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Overview

The application submission <u>checklist</u> is intended to help the Principal Investigator (PI) and his/her team submit the application to the Grants and Contracts Office (GCO) outlining procedure steps and best practices along the way. It incorporates relevant technical (InfoEd), administrative, budgetary, and compliance (PPHS/IACUC) policies and procedures that the PI and his/her team need to follow in order for the GCO to review and approve the application.

GCO Application Submission Process

Most research* and sponsored project applications are prepared in InfoEd and routed for approval through the department(s) in which there are key personnel each year of the project. There are very limited exceptions:

Exception to InfoEd Submission – BRANY Projects

Do not submit the project to the GCO if BRANY serves as the IRB and also negotiates the clinical trial agreement on behalf of Mount Sinai.

Exception to Yearly Submission – Expedited IRB Projects Without External Sponsored Project Funding If the IRB has provided a three year approval and there is no external sponsored project funding (ISMMS, industry clinical trials negotiated by FACTS, and cooperative trial research projects), GCO submissions will also only be required every three years.

Once the department(s) approves, the application is then routed to the GCO for review and approval. Even if the extramural funding agency does not require an institutional signature, all proposals must be submitted through InfoEd and reviewed and approved by the GCO prior to submission to the agency. The application must be submitted in InfoEd each year prior to the budget period end date. When final reports are due to the extramural agency after the project end date, you may submit the InfoEd final report after the project expires.

Although the PI must approve/sign off on the InfoEd application, he/she may delegate editing and entering information into the InfoEd proposal.

The PI is also responsible for submitting the application to the extramural funding agency unless the technical or funding agency requirements are such that GCO must submit the application. GCO must submit all Federal electronic applications (e.g., NIH grants, NSF grants) directly. In those cases, the PI submits to the GCO and the GCO approves and routes it onward to the extramural funding agency.

If a person participating in your project is both <u>non</u>-key personnel and faculty, please designate him/her as "key personnel" in the InfoEd Personnel tab and include a note in the Internal Documents tab instructing the GCO to change the person's status to "non-key personnel." By doing so, you will properly route the application to the person's department for review and approval.

<u>InfoEd Proposal Development (PD) and Proposal Tracking (PT): Submission and Sponsored Project</u>
Management Software System

InfoEd is the software program ISMMS uses to internally route and manage all research and sponsored project applications.

InfoEd is also used to submit competitive, NIH single project applications (e.g., New R03, Resubmission K08, Competitive Renewal R01) and other federal sponsored projects (e.g., New DOD grant) electronically to these agencies. In these cases, these applications are called "System to System Submissions" or "S2S." InfoEd is the system used to transmit the application directly to the sponsor.

All other applications are called "Non System to System Submissions" or "non-S2S." The system is used internally at ISMMS only and not to submit the application to the extramural funding agency. Examples of non-S2S applications are NIH multi-project applications (e.g., New P01, Resubmission P30), NIH annual RPPR applications, fellowships from a private foundation, and projects without external funding. Although many funding agencies use electronic submission systems, InfoEd is <u>not</u> used to transmit their applications directly to them.

<u>Sinai Central: Conflict of Interest (COI) and Suspension and Debarment (S&D) Forms</u>
Sinai Central is the electronic software system that is required for personnel to create and sign off on COI and S&D forms.

COI forms are required for all research applications except final reports regardless of funding source. All investigators sign the form. Federal COI regulations require that all Investigators must submit COI disclosures. An investigator is defined as someone responsible for the design, conduct or reporting of the study. ISMMS' policy is that the following personnel always meet this definition:

- PI
- Key Personnel
- Anyone with a role that includes the word Investigator (Example: Sub-Investigator)
- Primary Mentor on a Fellowship or Mentored Career Development Award
- Faculty Personnel, either key or non-key (with some very limited and well documented exceptions where the non-key faculty is not engaged in the research)

Other ISMMS personnel may meet the Investigator definition. ISMMS leaves the following to the discretion of the PI:

- Other Significant Contributor
- Consultant
- Non-faculty, non-key personnel

Please consider the role, rather than the title, of those involved in research and the degree of independence with which those individuals work. When the definition of investigator is limited to titles or designations (e.g., to principal investigators, key personnel, faculty), the risk increases of an unidentified FCOI that may compromise the research enterprise.

