc), per-diem should not be requested for this meal.

Honoraria/Consultants/Vendors

Investigators must inform Department administrators that services will be provided at least 3-4 weeks prior to service, to allow for proper process. Not doing so may prevent vendor from being paid.

Vendors must be registered in Banner as UI vendors prior to service/good being provided. Investigators must provide Department administrators with name and contact information of vendors. Administrators will contact vendors and request necessary documentation for Banner registration.

Based on amount and nature of services provided, payment mechanisms will differ.

- **Honorarium Payments**: An honorarium is a one-time payment of $5,000 or less, made to an individual who is not an employee of the University for a special and non-recurring activity or event for which no remuneration is collectible by law. Honoraria are typically paid to persons of scholarly or professional standing with the intent of showing appreciation for participation in University educational, research, or public service activities. If payment is negotiated and agreed upon, this is considered a contractual agreement, and should be processed as a payment for professional services, not as an honorarium.
- **Consultants**: Only individuals who are NOT current or retired University employees may serve as consultants. Federal/State employees may serve as consultants, if activities have been approved with their institution. Consultant agreement are considered as contractual agreement, and should be processed for professional services.
    - For services totaling less than $10,000/year: a "Contract for professional and Artistic services under $10,000" must be completed and processed. Vendor will need to invoice University for their services.
    - For services totaling more than $10,000/year, a "Contract Approval/Routing Form" (CARF) form and "Contract for Procurement of Services" must be completed and processed.

Participant stipends/gift cards

Important considerations:
1. Investigators should NOT use personal funds to pay research subjects. Reimbursement is not guaranteed and will require lots of documentation.
2. For one-time payments of less than $100, investigators may want to use a cash advance, or a gift card purchased through a program advance (see below).
3. Threshold for IRS-1099 reporting is $600/tax year. This amount is cumulative for the institution. For example, if subjects participate in a study at UIC and receives $150, and a study at UI-Rockford and receives $500, the University of Illinois has the obligation to generate a misc. 1099 tax form for this individual.

4. If study subject (including focus group) receive (1) payment of more than $100 at a time, *or* (2) more than $600 per calendar year for their participation, they must be registered in Banner as UI vendors, and will receive a check for reimbursement of their time.
5. Any cash/gift card payments to foreign nationals who are non-resident aliens are prohibited (regardless of how small the amount is), per IRS regulations. If investigator/study staff becomes aware of the non-resident alien status of a participant, it must be reported (for tax purposes).

Program (cash) advances

Overview and general considerations:

A program advance may be used when a unit needs to pay for a one-time event or program activity and it is not practical to use other payment methods. Program advances may not be used for travel-related expenses.

Cash or all forms of gift cards used to pay human subjects must be obtained or purchased using a program advance issued in the name of the faculty or staff member responsible for the program.

An employee can have only one outstanding program advance at any given time.

- Cash advances are processed through Payables.
- Note that a lead time (3-4 days) is required to process. Emergency requests/exceptions will be considered in exceptional circumstances.
- Custodian (payee) is *personally* responsible for the safe keeping and repayment of the advance. Lost or stolen advances cannot be replaced using any type of University fund. Careful storage and tracking of cash and/or gift cards (e.g., tracking log, keeping receipts, etc.) are highly recommended. Quarterly (or more often) reconciliation and replenishment (if needed) are recommended.

To open a program advance:
(see https://www.obfs.uillinois.edu/common/pages/DisplayFile.aspx?itemId=94864 for details):

1. Estimate how much money you will need for the first 60 days of study. Allow at least 2 business days for processing. If the program involves travel, use the T-Card (Travel Card) to pay for the travel portion. Obtain a program advance for all non-travel expenses.
2. Log in to TEM (Travel and Expense Management System). In the Create New area, select the Expense Report icon. If you need help identifying the icon, consult the job aid for System NavigationLink opens PDF file. In the Document Header screen, begin your Report Title with "ADV" so University Payables (UPAY) can expedite processing. Select "Advances" from the drop-down list in the Purpose field.
3. In the Document Header screen, select where you want to pick up the money from the drop-down list in the Special Handling field. Enter the expense report number (for example, ER00001234) in the Vendor Invoice #/Ref# field.
4. Proceed through the screens.

5. UPAY reviews the request and processes for payment. Payees will be notified at their University e-mail address when the payment is deposited to their payroll bank account. Alternatively, for cash advances, University Student Financial Services & Cashier Operations (USFSCO) will notify the Program Advance owner when the check will be ready for the payee to pick up, sign for, and cash the check. The check can be cashed at the Cashier's Office or another financial institution.

Management and closing

- To replenish a program advance, an Expense Report (ER https://www.obfs.uillinois.edu/common/pages/DisplayFile.aspx?itemId=94835) must be created by the Program Advance owner, or their Proxy, using the Purpose Employee Misc Expense Reimbursement. University Student Financial Services & Cashier Operations (USFSCO) will notify the Program Advance owner when the check will be ready for the payee to pick up, sign for, and cash the check. The check can be cashed at the Cashier's Office or another financial institution. Details at https://www.obfs.uillinois.edu/common/pages/DisplayFile.aspx?itemId=94876.
- Advances may not have to be closed every 6 months. They can be continued **if** (1) study is on-going, and (2) same custodian remains in charge. PI must confirm with Payables to ensure cash advance is extended.
- Program advances must be promptly closed (that is, accounted for, cleared, or repaid) upon completion of the event or program for which the advance was issued. Program advances not closed with 60 days of the event or program may be reported as taxable income to the employee in accordance with IRS regulations. Program advances not close within 90 days may be deducted from the employee's wages.
  If there is cash to be returned: Return the cash or check to your campus University Student Financial Services and Cashier Operations (USFSCO) along with a completed Travel or Program Advance Closure Form. Advise the cashier that you're closing a program advance. Keep the deposit receipt to submit in TEM (Travel and Expense Management System). Do not send cash or checks directly to University Payables (UPAY).
  Form available at https://www.obfs.uillinois.edu/common/pages/DisplayFile.aspx?itemId=94783

3.3.3. Subawards

Subaward agreements must be set up through department administration, using the ORS "Subcontract package", that includes subaward contact information (sub-PI and administrators), budget and SOW.

> **Subcontracts must be processed by ORS through a negotiator, and approved by The Board of Trustees of the University of Illinois Comptroller (Walter K. Knorr).**

Note:

Subcontractors may have their own subcontractors/subawardees. These must be reflected in budget, and their F&A costs included per subcontractor's policy.

4. Performance of Research

In most cases, investigators and their team receive an award to conduct research activities investigating the specific hypothesis(es) proposed in application, by following the methods described in the application. It is expected that the award will be applied to fund the activities stated in application.

Note:

If milestones/deliverables were set in the project submission or contract, investigators must be mindful to meet them. Some sponsors, such as PCORI, award contracts with specific milestones and reserve the right to suspend or cancel funding if milestones are not met to their satisfaction.

4.1. Administrative management
(adapted from obfs)

Administrative management of the award includes financial oversight and compliance.

4.1.1. Financial management
Activities include:

- Charge sponsored awards appropriately
- Monitor expenditures
- Transfer costs when necessary & appropriate
- Request budget adjustments when needed
- Resolve overdrafts
- Know the carryover terms of the award
- Prepare for additional work or funding

4.1.2. Compliance
When the institution accepts an award, we:

- Agree to adhere to all of the terms, conditions and guidelines.
- Have a fiduciary responsibility to spend the money in a reasonable and responsible manner.
- Must demonstrate adherence to the key cost principle (Reasonable, Allowable, Allocable, Consistent) for treatment of all costs.

Compliance is the adherence to policies of the university, sponsor, and federal regulations.

Being Compliant involves effective management of funds, evidence of proper internal controls to safeguard funds & property (e.g., tracking and documentation of all activities, especially cost shared

obligations and expenditures and supporting documentation for reports/bills prepared by department), and avoidance of fraud and institutional mismanagement of funds.

Principal Investigators:
Are accountable for the scientific and/or technical aspects and scientific conduct of the sponsored award.

- Oversee day-to-day management of the project's activities.
- Make budget allocation decisions.
- Are aware of expenditures charged to the sponsored award.
- Provide the required deliverables.

Business Managers:

- Understand the compliance requirements.
    - OBFS Policies and Procedures
    - OMB Circulars A-21, A-110, and A-133
    - Terms and conditions of awards
- Identify questionable transactions/prevent problems.
- Record transactions appropriately.
- Implement and adhere to internal controls.
- Assure complete and accurate recordkeeping.
- Protect the Principal Investigator (PI) and University.
- Contact GCO for any external sponsored award audits.
- Stay abreast of policy and regulation changes.

4.2.   Progress reports

Regular, periodic progress reports are required by most sponsors to evaluate project progress. Form and content vary, based on sponsor.

4.2.1. PCORI

Contractually, PCORI requests Principal Investigator to submit biannual reports, using Interim Progress Report template (http://www.pcori.org/funding-opportunities/awardee-resources). Note that report templates change often, and make sure latest version is used. The interim progress reports must be reviewed and signed by University Official, but will be submitted to PCORI by Principal Investigator.

Practically, the PI will prepare the full report. About a week prior to milestone, complete report will be printed, signed by PI, and brought to ORS with a "Request For Action" (RFA) form. When report has been endorsed by institution official, the PI will submit a full copy in pdf form (one file including signature page and appendices) to fundedpfa@pcori.org. Receipt will be acknowledged by PCORI.

The Program Officer will review report, and send additional questions, and/or organize a follow-up performance review with the PI.

4.2.2.   NIH: the Research Performance Progress Report (RPPR)

NIH is currently utilizing the Research Performance Progress Report (RPPR) functionality in the NIH Commons, which allows for the electronic submission of NIH Type 5 progress reports. PIs prepare and upload documents into Commons; ORS reviews, approves, and officially submits RPPR.

A PAF, one (1) copy of the "DRAFT" RPPR report and a detailed budget that matches the next year's total funding in the latest Notice of Award, is required prior to submission of the RPPR report to NIH.

Instructions (from ORS website)
1. Log in to eRA Commons.
2. Select **Status** from the top menu, then select List of Applications/Grants to find the grant number and select **RPPR** in the Action column on the right. Or select **RPPR** in the top menu and select the appropriate grant number in the *Manage RPPR* screen.
3. Select **Initiate** to begin the RPPR report.
4. Complete the RPPR report following the detailed instructions. As you move through the report sections, once files are uploaded or text boxes are completed be sure to press **SAVE** before moving on to the next section.

Please note, in Section A – Cover page, the following fields should be completed as follows: **For Administrative Official – select Mitra Dutta For Signing Official – select Mitra Dutta Please Note:** · Institutional information in this section is completed by ORS and is not editable. · If this section is not filled out correctly, the RPPR will be returned for correction and may cause delay in submission to NIH.

5. Once the report is complete select **Check for Errors**. Errors or Warnings will appear in *Manage RPPR* screen. Errors must be corrected in order for the report to be submitted to NIH. Warnings may appear but will not impact submission of the report to NIH. Any error or warning that appears to be a glitch in the eRA system, please contact the Commons Helpdesk directly. The Helpdesk contact information is found at the top of the screen.

6. When you are ready to submit the RPPR, select **Route**. The user's name, grantee institution and grant number will be displayed. For *Next Reviewer*, select **Dutta, Mitra (SO)** and include any necessary comments. Click **Submit**.

Please Note: If **Dutta, Mitra** is not selected, the RPPR will be routed incorrectly and ORS will not be able to access it causing a delay in submission.
7. Select **View** to open the compiled pdf copy of the RPPR report. Print one (1) copy of the "DRAFT" report and submit it to ORS, along with a PAF and a detailed budget that matches the Notice of Award amount for the next budget period. **Please be reminded the RPPR application will not be submitted to NIH without internal submission of the PAF to ORS.**

4.2.3. Other sponsors/funders

Investigators must check with their funding agency/sponsor to determine progress report requirements, including (1) content (financial information? Narrative? Bibliography?); (2) format; (3) role of PI and institutional official in preparing and submitting report.

4.3. Other considerations

4.3.1. Re-budgeting

Occasionally, sponsored funds may need to be reallocated, or moved from one budget category to another. These changes cannot increase or decrease the total budget. Some changes may also require prior approval by the sponsor; these will be described in the contract/award document.