S&D Forms are only required for projects in which the funding source is the Federal or State government. This could be when ISMMS is a subaward on another institution's NIH grant. Another example is when ISMMS receives funds directly from the NIH. Sinai Central will automatically require completion of the S&D Forms when Federal sources are selected as sponsors when the form is set up. All key personnel sign the S&D form.

Technical (InfoEd) Instructions

1. <u>Required Course</u> and <u>Training Policy</u>: Did the person(s) preparing the InfoEd application attend the required proposal development module course?

All new users, who will create or edit InfoEd proposals, are required to attend the InfoEd Proposal Development module prior to gaining access to the program. If the PI will not create or enter information into the application, PIs are encouraged but not required to attend the class.

If it is not possible for the new user to attend the class, he/she may assign a delegate, who has already attended the training, or the department's InfoEd administrator must take responsibility for training and supporting the new user.

In the case of either a PI or a user opting out of the course, please follow these instructions and use this suggested language. Open an InfoEd Ticket and from the "Help Topic" drop down menu, select "InfoEd / New User Request." In the "Issue Summary" field, please adapt the suggested language, "The PI, Dr. XX, will not attend InfoEd Required Training. The PI delegated the contact person in the above form to edit and create his/her proposal. I understand that Research IT can support the delegate (i.e., obtain assistance via the Research IT ticket system) but not the PI until he/she has attended the class." You do not need to open a ticket each time you submit an InfoEd application on behalf of the PI or user who did not attend the course. One time completion is sufficient.

Do not confuse enrolling new users in this course with adding new ISMMS personnel who are participating in your project into the InfoEd Personnel Pick List. See Q. 4 for further information.

2. PI Access: Does the PI have access to InfoEd?

The PI must have access to InfoEd to approve and submit the proposal even if he/she is not preparing the details of the application in InfoEd. In order to gain access to InfoEd, he/she can opt out of attending the InfoEd class. To request access, open an InfoEd Ticket and from the "Help Topic" drop down menu, select "InfoEd / New User Request." In the "Issue Summary" field, please adapt the suggested language, "Please allow the PI, Dr. XX, access to InfoEd. He/she has not attended the InfoEd Required Training. In addition, please delegate [name of person] and give him/her the ability to edit and create my proposals and make sure they are added to all the communications generated through InfoEd. I understand that Research IT can support the delegate (i.e., obtain assistance via the Research IT ticket system) but cannot support the PI until the PI has attended the class."

3. <u>Delegate New User</u>: Does the PI need to delegate anyone new to edit and view his/her proposal?

The PI can delegate any new staff or existing users to edit and view proposals on his/her behalf. Follow the <u>Delegate New User</u> instructions. In addition, click on the "BatchComms" button so the delegate can receive all communications sent via InfoEd.

The delegate can now see and edit all of the PI's protocols and proposals in InfoEd, including creating new proposals for the PI. However, delegates cannot sign off on InfoEd submissions. Only the PI can complete the "finalize" tab in InfoEd to approve and submit.

Alternatively, Research IT can add a delegate to the Pl's account. To do so, open an <u>InfoEd Ticket</u> and from the "Help Topic" drop down menu, select "InfoEd / Other." Request that the delegate receives editing access and all communications (e.g. "Batchcomms") sent via InfoEd.

4. Personnel: Would you like to save time by entering fewer personnel in the Personnel tab? Are there <u>new</u> personnel participating in your project that you need to add to the InfoEd Pick List?

You can data enter each person participating in your project individually or follow the shortcut instructions below. These instructions do not replace InfoEd's technical how to instructions on completing the Personnel tab. They are meant to clarify the personnel that the GCO requires on this tab.

- a. <u>Determining Personnel to Data Enter on Personnel Tab</u>
 - For applications that do <u>not</u> require a budget tab, you can omit non-key personnel, TBN positions, and consultants. Please review section "<u>17. Budget tab on InfoEd</u>" for the types of projects that do <u>not</u> require a budget tab.
 - For projects with subawards, always include the Subaward PI. Please review the "17.
 Data Entry on InfoEd Budget and Personnel tab" in GCO's Memo <u>Documentation and Instructions for Sponsored Projects with Subawards When ISMMS is the Prime Institution for further instructions.</u>
 - For non system to system applications, you can omit Other Significant Contributors. For example, if you have an OSC on a NIH non-competitive application (i.e., RPPR) you can leave him/her off the Personnel tab.

b. Adding New Personnel to the Personnel Tab

After determining that you need to add the individual to the Personnel tab (see 4a. above), the next step is to check if he/she is already included in the InfoEd Pick List. If the person is not included, please create an InfoEd ticket by clicking on the appropriate link below as soon as possible. Turnaround time for adding new personnel is typically 2-3 business days. To avoid submission delays, please check to see if the individual is already in the Personnel Pick List as soon as possible.

[] i. New Personnel at ISMMS - After clicking on link, select "InfoEd / New Personnel Request" from the "Help Topic" drop down menu, and complete form.
 [] ii. New Personnel at Sub-Awardee Institution - After clicking on link, select "InfoEd / New Subaward/Consultant Request" from the "Help Topic" drop down menu, and complete form.
 [] iii. New Consultant - After clicking on link, select "InfoEd / New Subaward/Consultant Request" from the "Help Topic" drop down menu, and complete form.

Do not confuse adding new ISMMS participating personnel into the InfoEd Personnel Pick List with the requirement of enrolling new users in the InfoEd Proposal Development module. See Q.1 above for further information.

5. New Extramural Funding Agency: Do you need to add the agency to the InfoEd database?

To avoid submission delays, check the sponsor list as soon as possible in the InfoEd Setup Questions tab of your proposal to determine whether you will need to add the agency. If the agency is not included in the list, please add the agency by creating an InfoEd ticket for a New Funding Agency Request. After clicking on link, select "New Funding Agency Request" from the "Help Topic" drop down menu, and complete form. Turnaround time is typically 2-3 business days.

6. Correct InfoEd Set Up/Instructions: Have you reviewed the InfoEd instructions for completing the tabs?

Administrative Instructions

7. Deadlines: Do you know when the sponsored project is due?

Manage your project deadlines by tracking when the application and other documentation are due to the Sponsor, the GCO and your Department. Note when holidays impact the deadlines.

a. Extramural Funding Agency (not applicable to research projects without external funding) This date is fixed with almost no exceptions. This date is the starting point for determining the GCO and Departmental deadlines.

b. Grants and Contracts Office

The GCO must be in receipt of the <u>COMPLETE AND FINAL</u> proposal, including completed and signed Sinai Central Conflict of Interest and Suspension and Debarment forms as appropriate, by these deadlines. Routing the application through the departments for approval occurs before GCO receipt.

Application Type	Deadline
ISMMS Sponsored Projects	1 Business Day
Federal Non-Competitive Applications	2 Business Days prior to extramural funding agency deadline
Federal Competitive Grant and Contract Applications	5 Business days prior to extramural funding agency deadline by 11 am
All other sponsored project applications**	1 Business Day prior to extramural funding agency deadline

]	Expedited Human Subject Research Without External Funding (e.g., ISMMS, industry clinical
	trials negotiated by FACTS, and cooperative trial research projects), are due to the GCO
	every three years.

[] All other research and sponsored projects are due to the GCO annually.

c. Department

Please check with the departmental administrator or assigned contact person for any additional information on departmental deadlines and processes. Also, determine if any key personnel or faculty are affiliated with other ISMMS departments and plan more time for the routing and approval process. See Overview section for including a person who is non-key and faculty on your InfoEd submission.

Forms

- 8. InfoEd eForm: Have you added the upcoming year's Investigator Form (IF) # to the eForm entitled "New/Comp Renew/Resub" or "Non Comp/Supp/NCE"?
 - Copy the IF # from the Sinai Central Investigator Form (IF) in Sinai Central...