The "Institutional / Organizational Prior Approval Systems (IPAS/OPAS)"form is used to request a budget reallocation. If no prior approval is required, send the completed IPAS/OPAS forms via email to the Assistant Director for Compliance.

For changes requiring prior approval, contact the Office of Research (ORS), who will assist in communicating with the sponsor to obtain approval.

4.3.2. "JV" transfer

A cost transfer occurs when expenditures charged on a particular C-FOAP are moved to another C-FOAP. A "Journal Voucher" (JV) transfer will be prepared by accounting, in collaboration with Department Administrators and PI. The following information is required:

1- Original account: $ amount, transaction doc number(s), posting date(s) for the charge(s)
2- Account to be charged to: grant code and fund number
3- Why the expenditures were charged to the incorrect CFOAP, the benefit or the reasoning for it being transferred to another CFOAP
4- If appropriate: why it is being requested 90 calendar days after the original transaction date, and what corrective action has been taken by the unit to eliminate the need for cost transfers over 90 calendar days.

If request is made more than 90 days after original charge, PI will need to sign JV request form (GC-81). Accounting will process with OBSF.

4.3.3. No-cost extension and Continuations, Renewals, and Supplements
(from obfs)

No-Cost Extensions: If the project will not be completed by the end date, a no-cost extension may be requested through the Office of Research Services (ORS). For eligible Federal awards, UIC has the authority to grant one-time extensions of up to 12 months when appropriate. Requests must be submitted with sufficient time to be processed before the project end date (e.g. a minimum of 30 days).

Continuations, Renewals, and Supplements: As soon as it is known that additional funding for the project will be requested or received, a new PAF should be submitted to the ORS. As with new awards, ORS sends a Notice of Executed Award (i.e. congratulatory letter) to the PI, department, and the Office of Grants & Contracts when an award has been fully executed. Awards are generally set up in Banner within 10 business days of this notice being received by Grants & Contracts. Additional funds cannot be set up in Banner until this notice is received from ORS.

4.3.4. Grant transfer to/from another institution

(from ORS)

Grants are awarded to institutions, not individuals. Therefore, the relinquishing institution must agree to transfer awards if/when its PI moves to another institution. One of the services provided by ORS includes assistance in transferring grants to UIC from other institutions (when a new PI is arriving at UIC) or from UIC to other institutions or entities (when a PI is leaving UIC). In all cases, it is recommended that a PI and his/her departmental administrator begin the formal process of requesting the transfer of your grant at least sixty days in advance of your move to the new institution. The timing of your transfer request can have significant implications. Also, the awarding agency must approve all grant transfers from one organization to another. Rules and regulations on grant transfers vary widely from funding agency to funding agency.

A "Request for PI Award Transfer/Relinquishment" form must be completed and submitted to ORS along with any applicable agency specific transfer form(s).

Do you have an NIH grant to transfer?

When an investigator transfers and requests continued support for a previously approved project at a new location, the NIH requires that a transfer application be submitted through the new institution. This application will receive an administrative review by grants management and program staff to determine if the transfer is appropriate and to determine the level of NIH funding. The decision to authorize transfer of the grant will be based upon the following criteria:

- the project has been relinquished by the original institution;

- the facilities and resources at the new location allow for the successful performance of the project; and

- the investigator plans no significant changes in research objectives and level of expenditures from those described in the previously approved project. If the proposed change of institution does not meet these criteria, competitive review will be required.

NOTE: It is recommended that the PI contact the Program Official to discuss the feasibility of the move; the Program Official will then review the request approve or disapprove the scientific information on the new application.

From the Original Grantee Institution, please submit:

1. Relinquishing Statement - A transfer application will not be processed until this form, signed by the proper institutional officials, has been received by the National Institute of Health (NIH). This form provides the effective date of relinquishment, estimated unexpended Direct Costs and Facilities and Administrative (F&A) Costs balances from the current budget period (carry-over of funds from previous budget periods should not be included in these amounts), and lists any transfer of equipment of an acquisition cost of $5,000 or more.

2. Final Invention Statement

3. Final Financial Report – Must be submitted within 90 days following the relinquishing date of the project. Financial reports are prepared and submitted to the sponsor by the Grants and Contracts Office.

From the New Institution, please submit:

1. Application face page (PHS Form 398).

2. A progress report for the current year, including a statement regarding the goals of the upcoming year. This is required for anniversary transfers and is strongly encouraged for mid-year transfers.

3. A statement concerning the current research plan and an indication of whether the original plan has changed. If changed, appropriate details should be provided.

4. If the application involves Multiple Principal Investigators, include a revised Multiple PD/PI leadership plan indicating how the transfer will affect the governance and organization of the leadership team.

5. A resources page including a description of the facilities at the new institution and the probable effect of the move on the project.

6. Budget pages. If the grant is transferring in the middle of a budget period, a partial year direct cost budget, at the relinquished direct cost level is required. For grants transferring on their anniversary date, a full year budget, at the committed direct cost level is required. Future year budget pages should also be provided at the committed direct cost level. For modular grants, only narrative budget information, including total direct costs and F&A costs is required.

   1. Important to Note: Generally, the negotiated F&A cost rate for the new institution will be applied to the direct costs for the grant, regardless if the rate is higher or lower than that of the old institution. If there are major increases in F&A costs in the current grant year, increases in the award will be contingent upon availability of funds. Future year F&A costs will be provided at the appropriate negotiated rate.

7. Updated biographical sketches for new key personnel.

8. Updated other support pages for all key personnel, if applicable.

9. A checklist page. Be sure to indicate the application type as "Change of Grantee Institution and provide the NIH Grant number.

10. Human and Animal Assurances and IRB and IACUC approval dates, if applicable.

11. Human subjects' education certification for key personnel, if applicable.

12. A list of equipment, as presented on the old institution's Relinquishing Statement, to be transferred. Such a listing in the application represents acceptance of title to the transferred equipment.

Non-Modular/Categorical Grant Award:

- ***Mid-year Transfer***: Please submit a detailed budget for the transfer budget period and include a budget for future year commitments if applicable. (Note: The transfer budget (DC + F&A) should not exceed the Total Costs relinquished from the previous institution).

- ***Anniversary Date Transfer***: Please submit a detailed 12-month budget for the noncompeting budget period and include future year commitments if applicable. (Note: Future year commitments should be based on the previously established Direct Cost levels).

Modular Grant Award:

- ***Mid-year Transfer***: Please submit a modular budget for the transfer budget period and include a budget for future year commitments if applicable.

- ***Anniversary Date Transfer***: Please submit a modular budget for the noncompeting budget period and include future year commitments if applicable. (*Note: Future year commitments should be based on the previously established Direct Cost levels*).
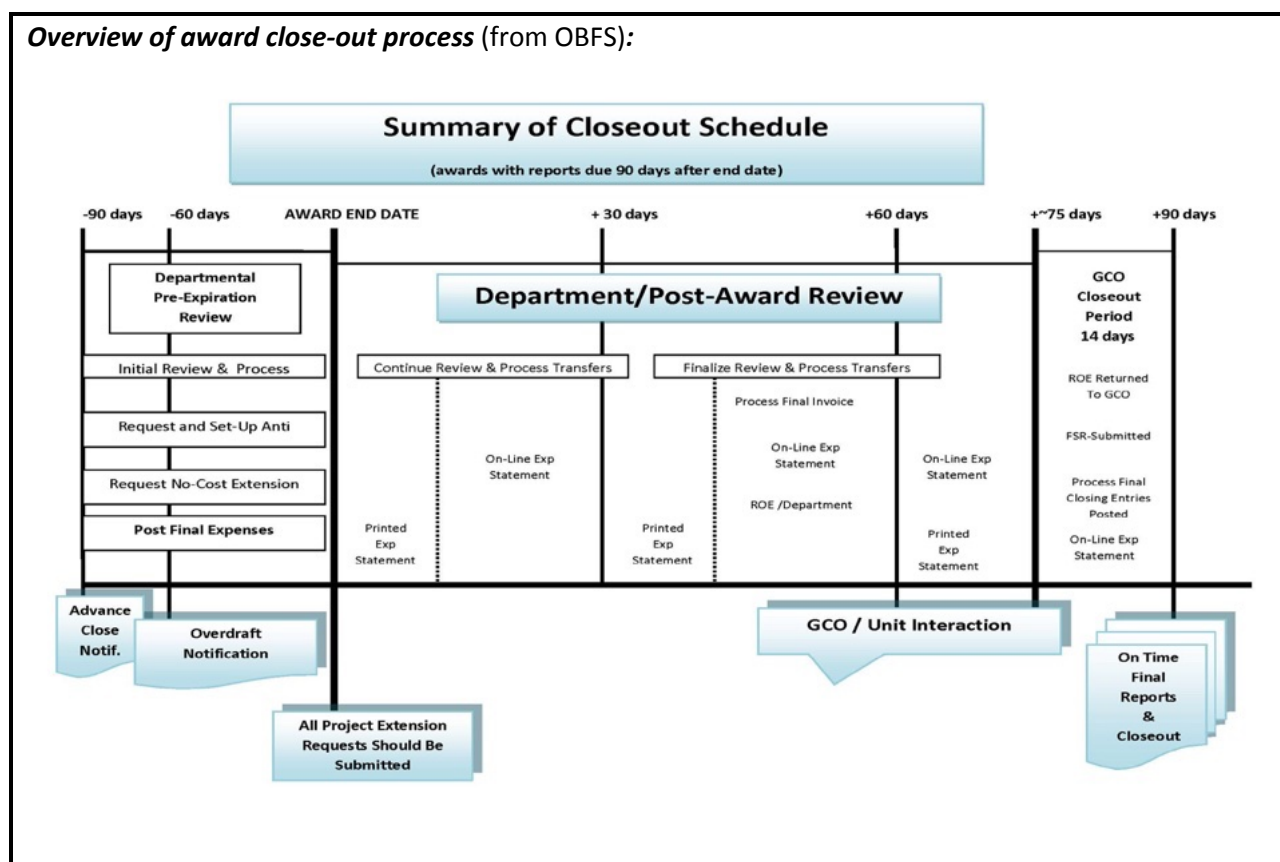
5. Close out

5.1.   Financial and administrative activities

Closeout requires balancing the budget, expenditures, billings and payments. This may entail removing an overdraft or refunding unspent amounts to the sponsor.

Specific requirements vary by sponsor; details are contained in your contract/award document. The award document will indicate if the sponsor requires a final invoice, a final project or financial report, and instructions for the disposition of an unspent balance.

Sponsored project closeout is the shared responsibility of principal investigator (PI), unit business office or department administrator, and central offices. Collectively, they are responsible for the closeout of expired awards no later than 90 days after the project end date.

Overview of award close-out process (from OBFS)*:*

5.1.1.   Closeout Responsibilities

(From https://www.obfs.uillinois.edu/common/pages/DisplayFile.aspx?itemId=96382 and https://www.obfs.uillinois.edu/bfpp/section-16-grants-research-contracts/sponsored-project-closeout/closeout-documents-responsibilities)

PI Responsibilities

The PI provides technical reports and/or deliverables to the sponsor within the specified time frame, or obtains the necessary extension. A copy of the report transmittal letter is to be sent to the Grants & Sponsored Projects Office.

The PI must disclose inventions in accordance with University regulations and as required by sponsor.

Unit Responsibilities

A computer-generated Notice of Terminating Accounts is sent to units 90 days before the expiration of a sponsored project. Units must inform the Grants & Sponsored Projects Office if they have information about continuation or renewal of a project. If not, the close-out procedures begin with the expiration date of the project. Generally, projects are to be closed within 90 days of expiration.

The unit responsible for the project is asked to provide the following information when it is applicable to the project:

- Status of the final technical report
- A listing of invention disclosures, or an indication that there were none
- Final subaward invoice voucher(s) signed by an appropriate departmental representative
- Final inventory of federally-titled equipment, if any
- For Federal non-research projects only, an accounting of unused expendable supplies (including expensed equipment) with an aggregate value of $5,000 or more
- An indication that all the charges to the project have been recorded or a listing of any pending and obligated costs
- Program income reports

The unit is also responsible for clearing cost overruns within 90 days after the project has terminated. The write-off of overruns remaining at termination of federally sponsored projects to appropriate institutional funds must be identifiable in the financial accounting records.