• ... and paste into the "Eform" in your InfoEd application.







9. Sinai Central Investigator Form (IF) and Conflict of Interest (COI) and Suspension and Debarment (S&D) Forms

Log In Site I Instructions for Completing IF -- COI -- S&D I

Have you created the Investigator Form? Are you checking that the appropriate persons have signed the generated COI and S&D forms? Do they know how to sign them?

a. Creating: Have you created the IF?

To create a new IF, go to:

<u>Log In Site</u> > GCO <u>or</u> COI > Investigator Forms > New Investigator Form

When a new Investigator Form is created, it will be given an "IF ID Number". Please insert this IF # into the "General Information Section" located at the top of the eForm.

b. Signing: Do the persons who need to sign the COI and S&D forms know how?

Once the user enters personnel on the IF, each person listed is automatically sent an e-mail notification to sign the appropriate form(s). To complete the COI and S&D forms, the project personnel can click on the link provided in the e-mail or access the form at this site:

Log In Site > GCO or COI > Investigator Forms > List Forms > Forms I Have to Complete > page icon:

If the status in the "Forms I Have to Complete" section is "Draft" or "Not Started," please complete the form(s). If the status in the "Forms I have to Complete" section is "Submitted," you have completed the form and no further action is necessary.

c. Tracking: Are you tracking to make sure everyone signs so your project is not delayed at the GCO? The person preparing the form(s) can track if all the form(s) have been completed by checking the status on Sinai Central.

To track the form(s), go to:

<u>Log In Site</u> > GCO <u>or</u> COI > Investigator Forms > List Forms > Forms I Manage Once the project status has been updated to "With GCO Coordinator," all forms have been completed and no further action is necessary. If the project status is "In Preparation," check to see who has not completed the form and follow up with him/her.

Incomplete Sinai Central forms result in delays of review of your application at the GCO. Set up Investigator Forms in Sinai Central as soon as possible to allow time for completion. See the Instruction links for additional IF, COI, and S&D information.

10. CITI COI Education Module: Have you checked to make sure all the investigators completed this training?

The completion date will for each individual will be listed next to their name as "FCOI Education Certifications XX/XX/XX" on the Investigator Form. Please see the example below. One month prior to the training expiration, the training date will also appear in red. The investigator also receives a notification from the Conflict of Interest (COI) Office to renew this training.



Individuals who have not completed the COI education module, can complete at this site:

https://www.citiprogram.org/members/index.cfm?pageID=50 > Log in through my Institution > View Courses > Add a Course > Choose FCOI > Submit > Start Now

Additional CITI instructions from the COI Office are added to the end of these instructions as an addendum.

As of 5/18/20, this training course has transitioned from PEAK to CITI Program. In the CITI Program site, be sure to add your Mount Sinai email address and life number to your institutional profile so that your certification date gets added to your project in Sinai Central (see screenshot above). If your COI training module that you had taken in PEAK has <u>not expired</u>, you <u>do not need</u> to take the training in CITI. For any questions or concerns, please contact the Office of Industry Engagement and Conflicts of Interest at Conflicts.of.Interest@mssm.edu or (212) 241-0845.

Completion of the COI education module is mandatory for all ISMMS investigators.

11. Sinai Central Annual COI Forms: Have you checked to make sure all the investigators completed these forms?

The completion date will for each individual will be listed next to their name as "COI Annual Forms" on the Investigator Form. Please see the example below.



Individuals who have not completed the annual COI form, can complete at this site: http://sinaicentral.mssm.edu > COI > Annual Report of Outside Relationships

Completion of the COI Annual Report form is mandatory for all ISMMS investigators.

Additional Documentation

12. Subawards – ISMMS as <u>Prime</u> Institution: Are you submitting a sponsored project with a subaward and does the subaward know what documentation to submit to you?

Finalize plans for subawards as soon as possible and obtain the required documentation. Please refer to GCO's memo entitled "<u>Documentation and Instructions for Sponsored Projects with Subawards When ISMMS</u> is the Prime Institution."