A cost overrun is the excess of expenditures over funding for a given project after:

- All corrections are made,
- All unallowable costs are removed, and
- All costs (except final report costs) incurred after the project termination date are removed

For a full description of the Cost Transfer policy, see Section 16: Grants and Research Contracts - Cost Transfers.

Grants & Sponsored Projects Office Responsibilities

The Grants & Sponsored Projects Office is responsible for assuring that all the University's obligations for the project have been met. This responsibility is fulfilled by coordinating with the units and principal investigators to provide the necessary reports and other documentation. In the case of projects with subawards, the Grants & Sponsored Projects Office ensures that subrecipients have submitted a final billing, and that it has been paid. The following final close-out documents are submitted to the sponsor, as required:

- Final billing and/or expenditure report
- Patent report
- Equipment report
- Release and assignment forms

The Grants & Sponsored Projects Office then closes general and subsidiary ledger accounts, and deobligates any unused balances, and returns funds to sponsor for all cost reimbursable awards.

Summary of close-out responsibilities (from OBFS):

Principal Investigator's Responsibility	Deliverables
Review Award Expenditures	Financial Report
Review and Approve Sub-recipient Reports	Final Technical Report
Finalize all related forms and reports	Technical Report Invention Report Patent Report Effort Report

Unit Financial Manager's Responsibility	Deliverable/ Implication
Confirm with funding agency that project is indeed ending	Timely closeout
Review award expenditures (over the life of project and at closeout)	Financial Report
Remit final payment to sub-awardees	Financial Report
Receive Final Invoice from Sub-awardees and remit payment	Final Invoice to prime agency and Financial Report
Reconcile grant fund – ensure costs are allowable, allocable, reasonable and consistent with the terms of agreement	Financial Report
Resolve overdrafts	Final Invoice and Financial Report
Review who has spending authority and notify individuals to stop processing charges to the project	Collect P-cards Close recurring charges (such as BRL or telecom) Close standing orders (for example, POs for lab supplies) Close or transfer payroll encumbrances
Provide cost share report	Final Invoice/report

Office of Grants & Contracts' Responsibility	Deliverable/ Implication
Send final invoice to sponsors/funding agencies	Cash receipt
Prepare and submit financial status report	Meet Compliance
Return unexpended balance per final report	Refund check
Prepare supporting forms and reports	Property Report Contractor's release form
Close sub-award/consultant encumbrances	Terminate grant/fund
Prepare and process closing entries	Terminate grant/fund

5.1.2. Sponsored Project Closeout Checklist
(from OBFS)

Changes that need to be processed	Complete
HR appointments have been changed	☐
Purchase Orders have been closed or changed	☐
Service units have been notified about change of C-FOAP	☐
P-card default C-FOAP have been changed	☐
Users have been notified that project has ended	☐

Expenses related to the project	Complete
All project-related expenses have been posted	☐
All unallowable late charges and excess costs have been removed	☐
All lump-sum advances have been cleared	☐
All sub-recipients' final invoices have been paid	☐
All encumbrances have been closed or removed	☐
All facilities and administrative costs and tuition remission costs have been assessed	☐
All adjusting journal entries have been posted	☐

Revenue related to the project	Complete
All payments have been received from sponsor	☐
All cost-share funding has been properly recorded	☐
All technical reporting requirements have been met	☐
All financial reporting requirements have been met	☐

For more University Policies and Procedures, see Appendix 1 "Closing a sponsored Project"

5.2.   Invention statement and certification

For all NIH awards, a **Final Invention Statement and Certification** (Form HHS 568) shall be executed and submitted <u>within 90 days</u> following the expiration or termination of a grant or award. The Statement shall include all inventions which were conceived or first actually reduced to practice during the course of work under the grant or award, from the original effective date of support through the date of completion or termination. The Statement shall include any inventions reported previously for the grant or award as part of a non-competing application. This reporting requirement is applicable to grants and awards by Department of Health and Human Services in support of research.

Form is available at: http://grants.nih.gov/grants/hhs568.pdf

This form ***must*** be signed by an official authorized to sign on behalf of the institution.

5.3.   Final progress report

Final progress reports are mandated by almost all sponsors/funders. In general, a final progress report is required for any grant that is terminated and any award that will not be extended through award of a new competitive segment from the same sponsor/funder. However, requirements for the contents of the final progress report vary, based on sponsor.

5.3.1. PCORI

The Patient-Centered Outcomes research Institute (PCORI) requests that awardees complete the detailed template **final progress report** (found at http://www.pcori.org/funding-opportunities/awardee-resources) by end date of contract.

In addition, PCORI Awardees should submit to PCORI for peer review a draft **final research report** after awardees have ensured results are submitted to ClinicalTrials.gov for applicable studies. The due date for peer review submission may not exceed 13 months from the primary completion date of the study. This report must provide the methodological details, describe the main study results, and interpret the findings for clinical or other decisional contexts. This report will be peer-reviewed. Awardees are expected to address the recommended revisions generated by the peer review process after which PCORI will accept the draft final research report.

5.3.2. NIH

The report is due within 120 days of the end of the project period. All grantees are strongly encouraged to submit the final progress report electronically through the eRA Commons.

There is no form page for the final progress report. At the top of the first page provide the grant number, project title, name of grantee organization, project period (start and end dates), name of the PD/PI, and clearly indicate "Final Progress Report."

The final progress report should include a summary of progress made toward the achievement of the originally stated aims, a list of significant results (positive or negative), and a list of publications. Grantees should also report additional information required by the awarding IC in program-specific final progress report instructions. The final progress report also should address the following when applicable:

1. Report on the final enrollment data for study subjects based on sex/gender, race, and ethnicity (use the PHS Inclusion Enrollment Report).

2. If appropriate, indicate whether children were involved in the study or how the study was relevant for conditions affecting children (see Public Policy Requirements and Objectives—Inclusion of Children as Subjects in Clinical Research).

3. Describe any data, research materials (such as cell lines, DNA probes, animal models), protocols, software, or other information resulting from the research that is available to be shared with other investigators and how it may be accessed. If the initial research plan addressed, or the terms of award

require, a formal plan for sharing final research data, model organisms, Genome Wide Association Studies data, or other such project-specific data, provide a final statement on the implementation of that plan.

4. Publications that were authored or co-authored by the PD/PI and arose from the award must include the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these Journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

5. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the final progress report.

Note:

If a competitive renewal (Type 2) application has been submitted, whether funded or not, the progress report contained in that application may serve in lieu of a separate final progress report at the discretion of the funding Institute/Center (IC).

To submit NIH Closeout documents via eRA Commons*: (from OVCR)*

1. The PI must log into Commons.

2. Click on the word STATUS in the blue toolbar across the upper part of the screen.

3. Once in STATUS screen, click on the 'List of Applications/Grants' hyperlink.

4. Locate the appropriate grant for closeout under the Application ID column on the left side. Once located, click on 'Requires Closeout' hyperlink in the corresponding right-hand column labeled ACTION.

5. In CLOSEOUT STATUS screen, click on:

   a.'Process Final Progress Report' in the ACTION column to upload the progress report file. Once final version is uploaded, press SUBMIT. Once it is submitted, NIH will be able to access it directly in Commons.

   b.'Process Final Invention Statement' in the ACTION column to complete the final invention statement. Press YES if inventions have been reported. Fill in all required fields and press SAVE. Or, press NO if no inventions have been reported on the project.

Once the Final Invention statement is completed and saved in Commons, ORS will receive an email from the Commons system that the Final Invention Statement is ready for review.

ORS will verify the statement's accuracy with the Office of Technology Management. If the submitted information in Commons does not match OTM's records, this will be communicated to the PI and business manager as further discussion or revisions may be required at OTM. If the information does match OTM's records, ORS will press SUBMIT in Commons. Once it is submitted, NIH will have access to the statement.

Please note, if the closeout link is unavailable in Commons, please contact the Commons Helpdesk for assistance.

5.3.3. Other sponsors/funders

Principal Investigators are encourage to contact the study sponsor/funder at least 90 days prior to the end of the project period to obtain guidance regarding material to be submitted at project close-out.

5.4.   Termination Notice (PHS 416-7)

This form is required for Fellowships and Training grants. It summarizes the information that must be supplied by Ruth L. Kirschstein National Research Service Award (NRSA) recipients on termination of their award and for a limited period thereafter. It must be submitted within 90 days of the fellow or trainee's appointment. This form may also be used to document the termination of appointments to non-NRSA institutional research training programs (e.g., T15), research education awards (e.g., R25), and institutional career development awards (e.g., K12).

Investigator Guide. UIC Department of Pediatrics, v.1.2, 5/19/2017

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Chapter 3
Institutional Review Board (IRB) and Human Research Compliance

By Hélène Gussin

In collaboration with Susanne Feret

[adapted from http://research.uic.edu/irb/]

SCOPE

This chapter will guide investigators to navigate the IRB process to initiate and maintain compliance with human research requirements.

1. Overview

All research activities that include humans must be reviewed and approved by the IRB, receive an exemption determination, or receive a determination of not human subjects research from the OPRS/IRB. An investigator must receive a written approval, exemption determination, or not human subjects determination prior to starting the research. This process is designed to ensure that during the conduct of the research the rights and welfare of human subjects are protected (minimizing risks, selecting subjects equitably without coercion, obtaining informed consent, ensuring privacy and confidentiality).

IRB approval is valid for a maximum of one year. Based upon the risk of the research or the inclusion of a particularly vulnerable population, the IRB may determine that a shorter approval period is appropriate. If the research is to continue beyond the current approval period, the investigator must submit a progress report (Continuing Review) for the IRB to review and approve prior to expiration. IRB approval for research must be maintained until all research activities are completed (data analysis, the final paper is accepted for publication, or the study site is closed).

An investigator must obtain prospective IRB approval for any change to any aspect of the research (design, subject number, subject population, eligibility criteria, procedures, questionnaire, consent document, recruitment material).

The investigator is required to notify the IRB promptly if subjects experience any unanticipated problems involving risks to subjects or others (physical injury, improper disclosure of private information, economic loss, other harmful or potentially harmful occurrences), subject complaint that involve unexpected risks or cannot be resolved, protocol violations, change to protocol made without prior IRB approval to eliminate apparent immediate hazard to a subject, noncompliance, or, for research conducted at the Jesse Brown Veterans Administration Medical Center (JBVAMC), any serious adverse event or unanticipated event.

Table of events, from sponsor notification to project close-out:

Time	Activity
Prior to development of IRB submission	Investigator training
Prior to start of research project	Initial IRB approval (process involves initial submission and, if required, response(s) to reviewer's comments) _Note_: also required by most sponsor/funders prior to executing contract or transfer of funds.
In the course of research project	Continuous review For any modification to protocol (e.g., research procedures, consent forms, instruments, etc.): amendment If problem occurs: protocol exception or prompt report
At the end of research project (closing)	Final report

IRB forms available at: http://research.uic.edu/compliance/human-subjects-irb/forms

2. Training

http://research.uic.edu/compliance/irb/education-training

Investigator training for all investigators and staff; HIPAA training for investigators and staff involved in research utilizing protected health information (PHI).

2.1. Initial training and continuing education

2.1.1. Investigator training

All UIC Investigators and key research personnel are required to meet the initial training requirements in human subjects protections *before their involvement in the research*.

The Principal Investigator is ultimately responsible to ensure that all individuals involved in the research receive both adequate training, including human subjects protection training, and oversight in accordance to the roles these individuals perform in the research. This includes students or other individuals having minor roles in the research who are not required to be listed on the research protocol.

- Initial Investigator Training (Investigator 101)
    - Online: CITI Initial Course
    - Live in-person session: see calendar

These are the ONLY beginning programs that qualify.

2.1.2. HIPAA Training

- ONLY required for investigators and key research personnel who are involved in research utilizing protected health information (PHI).
- HIPAA taken at University of Illinois Hospital & Health Sciences System (UI Health) or at other institutions WILL NOT qualify
- You must attend or complete the on-line course within the first three (3) months of employment.
    - HIPAA online
    - HIPAA In-person: see calendar

2.2. Continuing education

All UIC Investigators and other key research personnel involved in human subjects research must complete a minimum of two hours of continuing education in human subject protections every two years.