13. Subawards- ISMMS as <u>Subawardee</u>: Are you part of another institution's sponsored project as a subaward and do you know what documentation to submit to them?

Please refer to GCO's memo entitled "<u>Documentation and Instructions</u>: <u>ISMMS as a Subaward on a Sponsored Project Application</u>" as well as the instructions you receive from the prime institution for additional requirements.

14. Extramural Funding Agency Specific Requirements and Instructions: For non-S2S competitive submissions, have you uploaded these documents into the Internal Documents tab of your InfoEd proposal?

It is useful and may speed up GCO review if you upload non-S2S extramural funding agency specific requirements and instructions into the Internal Documents tab of your InfoEd proposal or include a document with the agency links to these documents. Funding agency specific requirements and instructions for S2S applications (e.g., new NIH R01, resubmission R21) are already included in the InfoEd Setup Tab.

15. Approvals/Routing to GCO: Are you checking the InfoEd routing queue making sure all the department(s) sign in a timely manner, especially for submissions with key personnel from 2 or more departments?

After the PI has finalized his/her application, please check the approval routing queue by clicking on the paper scroll icon located to the right of "Components for Initial Application" heading in the Internal Documents tab of the InfoEd application. It is especially important to check that the required signatories have signed when there are key personnel from 2 or more departments. Please allow adequate time for this process.

Budgetary Instructions

16. Departmental Requirements: Have you checked with your department for their requirements?

Please check with a departmental administrator for any additional requirements.

17. Budget Tab on InfoEd: Would you like to data enter less budget information?

For S2Ss, InfoEd is used to submit NIH and other federal sponsored projects to these agencies directly. On S2S applications you need to enter more budget details because InfoEd exports this information into the grants.gov SF 424 agency forms which are submitted to the extramural funding agency. The agency requires this information on their forms.

For non-S2Ss, InfoEd is used internally at ISMMS only. Less information is needed on the InfoEd budget tabs.

Do not complete the InfoEd budget tab for the following projects:

- ISMMS funded
- Projects in which the extramural funding agency provides funding by milestone (i.e., per subject or per sample) payment. Examples are pharmaceutical sponsored multicenter clinical trials, NIH CALGB protocols or biotech companies paying per sample.
- No cost extensions

In the InfoEd Setup Questions tab, you would choose "Non-S2S, no budget." By doing so, you will not have an option to complete a budget tab.

For projects that require a budget, you can data enter the direct cost budget in the "Budget Items" tab in its entirety or follow the shortcut instructions below. Always complete the "F&A" tab. These instructions do not replace InfoEd's technical instructions on completing the Budget Items tab. They are meant to clarify the budget information that the GCO requires on this tab.

a. <u>Non-Federal Competitive</u> (Non-S2S) Projects
 Examples: New foundation grant, new NYSDOH grant

Enter budget for Y1 only into the InfoEd budget tab.
 GCO does not require data entry of future years in InfoEd at the time of initial submission. If funded, you will enter budgets for future years as part of your future progress report submissions.

Please continue to include the entire project period date (not Y1 only) in the Set Up question tab.

- ii. Enter budget as follows:
 - Personnel

In Budget Items > Personnel Costs, data enter each personnel line individually with % effort, base salary (for key personnel only), salary requested, and fringe benefits.

- Non- Personnel Costs

In Budget Items > Non-Personnel Costs, all other direct costs can be added in a <u>cumulative</u> <u>sum</u> in Other Costs> label as "non-personnel costs."

For example, if your budget includes a consultant for \$5,000, travel costs for \$1,000, and supplies for \$2,000, enter \$8,000 in Other Costs and label this as "non-personnel costs."

- iii. For projects with subawards, refer to the GCO memo entitled "<u>Documentation and</u> <u>Instructions for Sponsored Projects with Subawards When ISMMS is the Prime Institution</u>" for instructions on entering the subaward budget (p.9).
- b. Non-Federal Non-Competitive (non-S2S) Projects

Example: 2nd year of a 4 year grant from a private foundation.