Every two years you are required to fulfill 2 continuing education credits. Don't let lapsed education requirements hold up your protocol!

What qualifies for CE?

- Online courses
    - 2 credits
        - CITI Refresher
        - Good Clinical Practice
        - Obtaining Effective Informed Consent
        - Community Engaged Research Consenting Process
    - 1.5 credits
        - FAQs Regarding UIC's Human Subjects Research Policies and Procedures
    - 0.5 credits
        - AAHRPP and the UIC Human Research Protections Program: What Investigators Need to Know
        - Lapses in IRB Approval
- OPRS presentations: check our calendar
- Department presentations (requires OPRS pre-approval): check with your department
- Conferences and seminars (requires OPRS pre-approval)

3. Submission of material to the IRB

3.1. Process

The Office of the Vice Chancellor for Research (OVCR) and the Office for the Protection of Research Subjects (OPRS) accepts submissions to the IRB through OPRS Live, an electronic IRB submission system. OPRS Live can be accessed by investigators in all UIC colleges through the following url: https://oprslive.ovcr.uic.edu/

A brief tutorial on registering and using the OPRS Live system is available here.

3.2. Is it research involving human subjects? Determination of Whether an Activity Represents Human Subjects

When an activity is thought to not represent human subjects research, the form "Determination of Whether An Activity Represents Human Subjects Research" should be completed and submitted to the OPRS. The OPRS waives the requirement for submission of the human subjects determination form when the activity is limited to one or more of the categories below unless required for publication or by the sponsor:

- The project is limited to accessing one or more of the following public use datasets: Inter-University Consortium for Political and Social Research (ICPSR), U.S Bureau of the Census, National Center for Health Statistics, National Center for Educational Statistics, U.S. Bureau of Labor Statistics, National Election Studies, National Crime Victimization Survey: School Crime Supplement, 2003, National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), National Survey of America's Families (NSAF), and PRAMS.
- The project is limited to course-related activities designed specifically for educational or teaching purposes; where data is collected from and about human subjects as part of a class exercise or assignment and is not intended for use outside of the classroom.
- The activity is a case report involving the observation of a single patient whose novel condition or response to treatment was guided by the care provider's judgment regarding the best interest of the individual.
- The project involves research that is limited to death records, autopsy materials, or cadaver specimens (provided that the cadaveric tissues/cells are not used for clinical investigations).

Any activity that is thought to not represent human subjects must be submitted to the OPRS for a determination. The determination whether an activity representing human subject research is performed by designated OPRS staff. Form available at: http://research.uic.edu/determination

4. Initial submission

Templates available at: http://research.uic.edu/compliance/human-subjects-irb/investigators-research-staff/submission/initial-review-applications

4.1. Development/Center/Training grant

In accordance with 45 CFR 46.118, UIC recognizes that there are some applications for grants, cooperative agreements, or other applications that are funded by federal departments or agencies with the knowledge that subjects may be involved within the period of support, but these applications do not include specific plans for human subjects research in order to accomplish the aims of the application. This Development/Center/Training grant application is to be used by investigators whose application falls into one or more of the following categories:

1.   "Core" or "Center" grants—these are institutional grants that will support individual research projects that are "yet to be determined" at the time of submission of the grant application, when the Core or Center grant will not enroll subjects directly, but supports separate protocols involving human subjects.

2.   Training grants—these applications request funding for research fellows or others who will be supported for the purpose of implementing human subject research, but the specific studies on which they participate are not part of the training grant application.

3.   Development only applications—these applications include plans for the development of specific human subjects research studies, but those studies will only be initiated after some

preliminary projects are completed (e.g., development of instruments or compounds, or prior animal studies).

At UIC, IRB approval is required for "Core", "Center" and training grant applications using this application form. Regardless of the category above, *under NO circumstances may an investigator initiate human subjects research by the grant/contract, including pilot studies, prior to the review and approval of a separate IRB application or a Claim of Exemption (through OPRS).*

http://research.uic.edu/compliance/human-subjects-irb/investigators-research-staff/submission/development/center/training

4.2.   Convened IRB Review (Full Board)

Studies that involve more than minimal risk and/or involve particularly vulnerable populations (i.e., prisoners, individuals with diminished capacities) require Convened Review. These studies require a review of the proposed research at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present .

4.3.   Expedited IRB Review

Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research. Expedited review is performed by the IRB chair, a designated voting member, or a group of voting members rather than by the entire convened IRB.

4.4.   Exempt Review

When it is determined that the involvement of human subjects is in one of the six exempt categories listed in the Regulations [45 CFR 46.101(b)], it is exempt. The exempt categories include certain educational practices and tests, innocuous surveys of adults, study of existing data, public service programs and food evaluations. Any research study involving human subjects thought to be exempt must be submitted to the OPRS for an exemption determination. Exemption review is performed by senior OPRS staff and designated IRB members.

Minimal risk – The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

See Federal Policy for the Protection of Human Subjects (45 CFR 46.100(b) for a detailed description of exemption categories.

4.5.   Tips for successful submission

Tip	What to do

1. Be precise in your language	o You are submitting an "Application" for IRB review, not an "IRB" for IRB review.
	 o Each type of Application (EXEMPT, EXPEDITED, CONVENED) has a separate instruction sheet that should be read and referred to when completing the Application.
	 o Adults (over age 18) provide "Consent."
	 o Children provide "Assent."
	 o Parents provide "Parental Permission" for their children to participate in research and sometimes also "Consent" to participate in research with their child (e.g., mother-daughter dyads). You can submit a combination Parental Permission/Adult Consent document by using "You and your child are being asked to …" throughout the document.
	 o All informed consent documents should be written at a level appropriate to the population being recruited.
	 o Use UNIQUELY IDENTIFYING FOOTERS to identify your various documents. Do not use the same footer for all documents (e.g., "Very Important Study", version 1, 6/1/2007, page 1 of 3). Instead, you should use:
	     ▪ Consent Document for Very Important Study, version 1, 6/1/2007, page 1 of 3
	     ▪ Assent Document for Very Important Study, version 1, 6/1/2007, page 1 of 2
	     ▪ Recruitment Flyer for Very Important Study, version 1, 6/1/2007
	     ▪ Recruitment Script for Very Important Study, version 1, 6/1/2007. page 1 of 6

2. Pay attention to grammar and punctuation	The IRB must determine that the investigator is qualified to conduct the proposed research ethically and responsibly. If the Application and consent documents are fraught with grammatical and typographical errors it does not inspire confidence in the Principal Investigator and may impact how the IRB reviews the proposal. Additionally, the errors may adversely impact the subjects' ability to comprehend the consent documents.
3. Avoid deadline days	o There are no deadline days for Applications submitted for EXEMPT or EXPEDITED review. Applications submitted for CONVENED review have deadline days that are listed on the OPRS website. o The sooner the Application is submitted, the sooner it will be reviewed (i.e., first in, first served)

	o You should avoid deadline days, because many people submit Applications on deadline days and the volume may impact timeliness.

4. Include a research protocol with your Application	o Each Initial Review Application (EXEMPT, EXPEDITED, CONVENED) requires submission of a research protocol in addition to the IRB Application form. The protocol represents the primary documentation of the proposal for the purpose of IRB review. The protocol should provide a complete explanation of the research plan, and should be used as the basis for completion of the other IRB submission documents. The Application form is used to summarize the research protocol and to provide specific information about the human subjects protection issues related to the protocol. In general, a protocol should contain as many of the following elements as are applicable to the type of research.
	1. Title page including title, investigators, affiliations, sponsor, and protocol version number and date.
	2. Study Hypothesis and Specific Aims (purpose, objectives)
	3. Background and Significance
	4. Methods
	   a. Research Design
	   b. Eligibility Criteria
	   c. Justification for inclusion of any special or vulnerable populations
	   d. Plans for subject selection, recruitment, and documentation of informed consent
	   e. Description of Procedures
	   f. Statistical Methods
	     • Planned statistical analysis
	     • Rationale for selection of subject
	5. Safety Monitoring and Assessment (if relevant, include provisions for managing adverse reactions)
	6. Data management (when relevant, address measures of privacy protection, coding, storage of information)
	7. For multi-site protocols, an overall study management plan should be provided.
	8. Relevant Literature
	
	Notes:
	o Please refer to Section 6 of the "E6 Good Clinical Practice Consolidated Guidance" and "The IRB Information Sheets-A self-Evaluation Checklist for IRBs" for additional FDA guidance regarding elements of clinical trial protocols.
	o If your research is federally funded, you must submit the entire research grant or the relevant portions of the grant subcontract

	(i.e., cover page, portions of the grant that pertain to research conducted at UIC, and signature page). o UIC policy requires that the research protocol be a separate document from the research grant, grant sub-contract, or contract proposal (scope of work). This policy is consistent with Federal guidance from OHRP *Guidance on Written IRB Procedures* (January 15, 2007). o If submitting your thesis or dissertation research, a copy of your proposal may be used as the research protocol as long as it reflects the research as it is currently being conducted.
5. Have someone independent of the research proof-read your documents	o Applications frequently contain technical jargon that is clear to the PI, but confusing to others. o Review the protocol, Application, recruitment materials and consent documents for consistency in regards to number of subjects, procedures, payment of subjects, etc. o Do the timelines make sense? Is there a logical path for subject recruitment, consent, participation, compensation and follow-up? o The Application is an opportunity to educate the IRB. Do not assume that the IRB knows as much as the PI about the research.
6. Ask OPRS for a pre-review	o OPRS cannot design the research, but the staff can provide guidance on the best way to present information regarding your research to the IRB and how best to complete the Application forms. o Investigators who are new to UIC or who are commencing research in a new area are encouraged to seek a pre-review of their research to facilitate IRB review o Although a pre-review will delay IRB submission by 1-2 weeks, it will typically reduce the overall review time by identifying and helping to correct or resolve problems that may delay IRB approval. o Before making an appointment for a pre-review, complete your research protocol, the Application form, recruitment materials and informed consent documents. Once draft versions of the above have been completed, they can be emailed to OPRS staff at uicirb@uic.edu to review or you can request an in-person consultation by calling the OPRS office at 312-996-1711.
7. Allow adequate time for IRB review	o Claims of Exemption: approximately 1 week o Expedited Initial Review: approximately 2 weeks o Convened Initial Review: approximately 3 weeks o If you have not heard from OPRS within the above timeframe contact OPRS by phone: 312-996-1711 or email: uicirb@uic.edu o Do not assume the IRB review will result in an approval of the research the first time the IRB reviews the research.

	o If you are submitting a Continuing Review application, submit it approximately 45 days prior to the expiration date, but not earlier. Do not rely on OPRS to remind you about the expiration date. The expiration date can be found in your approval letter and is stamped on your consent documents (if applicable).
8. Submit all appendices, recruitment and informed consent documents	o Include copies of all flyers, scripts, recruitment letters, email announcements, brochures, etc. o Submit all questionnaires, survey instruments, interview guides, discussion guides or data collection instruments that will be used. o Submit separate Appendices A and E and the investigational drug brochure (IB) or approved product information for each drug or biologic (approved as well as investigational agents) administered or prescribed solely due to the subject's participation in the research. o Include Appendix D for studies that involve tissue banking, DNA and databases. o Include Appendix F, Department Review, if submitting for convened IRB review. o Include Appendix H for research involving protected health information (PHI). o Attach a copy of the data collection instrument to the IRB application if the research involves the collection and recording of information from the medical record (e.g., retrospective chart review). o Include copies of all consents, assents, parental permissions, and HIPAA authorizations. **Use UIC templates**, found at http://research.uic.edu/compliance/human-subjects-irb/forms o Submit each document separately so OPRS staff can stamp each document with an approval/expiration date and return it to you after IRB approval. Allow adequate space on each document for the approval stamp. o If you are requesting Waivers please explain, in the Application, why the waiver(s) is/are necessary. o Once you have been assigned a protocol number by OPRS refer to that number when communicating with OPRS.

5. Continuing review

1. In accordance with federal regulations, UIC policy requires that IRB-approved research be reviewed at intervals appropriate to the degree of risk and at a minimum of once per year for both federally funded and non-federally funded research. Research that is not reviewed at least once a year is deemed to be lapsed in IRB approval and a notice of expiration of IRB approval must be issued.

2. Continuing review of research must be substantive and meaningful. The approval criteria at 45 CFR 46.111 (and at subparts B, C, and D of 45 CFR part 46, when applicable) or 21 CFR 56.111 must be satisfied when the IRB conducts continuing review of research either at a convened meeting or under an expedited review procedure. These criteria include determinations by the IRB regarding minimizing risks, risks reasonable in relation to potential benefits, equitable selection of subjects, obtaining and documenting informed consent, monitoring safety, protection of privacy and maintenance of confidentiality, and additional safeguards for subjects likely to be vulnerable to coercion or undue influence

3. Continuing review is allowed to stop only when the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, research is no longer active for long term follow up and collection and analysis of individually identifiable private information has been completed.

http://research.uic.edu/compliance/human-subjects-irb/investigators-research-staff/after-irb-approval-obtained/submitting

6. Amendments

http://research.uic.edu/compliance/human-subjects-irb/investigators-research-staff/after-irb-approval-obtained/amendments

1. UIC OPRS reviews all amendment requests to previously approved research applications or exempt research to determine whether the amendment affects the risk/benefit analysis or exempt status of the research study.

2. Amendments for both federally and non-federally funded research must be approved by the convened IRB or, when the change meets the criteria of minor, by the Chair or designee using the expedited process before the investigator or their research team may implement the amendment. An investigator PI may implement a change to the approved protocol prior to IRB approval only when necessary to avoid an immediate hazard to the subject.

3. Minor changes in research previously approved by the convened IRB or expedited process is eligible for expedited review.
    1. Minor changes represent:
        1. changes not materially affecting the assessment of risk and benefit;
        2. changes not substantially changing the specific aims or design of the study;
        3. for protocols initially approved by expedited review process, the research continues to pose no more than minimal risk; and
        4. new or revised procedures are consistent with the expedited categories 1-7.
    2. Examples of minor changes include:
        1. administrative or editorial changes,
        2. minor consent form revisions (e.g., grammar corrections, change in contact information, editorial changes that clarify but do not change the material),
        3. addition of procedures that do not increase risks, such as expanding collection of information or samples already being obtained for non-research purposes,
        4. changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods,

5. non-substantive changes to study documents such as surveys, questionnaires or brochures,
6. new study documents to be distributed to or seen by subjects that are similar in substance to those previously approved,
7. changes in the amount or process for compensating subjects that do not significantly impact the risks or benefits,
8. decrease in the number and volume of sample collections as long as they do not negatively alter the risks or benefits,
9. addition or removal of co-investigators, key personnel or performance sites (when do not adversely affect study resources),
10. increasing subject enrollment,
11. addition of template short form consents and
12. foreign language translations of materials already approved.
3. Examples changes that are not minor include:
    1. new or expanded procedures (e.g., tissue biopsy, more frequent blood drawings) or changes in design (e.g., add or remove treatment arm, new study population) that increase risks or adversely impact the risk-benefit ratio,,
    2. changes in eligibility criteria that impact the risk-benefit ratio (e.g., lowering or raising the age limit),
    3. information concerning previously unknown risks or lack of benefit that is substantial or adversely affects the risk-benefit ratio, significant changes to materials to be given to subjects (e.g., new information about frequency or severity of adverse effects, negative outcomes from related studies), and
    4. replacement of principal investigator.
4. Protocols previously meeting the criteria for expedited review will subsequently require review by the convened IRB when the changes proposed in the amendment increase the risk level to more than minimal or involve procedures which do not fall within one or more of the seven categories eligible for expedited review (refer to UIC HSPP Policy *Expedited Review*).

7. Reporting problems to the IRB

http://research.uic.edu/irb/investigators-research-staff/when-problems-occur

7.1.   Protocol exception

Request represents:

- An exception to the protocol to allow the enrollment of or modification of procedures for a single subject.
- An exception to the protocol to allow the enrollment of or modification of procedures for small number of subjects (justification for why an amendment cannot be submitted is required.)
- An exception to allow currently enrolled subjects to continue some or all research activities during a lapse in IRB approval or suspension. Enrollment of new subjects is not allowed, except in extraordinary circumstances.

7.2.   Prompt reporting

UIC policy requires investigators to promptly report all unanticipated problems involving risks to subjects or others (referred to as unanticipated problems in this policy) to the UIC OPRS/IRB. Events determined by the IRB to represent unanticipated problems are reported to the institutional official and regulatory agencies as described in the UIC HSPP policy *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-compliance*.

The investigator is responsible for reporting adverse events and problems to the sponsor and any other agencies as specified in the protocol, data safety monitoring plan or other agreements.

7.2.1.   Useful definitions

1. **Unanticipated problems involving risks to subjects or others:** refers to a problem, event or information item that is unexpected, given the nature of the research procedures and the subject population being studied; related or possibly related to participation in research and suggests that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

2. **UNANTICIPATED**: means that the specificity, severity or frequency of the event is not expected based on (a) information contained in the protocol, investigator's brochure, informed consent document, drug or device product information or other research materials; and (b) the characteristics of the subjects, including underlying diseases, behaviors, or traits. Similarly, according to, unanticipated and unexpected refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.

3. **RELATED OR POSSIBLY RELATED** means that the event is more likely than not to have been caused by the procedures associated with the research. According to VHA Handbook 1058.01, related means the event or problem may reasonably be regarded as caused by, or probably caused by, the research.

4. **GREATER RISK OF HARM** means the research causes harm (including physical, psychological, economic, legal or social harm) to subjects or others (e.g., family members, co-workers, study staff) or places them at a greater risk of harm than was previously known or recognized.

5. **SERIOUS PROBLEM**: Problem that involves substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of research subjects, research staff, or others; or substantively compromises the effectiveness of a facility's human research protection or human research oversight programs.

6. **ADVERSE EVENT**: An untoward physical or psychological occurrence in a human subject participating in research which occurs during the study having been absent at baseline or, if present at baseline, appears to worsen. The event may be any unfavorable outcome, including abnormal laboratory result, symptom, disease or injury. Adverse events may be expected or unexpected, may not necessarily be caused by the research, and may be serious or not. Adverse events that are unanticipated, related to the research and serious or involve risks to subjects or others qualify as a subset of unanticipated problems.

7. **SERIOUS ADVERSE EVENT:** Adverse events classified as serious include those resulting in death, life-threatening injury, hospitalization or prolongation of hospitalization, persistent or significant disability, or a congenital anomaly or birth defect. Events not meeting the above criteria but requiring intervention to prevent one of these outcomes are also considered serious adverse events.

8. **Unanticipated Adverse Device Effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device used during human subjects research if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

9. **Internal/LOCAL**: Events or problems occurring at UIC, JBVAMC or other sites where the UIC IRB has oversight responsibility for the research and UIC IRB is the IRB of record).

10. **External**: Events occurring at non-UIC sites, i.e., where UIC IRB has no oversight responsibilities.

11. **Protocol violation**: Any deviations, whether accidental, unintentional or intentional, from the IRB-approved protocol that are implemented prior to IRB approval. Major protocol violations are those that cause harm to subjects or others, place them at increased risk of harm, impact the scientific integrity of the research, compromise the human subject protection program, have the potential to recur or represent possible serious or continuing non-compliance Major protocol violations may represent an unanticipated problem (particularly when unintentional) and/or potential serious noncompliance and require prompt reporting. Minor protocol violations are those not meeting at least one of the criteria in the preceding sentence and do not require reporting to the IRB. They should be reported to the sponsor as described in the protocol and written documentation of their occurrence filed with the investigator's study records.

12. **NON-COMPLIANCE**: Conducting research involving human subjects in a manner that intentionally or unintentionally fails to comply with federal or state regulations, VHA Handbook 1200.05, UIC HSPP policies, or the requirements or determinations of the IRB. Examples include, but are not limited to, initiating research prior to IRB approval, implementing changes in the IRB-approved protocol without prior IRB approval, using inadequate procedures for informed consent, failing to meet education and training requirements and lapses in IRB approval.

13. **SERIOUS NON-COMPLIANCE**: Non-compliance that results in either substantive harm (or genuine risk of substantive harm) to the safety, rights or welfare of human subjects, research staff or others, substantively compromises the effectiveness of the HSPP or substantively impacts the integrity of the research. .

14. **CONTINUING NONCOMPLIANCE**: Persistent failure to conduct research in compliance with federal or state regulations, VHA Handbook 1200.05 (if applicable), or requirements or determinations of the IRB.

15. **RISK**: A risk may reflect potential physical, psychological, social, or economic harm.

16. **ADMINISTRATIVE HOLD**: An administrative hold is a voluntary action by an institutional official, investigator or sponsor to temporarily or permanently stop some or all research activities as a modification to approved research. The administrative hold does not apply to interruptions of research related to concerns regarding the safety, rights or welfare of human research subjects or others. Administrative holds are not considered suspensions or terminations, and do not meet reporting requirements to OHRP, FDA and other federal agencies. Although the investigator may discuss this action beforehand with the IRB, IRB chair, OPRS Director, OPRS Associate Director or Assistant Director, the hold must be initiated voluntarily by the investigator and must not be used to avoid IRB mandated suspension or termination or reporting requirements. During administrative hold, the research remains subject to continuing review and requirements for reporting non-compliance and unanticipated problems involving risks to subjects or others

7.2.2.   Events Requiring Prompt Reporting to the IRB and the Schedule for Reporting

7.2.2.1.   *Events Requiring Reporting to the IRB within 5 Business Days of the Investigator Becoming Aware*

- Local, serious adverse events which are unanticipated
- Unanticipated adverse device effects
- Serious unanticipated problems
- Major protocol violations that are unplanned and unintentional
- Apparent serious noncompliance
- Apparent continuing noncompliance
- Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects
- Incarceration of a subject in a protocol not approved to enroll prisoners

*7.2.2.2.   Events Requiring Reporting to the IRB within 15 Business Days of the Investigator
Becoming Aware*

- Local adverse events or problems that are unanticipated and, while not meeting the criteria of serious, indicate research is associated with a greater risk of harm to participants or others than previously known.
- External adverse events that are unanticipated, indicate research associated with a greater risk of harm to participants or others than previously known and more likely than not to have been caused by the procedures associated with or subject's participation in the research. An analysis from sponsor, coordinating center or DSMB/DMC supporting that the event or problem meets the 3 criteria above must be included.
- New information indicating an unexpected change to the risks or benefits of the research (i.e., an unanticipated problem).
- Administrative hold by investigator, sponsor, regulatory authorities or other entities.
- Other events requiring prompt reporting by sponsor.

7.2.2.3.   Events That Do Not Require Reporting to the IRB

- Local adverse event or problem that is expected or is not associated with a greater risk of harm to participant or others than previously know
- External adverse event or problem lacking an analysis documenting that it is unanticipated, related or possibly related and associated with a greater risk of harm than previously known
- Individual IND safety or FDA MedWatch reports from external site
- Minor protocol violation

However, reporting of some of the events above are required at continuing review

7.3.   Procedure

7.3.1.   Reporting and Submission by PI

1. The investigator informs the IRB of an event requiring prompt reporting by submitting the UIC OPRS *Prompt Reporting to the IRB* form to OPRS within 5 working days of becoming aware of any events listed in IV.A. of the Policy section above or within 15 days for those listed in IV.B. of the Policy section above.
2. The prompt reporting criteria depend on the investigator to decide whether the event is anticipated or unanticipated, serious or not, or does or does not indicate the research is associated with a greater risk of harm than previously known. The investigator is not asked to decide whether the event is related to the research, except with external adverse events.
3. For research being conducted at JBVAMC, the unfounded classification of a serious adverse event as anticipated constitutes serious noncompliance.
4. Unanticipated problems, unexpected adverse events or other prompt reporting events occurring at the Northwestern University (or an NU affiliate) performance site for research

approved by the Collaborative IRB (UIC IRB#4) are reported by investigators to the NU OPRS. These reports are forwarded by NU OPRS to UIC OPRS and the Collaborative IRB. For all other performance sites where the UIC IRB has oversight responsibility, the reports are forwarded directly to the UIC OPRS.

5. Examples of materials that should be submitted with the prompt reporting form include, when available, case report forms, DSMB/DMC reports, updated investigator brochures, amendment applications with revised protocol or consent form, or sponsor communications.

6. Prior to accepting the submission report, the OPRS entry staff ensures that:
   1. The report form is correctly filled out;
   2. Reports of external adverse events include documentation indicating the event meets the criteria of an unanticipated problem/ event; and
   3. Individual IND safety or FDA MedWatch reports are returned to investigators unless identified as unanticipated problems/ events.

7.3.2. Review by IRB

7.3.2.1. Initial Review by IRB Assistant Director (AD)

The Assistant Director of the assigned IRB reviews the reports for completeness and evaluates whether they meet the criteria for a reportable event are met.

- If the AD does not confirm the investigator assessment of unanticipated and serious or greater risk of harm than previously known the report is returned to the investigator with notice that the problem does not meet criteria for prompt reporting and whether other reporting requirements exist (i.e., continuing review, non-compliance). The IRB is notified of the AD's action at the next scheduled meeting via the agenda.

- If the event is determined to potentially meet the criteria of unanticipated and serious or greater risk of harm than previously known, the AD refers the problem/ event to a qualified IRB member-reviewer (the Chair or designee determined by the Chair) ,or alternatively, the convened IRB if a meeting is scheduled within the 5 or 15 day timeline for review.,

- For events referred to the Chair, designee or convened IRB, the AD consults with the chair (or designee) to determine if immediate action by the Chair (or designee) is needed to protect the rights and welfare of human subjects. Immediate action may include, but is not limited to, suspension of part (e.g., new subject recruitment) or all of the research (refer to UIC HSPP policy *Administrative Hold, Suspension, or Termination of IRB Approval*).

Additional Expertise. At any point during the review process, the IRB Assistant Director, IRB Chair (or designee) or convened IRB may request additional expertise.

7.3.2.2. Review of events considered by the AD to represent unanticipated problems/ events

Review by the Chair, IRB member designated by the Chair or convened IRB must occur within 5 business days for serious unanticipated problems, serious adverse events and other events listed in section 7.2.2.1, within 15 business days for unanticipated problems and other events listed in section 7.2.2.2. If

an IRB meeting is scheduled within the 5 or 15 day interval, respectively, the Chair may refer the matter to the convened IRB.

Determinations by the Chair or Designee or Convened IRB include:

1. Additional information or modifications needed before making a final decision.
2. The problem or event does not meet the 3 criteria of an unanticipated problem.
3. The problem or event represents a serious unanticipated problem or local serious unanticipated adverse event.
4. The event represents an unanticipated problem or unanticipated adverse event, and, while not serious, does indicate the research is associated with a greater risk of harm than previously known and the level of risk is greater than minimal.
5. The event represents an unanticipated problem or unanticipated adverse event, and, while not serious, does indicate the research is associated with a greater risk of harm than previously known and the level of risk is not greater than minimal.

7.3.2.3.   When unanticipated problem determination made by the Chair or designee

1. Serious unanticipated problem or local serious unanticipated adverse event: The Chair or designated reviewer also decide the need for any actions necessary to prevent an immediate hazard to subject. This finding is referred to the convened IRB at their next meeting to determine whether other actions are warranted.
2. Unanticipated problem that is not serious but indicates research is associated with a greater risk of harm than previously known: and the level of risk is greater than minimal: The Chair or designated reviewer decide the need for any immediate actions. This finding is referred to the convened IRB at their next meeting to determine whether other actions are warranted.
3. Unanticipated problem that is not serious but indicates research is associated with a greater risk of harm than previously known and the level of risk is not greater than minimal: The Chair or designated reviewer decides the need for any corrective actions. The determination and corrective action are communicated to the convened IRB at their next meeting via the agenda.

7.3.2.4.   Actions recommended by the Chair or designee/convened IRB

Actions may include:

1. Suspension of the research;
2. Modification of the information disclosed during the consent process;
3. Notification of current participants when such information may relate to the subject's willingness to continue participation;
4. Providing additional information to past subjects;
5. Requiring current subjects to re-consent to participation;
6. Alteration of the frequency of continuing review;
7. Monitoring of the research or the consent process;

8. Referral to other organizational entities (e.g., ORS, ethics officer, Associate Director for Compliance, Radiation Safety); and
9. Modification of protocol.
10. Additionally, if the convened IRB decides a protocol or consent modification is warranted, the IRB must also determine :
    - Whether or not previously enrolled subjects must be notified of the modification and, if so,
    - When such notification must take place and how such notification must be documented.

Notes:

- The finding and any IRB stipulated actions are noted in the protocol file and meeting minutes, and are communicated to the investigator. Copies of the communication are provided to academic Department Head, other relevant UIC oversight committees (e.g., investigational drug service, IBC, radiation safety, cancer center), UIC HPA, JBVAMC R&D Committee (if JBVAMC is a performance site), and NU OPRS (if NU is a performance site).
- The IRB also determines for subject complaints, protocol violations, changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects, and allegations of non-compliance whether they represent non-compliance and, if so, whether the finding of non-compliance is serious or continuing as described in the UIC HSPP policy *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*. The IRB may also, at their discretion, make a determination of noncompliance for any other reports received.
- Events determined by the IRB to be unanticipated problems, require suspension or termination of approval or represent serious or continuing non-compliance are reported to institutional official and regulatory agencies as described in the UIC HSPP policy *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-compliance*.

8. Closing protocol

http://research.uic.edu/compliance/human-subjects-irb/investigators-research-staff/after-irb-approval-obtained/final-report

Investigators, or other responsible parties as applicable, **must** file a Final Report form to request study closure with OPRS for IRB approved and exempt studies upon completion of the study.

- A Final Report form **must** be submitted even if
    - o the research was never initiated;
    - o no subjects were enrolled; or
    - o the research is being terminated earlier than originally planned.
- Once a study has been closed via a Final Report form, it cannot be re-opened.
    - o If a later use for the research data is identified, then the PI must submit a new research application for the use of the previously collected data.
    - o The later use of the data may qualify for an exemption, if the existing data is recorded without identifiers. Please contact OPRS for more information.

9. IRB submission checklists

Submissions can be made through OPRS Live by investigators in all UIC colleges through the following url: https://oprslive.ovcr.uic.edu/. Please use the forms generated via OPRS Live for your submission.

9.1. Initial application, health and biological sciences

Checklist: Initial Review Application Health and Biological Sciences
Submission Materials:
Please collate your submission, include the required number of copies, and place documents in the following order:

For Convened Review (greater than minimal risk research)
☐ Initial Review Application
    ☐ **One (1) signed original** (for the IRB Files) of the application: Appropriate departmental signatures (and signature of faculty sponsor, if PI is a student, fellow, or resident).
    ☐ **Twenty (20) identical copies** (for the IRB board and reviewers)

For Expedited IRB Review (no greater than minimal risk)
☐ Initial Review Application
    ☐ **One (1) signed original** (for the IRB Files) of the application: Appropriate departmental signatures (and signature of faculty sponsor, if PI is a student, fellow, or resident).
    ☐ **One (1) identical copy** (for the IRB reviewer)

If applicable, include the following documents:
Convened review: one (1) original and twenty (20) copies.
Expedited review one (1) original and one (1) copy.
☐ Appendices:

☐ Appendix A1	☐ Appendix G	☐ Appendix O
☐ Appendix A2	☐ Appendix I	☐ Appendix P
☐ Appendix B	☐ Appendix J	☐ Appendix Q
☐ Appendix C	☐ Appendix K	☐ Appendix S
☐ Appendix D1	☐ Appendix L1	☐ Appendix U
☐ Appendix D2	☐ Appendix L2	☐ Appendix V
☐ Appendix E	☐ Appendix N	☐ Appendix Z

☐ Significant Financial Interest – Disclosure and Management Plan (SFI-DMP)
☐ Any other committee review and approval that was required prior to submission to OPRS (e.g. Dissertation Committee, Cancer Center, Radiation Safety, CRC or IBC review).
☐ Copies of all proposed recruitment materials (advertisements/flyers)
☐ Copies of all informed consent/assent documents or verbal scripts, and HIPAA authorizations.
☐ Copies of all questionnaires, survey instruments, interview questions, discussion guides and/or data collection instruments that will be used.

Include three (3) copies for Convened Review and two (2) copies for Expedited Review:
☐ Research Protocol* (with version number and date)
☐ Supporting documents, including letters of support or agreement and approval notices from other institutions.
☐ Documentation specified in Appendices A1, A2, K, Q and S.

If research is federally funded, three (3) copies for Convened Review and two (2) copies for Expedited Review of the following:
☐ Federal Grant, Contract or Sub-contract
☐ DHHS Approved sample Informed Consent Template (when it exists)
☐ DHHS Approved Protocol (when it exists)

If research is regulated by Food and Drug Administration, **three (3) copies for Convened Review and two (2) copies for Expedited Review of the following:**
☐ Investigator Brochure or FDA approved product information

☐ When research involves investigational drug or biologic, attach verification of IND Number: IND approval letter from FDA, sponsor's protocol with printed IND or letter from sponsor.

☐ When UIC investigator holds IND, IND approval letter from FDA required.

☐ For Medical Device: IB, device manual or FDA approved product labeling

☐ If FDA has made the device risk determination, include the FDA determination letter of non-significant risk.

☐ For significant risk device, include the IDE approval letter.

☐ If device is approved or cleared, attach a copy of the FDA PMA or 510(k) approval letter or approved labeling.

☐ FDA form 1572☐ CV(s)/biosketch of Principal Investigator

☐ Professional/medical license(s) for PI and Co-PI

If research is being conducted at Jesse Brown VAMC, please complete the Jesse Brown VAMC Submission Checklist also.

*Definition: Research Protocol

The research protocol represents the key study document for describing the objectives, design, methodology, organization and data analysis of the proposed research, and is the primary documentation of the proposal for the purpose of IRB review. The protocol is used by the research staff or team to understand the procedures or tasks currently involved in the research.

The research protocol is a separate document from the research grant, grant sub-contract, or contract proposal (scope of work). For industry-sponsored research, the protocol is generally provided by the sponsor. For investigator-initiated research, the protocol is generally written by the Principal Investigator. If the Principal Investigator is a student, the thesis or dissertation proposal may be used as the research protocol.

Whatever the origin of the protocol, the protocol should be revised as needed to be current to the research as it is actually being conducted. Any changes to the research should be submitted as amendments to the IRB.

The protocol must clearly identify the title, version number and date of the protocol and all pages must be numbered.

Although the format and terminology may differ, the UIC IRB typically expects the research protocol to contain the following:

1. Title page including title, investigators, affiliations, sponsor, and protocol version number and date.
2. Study Hypothesis and Specific Aims (purpose, objectives)
3. Background and Significance
4. Methods
   a. Research Design
   b. Eligibility Criteria
   c. Justification for inclusion of any special or vulnerable populations
   d. Plans for subject selection, recruitment, and documentation of informed consent
   e. Description of Procedures
   f. Statistical Methods
      i. Planned statistical analysis
      ii. Rationale for selection of subject
   g. Safety Monitoring and Assessment (if relevant, include provisions for managing adverse reactions)
   h. Data management (when relevant, address measures of privacy protection, coding, storage of information)
5. For multi-site protocols, an overall study management plan should be provided.
6. Relevant Literature

NOTE: Retain a copy of the complete Initial Review Application packet for your records.

9.2. Initial application, health and biological sciences

Checklist: Initial Review Application Social and Behavioral Sciences
Submission Materials:
Please collate your submission, include the required number of copies, and place documents in the following order:

For Convened Review (greater than minimal risk research)
☐ Initial Review Application
  ☐ **One (1) signed original** (for the IRB Files) of the application: Appropriate departmental signatures (and signature of faculty sponsor, if PI is a student, fellow, or resident).
  ☐ **Twenty (20) identical copies** (for the IRB board and reviewers)

For Expedited IRB Review (no greater than minimal risk)
☐ Initial Review Application
  ☐ **One (1) signed original** (for the IRB Files) of the application: Appropriate departmental signatures (and signature of faculty sponsor, if PI is a student, fellow, or resident).
  ☐ **One (1) identical copy** (for the IRB reviewer)

If applicable, include the following documents:
Convened review: one (1) original twenty (20) copies
Expedited review: one (1) original and one (1) copy)
☐ Appendices:

☐ Appendix B	☐ Appendix G	☐ Appendix L1	☐ Appendix S
☐ Appendix C	☐ Appendix I	☐ Appendix L2	☐ Appendix U
☐ Appendix D1	☐ Appendix J	☐ Appendix P	☐ Appendix V
☐ Appendix D2	☐ Appendix K	☐ Appendix Q	☐ Appendix Z

☐ Significant Financial Interest – Disclosure and Management Plan (SFI-DMP)

☐ Any other committee review and approval that was required prior to submission to OPRS (e.g. Dissertation Committee, Cancer Center, Radiation Safety, CRC or IBC review).
☐ Copies of all proposed recruitment materials (advertisements/flyers)
☐ Copies of all informed consent/assent documents or verbal scripts, and HIPAA authorizations.
☐ Copies of all questionnaires, survey instruments, interview questions, discussion guides and/or data collection instruments that will be used.

Include three (3) copies for Convened Review and two (2) copies for Expedited Review:
☐ Research Protocol* (with version number and date)
☐ Supporting documents, including letters of support and approval notices from other institutions
☐ Documentation specified in Appendices K, Q and S.

If research is federally funded, , three (3) copies for Convened Review and two (2) copies for Expedited Review of the following:
☐ Federal Grant, Contract or Sub-contract
☐ DHHS Approved sample Informed Consent Template (when it exists)
☐ DHHS Approved Protocol (when it exists)

If research is being conducted at Jesse Brown VAMC, please complete the Jesse Brown VAMC Submission Checklist also.

*Definition: Research Protocol

The research protocol represents the key study document for describing the objectives, design, methodology, organization and data analysis of the proposed research, and is the primary documentation of the proposal for the purpose of IRB review. The protocol is used by the research staff or team to understand the procedures or tasks currently involved in the research.

The research protocol is a separate document from the research grant, grant sub-contract, or contract proposal (scope of work). For industry-sponsored research, the protocol is generally provided by the sponsor. For investigator-initiated research, the protocol is generally written by the Principal Investigator. If the Principal Investigator is a student, the thesis or dissertation proposal may be used as the research protocol.
Whatever the origin of the protocol, the protocol should be revised as needed to be current to the research as it is actually being conducted. Any changes to the research should be submitted as amendments to the IRB.

The protocol must clearly identify the title, version number and date of the protocol and all pages must be numbered.

Although the format and terminology may differ, the UIC IRB typically expects the research protocol to contain the following:
1. Title page including title, investigators, affiliations, sponsor, and protocol version number and date.
2. Study Hypothesis and Specific Aims (purpose, objectives)
3. Background and Significance
4. Methods
   a. Research Design
   b. Eligibility Criteria
   c. Justification for inclusion of any special or vulnerable populations
   d. Plans for subject selection, recruitment, and documentation of informed consent
   e. Description of Procedures
   f. Statistical Methods
      i. Planned statistical analysis
      ii. Rationale for selection of subject
   g. Safety Monitoring and Assessment (if relevant, include provisions for managing adverse reactions)
   h. Data management (when relevant, address measures of privacy protection, coding, storage of information)
5. For multi-site protocols, an overall study management plan should be provided.
6. **Relevant Literature**

NOTE: Retain a copy of the complete Initial Review Application packet for your records.

9.3. Amendment

Checklist: Amendments Application
Submission Materials:
Please **collate** your submission, include the **required number of copies,** and place documents in the following order:

I. Review of Minor Changes by Expedited Procedure or Exempt Review

A. For Amendments to the Research Protocol and/or revised Protocol Application Form:
One (1) signed original application (for the IRB Files)
AND
One (1) identical collated copy (for the IRB reviewer) of the following documents:
- ☐ Amendment Form (If PI is a student, fellow, or resident signature of faculty sponsor is required)
- ☐ Any document(s) from the sponsor or multi-center trial coordinator concerning the amendment
- ☐ Amended page(s) of IRB Research Protocol Application and, applicable Appendices
- ☐ Revised Research Protocol

B. For Amendments to the Informed Consent/Assent Document and/or to the HIPAA Research Authorization:
One (1) signed original application (for the IRB Files)
AND
One (1) identical collated copy (for the IRB reviewer) of the following documents:
- ☐ Amendment Form **(**If PI is a student, fellow, or resident signature of faculty sponsor is required)
- ☐ Revised informed consent/assent document(s)
- ☐ Revised HIPAA Research Authorization
- ☐ Any document(s) for the sponsor or multi-center trial coordinator concerning the amendment to the informed consent/assent document(s)
- ☐ Unmarked copy of the revised informed consent/assent document(s)
- ☐ Unmarked copy of the revised HIPAA Research Authorization.

C. For Amendments to the Research Protocol and/or Protocol Application Form AND The Informed Consent Document(s) and/or the HIPAA Research Authorization Form:

One (1) signed original application (for the IRB Files)
AND
One (1) identical collated copy (for the IRB reviewer) of the following documents:
- ☐ Amendment Form (If PI is a student, fellow, or resident signature of faculty sponsor is required)
- ☐ Any document(s) from the sponsor or multi-center trial coordinator concerning the amendment
- ☐ Amended page(s) of IRB Protocol Application and applicable Appendices
- ☐ Revised Research Protocol
- ☐ Revised informed consent/assent document(s)
- ☐ Revised HIPAA Research Authorization
- ☐ Any document(s) for the sponsor or multi-center trial coordinator concerning the amendment to the informed consent/assent document(s)
- ☐ Unmarked copy of the revised informed consent/assent document(s)
- ☐ Unmarked copy of the revised HIPAA Research Authorization

II. Review of Amendment and other changes requiring Convened Review

A. For Amendments to the Research Protocol:
One (1) signed original application (for the IRB Files)
AND
Twenty (20) identical collated copies (for the IRB board and reviewers) of the following documents:
- ☐ The Amendment Form (If PI is a student, fellow, or resident signature of faculty sponsor is required)
- ☐ The Amended page(s) of IRB Protocol Application and applicable Appendices
- ☐ Any document(s) from the sponsor or multi-center trial coordinator concerning the amendment

Three copies of the following (for the IRB board and reviewers) documents:
- ☐ Revised Research Protocol

B. For Amendments to the Informed Consent/Assent Document and/or the HIPAA Research Authorization:
One (1) signed original application (for the IRB Files)
AND
Twenty (20) identical collated copies (for the IRB board and reviewers) of the following documents:
- ☐ The Amendment Form (If PI is a student, fellow, or resident signature of faculty sponsor is required)
- ☐ Any document(s) from the sponsor or multi-center trial coordinator concerning the amendment
- ☐ The Amended page(s) or Revised Research Protocol / Research Protocol Application
- ☐ The revised informed consent/assent document(s)
- ☐ The revised HIPAA Research Authorization
- ☐ Any document(s) for the sponsor or multi-center trial coordinator concerning the amendment to the informed consent/assent document(s)
- ☐ An unmarked copy of the revised informed consent/assent document(s) and/or the Authorization Document
- ☐ An unmarked copy of the revised HIPAA Research Authorization

C. For Amendments to the Research Protocol and/or Protocol Application Form AND The Informed Consent Document(s) and/or the HIPAA Research Authorization Form:
One (1) signed original application (for the IRB Files)
AND
Twenty (20) identical collated copies (for the IRB board and reviewers) of the following documents:
- ☐ The Amendment Form (If PI is a student, fellow, or resident signature of faculty sponsor is required)
- ☐ Any document(s) from the sponsor or multi-center trial coordinator concerning the amendment
- ☐ The Amended page(s) of the IRB Application and applicable Appendices
- ☐ The revised informed consent/assent document(s)
- ☐ The revised HIPAA Research Authorization
- ☐ Any document(s) for the sponsor or multi-center trial coordinator concerning the amendment to the informed consent/assent document(s)
- ☐ An unmarked copy of the revised informed consent/assent document(s) and/or the Authorization Document
- ☐ An unmarked copy of the revised HIPAA Research Authorization

Three copies of the following documents (for the IRB board and reviewers):
- ☐ Revised Research Protocol

NOTE: Retain a copy of the complete Amendment Application packet for your records.

9.4. Continuing review

Checklist: Continuing Review Application

Submission Materials: Please collate your submission, include the required number of copies, and place documents in the following order:

A. For protocols that were approved by Convened IRB Review

One (1) signed original (for the IRB Files) of the application: Appropriate departmental signatures (and signature of faculty sponsor, if PI is a student, fellow, or resident) **AND**

Twenty (20) identical copies (for the IRB board and reviewers) of the following documents:
- ☐ Continuing Review Application
- ☐ Approved consent documents, including parental permissions, assents, and authorizations
- ☐ Current recruiting materials
- ☐ Any reports to or from the FDA or sponsors since the last initial or continuing review, including the most recent progress report, DSMB or DMC report, or adverse event summary for all Grant Agency funded studies.

Three (3) copies of the following document:
- ☐ Current research protocol with amendments incorporated.
- ☐ **Current Investigator Brochure (if FDA regulated)**

If additional subjects will be enrolled, include One (1) copy of the following documents:
- ☐ Unmarked copies of the informed consent document(s), including any parental permission document(s) and assent document(s).
- ☐ Unmarked copy of all recruiting materials.

(The unmarked copies will be stamped with the date of approval and returned for your use when enrolling subjects)

B. For protocols that were approved by Expedited IRB Review OR protocols that were approved by Convened IRB Review, but now qualify for Expedited Review*, you will need 2 copies of the entire application and supporting documents,

One (1) signed original (for the IRB Files); **One (1) identical copy** (for the IRB reviewer).

Both include:
- ☐ Continuing Review Application with appropriate departmental signatures (and signature of faculty sponsor, if PI is a student, fellow, or resident)
- ☐ Approved consent documents, including parental permissions, assents, and authorizations
- ☐ Current recruiting materials
- ☐ Any reports to or from the FDA or sponsors since the last initial or continuing review, including the most recent progress report, DSMB or DMC report, or adverse event summary for all Grant Agency funded studies.
- ☐ Current research protocol with amendments incorporated.
- ☐ **Current Investigator Brochure (when one exists; FDA Regulated Research)**

If additional subjects will be enrolled, include one (1) copy of the following documents **(the unmarked copies will be stamped with the date of approval and returned for your use when enrolling subjects)**:
- ☐ Unmarked copies of the informed consent document(s), including any parental permission document(s) and assent document(s).
- ☐ Unmarked copy of all recruiting materials.

* Your research may be eligible for review under expedited review procedures [45 CFR 46.110(b)(1)], if all of the following accurately describe your research:
(a) the research is permanently closed to the enrollment of new subjects **AND**
(b) all subjects have completed all research-related interventions **AND**
(c) the research remains active only for long-term follow-up of subjects **OR**
No subjects have ever been enrolled in the research at UIC or Jesse Brown VAMC, and no additional risks have been identified since the last approval **OR**
The remaining research activities are limited to data analysis only **OR**
The research is not conducted under an IND or IDE, and the IRB has previously determined at a convened meeting that the research involves no greater than minimal risk, and no additional risks have been identified.

NOTE: Retain a copy of the complete Continuing Review Application packet for your records.

10.   Other regulatory compliance requirements

10.1. Clinicaltrials.gov registration

[adapted from https://clinicaltrials.gov]

10.1.1. What studies are registered?

ClinicalTrials.gov is a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The Web site is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study. In some cases, results of the study are submitted after the study ends. This Web site and database of clinical studies is commonly referred to as a "registry and results database."

Most of the records on ClinicalTrials.gov describe clinical trials (also called interventional studies). ClinicalTrials.gov also contains records describing observational studies and programs providing access to investigational drugs outside of clinical trials (expanded access). Studies listed in the database are conducted in all 50 States and in 192 countries. ClinicalTrials.gov does not contain information about all the clinical studies conducted in the United States because not all studies are required by law to be registered (for example, observational studies and trials that do not study a drug, biologic, or device).

> **Based on the nature of the project and on sponsor requirement, registration on clinicalTrials.gov may be necessary. Investigators must check funder/sponsor's guidelines to ensure compliance with registration requirements.** For example, a trial funded by PCORI must be registered, even if it does not study a drug, biologic, or device.

10.1.2. What is included in study record?

Each ClinicalTrials.gov record presents summary information about a study protocol and includes the following:

- Disease or condition
- Intervention (for example, the medical product, behavior, or procedure being studied)
- Title, description, and design of the study
- Requirements for participation (eligibility criteria)
- Locations where the study is being conducted
- Contact information for the study locations
- Links to relevant information on other health Web sites, such as NLM's MedlinePlus for patient health information and PubMed for citations and abstracts of scholarly articles in the field of medicine.

Some records also include information on the results of the study, such as:

- Description of study participants (the number of participants starting and completing the study and their demographic data)
- Outcomes of the study
- Summary of adverse events experienced by study participants

The full history of the changes made to a record can be accessed by viewing the archival version of the record on the ClinicalTrials.gov archive. Once a study is registered on the site, the information about it is not removed.

10.1.3. Registration process

1. **Apply for an account**: ClinicalTrials.gov establishes one PRS account for an organization (such as a company, university, or medical center). Each PRS account is managed by one or more administrators who may add an unlimited number of user logins. The UIC administrator is Lisa Pitler (lpitler@uic.edu). PIs must contact Ms. Pitler to request an account, and to ask for access for study managers.
2. **Log** into the Protocol Registration and Results System (PRS)
3. **Enter the required and optional data elements**. ◦For basic help with using PRS, review the Quick Start Guide found in the Help section of the PRS main menu. More detailed instructions are available in the PRS User's Guide, also found on the PRS main menu.
4. **Preview, inspect, and release (submit) the record**. ◦See the ClinicalTrials.gov protocol review criteria (PDF) for a description of items that should be addressed before releasing the record to ClinicalTrials.gov.
5. **Verify** in PRS that the Record Status is released. The record will not be processed by ClinicalTrials.gov unless it is released. Only the Responsible Party or a PRS account administrator can release the record.
6. **ClinicalTrials.gov Protocol Information Review Process**: A ClinicalTrials.gov staff member will review the study record after it is released (submitted) and before it is published on ClinicalTrials.gov. This review will focus on apparent validity (when possible), meaningful entries, logic and internal consistency, and formatting. You may be asked to clarify items or make corrections to the record before publication. Please note that the review process may take up to a few days. Ensuring that the record is consistent with the ClinicalTrials.gov protocol review criteria (PDF) before releasing it will expedite publication on the site.

After you release a record and it is accepted by review staff for publication, the record, including its NCT Number, will be available on ClinicalTrials.gov within 2–5 business days.

10.1.4. Required Registration Updates

Responsible Parties should update their records within 30 days of a change to any of the following:
- Recruitment Status and Overall Recruitment Status data elements on ClinicalTrials.gov
- Completion Date (see Primary Completion Date data element on ClinicalTrials.gov).

Other changes or updates to the record must be made at least every 12 months. It is recommended that the Record Verification Date be updated at least every 6 months for studies that are not yet completed, even if there were no changes to the record.

For certain clinical trials, the Responsible Party should submit summary results no later than 12 months after the Completion Date, defined in the law as date of final data collection for the prespecified "primary outcome measure" (see Primary Completion Date data element on ClinicalTrials.gov).

10.2. Conflict of interest

For federal grants, and some non-federal awards, investigators and key personnel will need to provide assurance that they have no conflict of interest, or disclose such conflict. UIC is registered with FDP Clearinghouse. Practically, this means that disclosure and certification will be done "in house", in most cases.

COI training and disclosure includes several components:
- COI training
- Reporting of Non-University Activities (RNUA)
- Sponsor-specific questionnaire.

Both FCOI training and SFI disclosure are required for investigators to meet the federal regulations.

10.2.1. COI training
The training modules can be found here: https://research.uic.edu/coi/education-training

10.2.2. Reporting of Non-University Activities (RNUA)
Required for compliance with State of Illinois regulations. Module is found at:
https://myresearch.uillinois.edu/myDisclosures/

10.2.3. Sponsor-specific questionnaire
When federal award is made, investigators and key personnel listed on proposal must also complete a sponsor-specific questionnaire. The sponsor specific significant financial interest (SFI) disclosure must be completed electronically by University investigators at START myDisclosures:
1- Log in:
https://myresearch.uillinois.edu/myDisclosures/
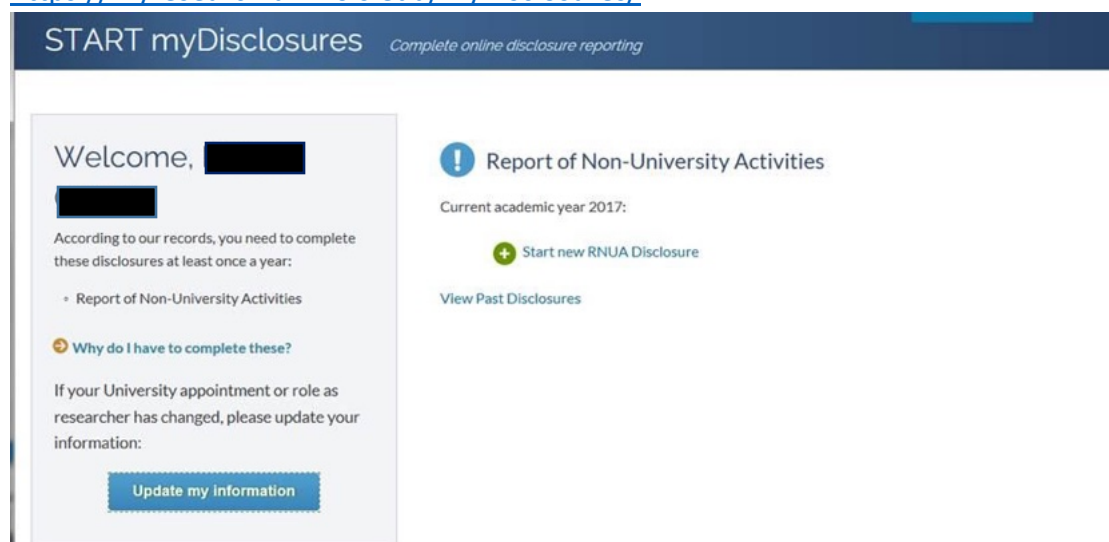
2- When you reach screen pictured above, click on blue box "Update my information"

3- The following screen will appear:

You must check "YES" for question #2

4- After you submit, a sponsor-specific disclosure will appear, that you must complete.

5- When done, system will be updated with your certification. Please let Department Administrator know when completed. The COI officer will then release the grant back to NIH, and award can be processed.

Appendix 1: Closing a sponsored Project

Business and Financial Policies and Procedures

OBFS Home » Policies and Procedures » Section 16: Grants and Research Contracts » Sponsored Projects Closeout » Close a Sponsored Project
https://www.obfs.uillinois.edu/bfpp/section-16-grants-research-contracts/sponsored-project-closeout/sponsored-project-closeout-print

Close a Sponsored Project

Policy Statement

The University of Illinois has a responsibility to close out completed sponsored projects in compliance with federal regulations, sponsor policy, and award terms and conditions. Office of Management and Budget (OMB) Circular A-110 (2 CFR 215) and Uniform Guidance (*2 CFR 200.343 Closeout*) require that final financial, performance, and other reports be submitted within 90 calendar days after the project end date. It is the University's policy that all required closeout deliverables be submitted to the sponsor within this stated timeframe. In the event that sponsor policy or specific award terms and conditions prescribe otherwise, such policy or terms and conditions shall prevail.

Before you Begin

Sponsored project closeout is the shared responsibility of principal investigator (PI), unit business office or department administrator, and central offices. Collectively, they are responsible for the closeout of expired awards no later than 90 days after the project end date.

As the administrator of your sponsored project, be mindful of its end date and terms and conditions, and accordingly take the necessary actions leading to a timely closeout.

Begin

To close a sponsored project, the Principal Investigator (PI) and the Unit Business Office are expected to take actions before and after project end date, as outlined in this procedure.

What to Do BEFORE Project End Date

Approximately 90 days before the expiration of a sponsored project, your campus post-award office, Grants & Contracts Office (GCO), sends you (unit business office) a monthly report of your projects that will end in 90 days. Between that time and expiration date, the **Principal Investigator (PI)** and **Unit Business Office** are expected to do the following:

- Inform GCO immediately if you have information about a continuation or extension of any expiring projects. This will stop the closeout process.
  - Process extension requests as required per sponsor guidelines, or 90 days prior to project end date.
  - Request an anticipation grant/fund or use of an expired or overspent grant/fund (*GC70: Request to Establish an Anticipation Grant/Fund - Request to Use Expired or Overdrafted Grant/Fund*), if applicable.
- Review accounting statements to date and ensure that all expenses charged to the award thus far are allowable, per the OMB Circular A-110 or Uniform Guidance and the terms of the award.
- Determine whether the project will end up with an unobligated (or unexpended) balance, and be aware of the award terms regarding treatment of such a balance: Can the unobligated balance be automatically carried forward? Or must it be returned to the sponsor? (Consult your campus GCO sponsored award contact, if you need assistance.)
- Review status of subrecipient invoicing to date as to accuracy and timeliness.
- Notify service centers with recurring billings (e.g. animal charges, printing, etc.) of the sponsored project expiration date and provide a new C-FOAP, if applicable.
- Ensure that all project costs, except incidental costs related to the creation of the final report (for example, photocopying or binding) are incurred or obligated by the project end date. For information about cost transfers, consult Process Current Cost Transfers for Sponsored Projects or Process Non-Current Cost Transfers for Sponsored Projects.
- Promptly remove cost overruns (overdrafts) if no additional funding is expected from the sponsor.
- Notify your campus GCO of issues with the sponsoring agency that would prevent collection of any outstanding accounts receivable.

What To Do AFTER Project End Date

The closeout process starts with the project end date. Within the next 45 to 60 days, the **Principal Investigator (PI)** and **Unit Business Office** are expected to do the following:

- Remove all costs incurred outside the performance period, except allowable pre-award costs.
  - Generally, "pre-award" costs are allocable to the time period of the forthcoming new or competing continuation award and may be incurred up to 90 days prior to the beginning date of the project or budget period in accordance with the sponsor's guidelines. Also, pre-award costs must be adequately justified to indicate that advanced funding is necessary for the effective and economical conduct of the project, and must be allowable under the terms of the forthcoming award.
  - Post-award or after-term charges that are deemed non-applicable or unallowable must be transferred off to an appropriate funding source.
- Remove cost overruns (overdrafts) within 45 days after the project has expired to allow for submission of the federal financial report no later than 90 days after the project end date. Overdrafts must be transferred to an unrestricted funding source.
- Remove costs resulting from sponsor disallowances, or other unallowable costs per the terms of the award—as advised by your campus GCO sponsored award contact.
- Review open obligations (encumbrances/purchase orders/payroll commitments), and ensure that they are liquidated, cancelled, or moved to other appropriate funding sources.
- Confirm that all subrecipients have completed their scope of work, including all required deliverables, and submitted their final billing according to the terms of their agreement.
- Ensure that all project costs have been recorded. Process final expenditures per the due date of a final bill or financial report to allow for timely submission of the bill or report, as indicated in the following table.

If Sponsor Final Billing/Closeout Is Required	Then, Final Submission of Expense Transactions Is Due
30 days after project end date	15 days after project end date
60 days after project end date	30 days after project end date
90 days after project end date	60 days after project end date

- Validate final expenditure report prior to submission of final invoice or federal financial report.

- Prepare and submit the final technical report and/or deliverables to the sponsor.
- Submit form listing invention disclosures, or indicate that there were none.
- Submit a final inventory of federally-funded equipment, if any.
- Submit, for federal projects, an accounting of unused expendable supplies (including expensed equipment) with an aggregate value of $5,000 or more, as applicable.
- Provide your campus GCO an accounting of program income or cost share commitments, as applicable, if these items are not tracked centrally on your campus.