Enter budget for the upcoming year by major cost category only. Follow instructions in 17a. above. It is the same data entry as a non-federal competitive project.

- Federal Competitive Detailed Budget/Non Modular (S2S) Projects
 Examples: Competitive Renewal NIH R01 in which the budget is greater than 250,000 in DC each year, New DOD grant, Resubmission NSF grant
 - i. You must enter the complete detailed budget for each year as per the budget instructions in the <u>SF424 Guide</u>. For all competitive sponsored projects where the Federal agency requires detailed budgets, the InfoEd program will export the data you entered and populate the Federal SF424 budget forms.
 - ii. For projects with subawards, refer to the GCO memo entitled "<u>Documentation and</u> <u>Instructions for Sponsored Projects with Subawards When ISMMS is the Prime Institution</u>" for instructions on data entering the subaward budget (p.9).

d. NIH Competitive Modular (S2S) Projects

Examples: Competitive Renewal NIH R01 in which the budget is 250,000 or less each year, New R21, Resubmission R03

- i. Enter budget for all project period years in the categories below.
- ii. Enter each Personnel line individually with % effort, base salary (for key personnel only), salary requested, and fringe benefits.
- iii. Enter one cumulative amount combining these costs as follows:
 - Consultants
 - Travel
 - Supplies
 - Other Costs

These direct costs can be added in Other Costs> label as "non-personnel costs." All non-personnel costs that are not excluded from F&A can be entered in one cumulative sum.

For example, if your budget includes a consultant for \$5,000, travel costs for \$1,000, and supplies for \$2,000, enter \$8,000 in Other Costs and label this as "non-personnel costs." Please remember that you still need to enter the consultant's name in the Personnel tab of InfoEd.

- iv. Enter each of these costs individually, as follows:
 - Equipment
 - Equipment Software (greater or equal to \$1,500 and non-renewable)
 - Genomic Arrays
 - Patient Care Costs (choose outpatient or inpatient)
 - Tuition & Fees

These costs are excluded from F&A. They must be itemized as specified above for the InfoEd program to correctly calculate F&A. For projects with genomic arrays, you will need to manually enter the F&A rather than use the automatic calculation feature.

- v. Enter each of these costs <u>individually</u>, as follows:
 - Graduate student direct compensation
 - Graduate student health insurance

If there are graduate students participating on your project, do not enter salary and fringe amounts. Do enter costs as noted above. Please remember that you still need to enter the graduate student's name in the Personnel tab of InfoEd.

vi. For projects with subawards, refer to the GCO memo entitled "<u>Documentation and</u> <u>Instructions for Sponsored Projects with Subawards When ISMMS is the Prime Institution</u>" for the instructions on data entering the subaward budget (p.9).

e. Federal Competitive / NIH ASSIST Projects (non-S2S) Projects

Examples: new P01 grant, competitive renewal P50 grant

i. Enter budget for Y1 only.

GCO does not require data entry of future years in InfoEd at the time of initial submission. If funded, you will enter budgets for future years as part of your future progress report submissions.

Please continue to include the entire project period date (not Y1 only) in the Set Up question tab.

- ii. Add Personnel and Budget items in each subproject folder and not in the overall personnel or budget tabs. Please download InfoEd's <u>instructions</u> on "Program Projects" in "Essentials for All InfoEd Users."
- iii. Follow instructions in 17d. ii vi above.
- iv. Label each cost beginning with Project / Core Name. Example: "Core A: All Other Direct Costs." In this example, this could include Consultants, Travel, Supplies, and Other Expenses. See 17.d.iii.
- f. Federal Non-Competitive (non-S2S) Projects

Examples: Y2 of NIH R21, Y3 of NIH P01, Y4 of NIH R01

Enter budget for the upcoming year. Follow instructions in 17d. ii – vi above.

g. <u>ISMMS as the Subawardee: All</u> (non-S2S) Projects

Examples: ISMMS is a Subaward on a Grant that another Institution is submitting to the NIH; ISMMS is a Subaward on a Grant that another Institution is submitting to a Foundation

When the funding source is non-federal and the sponsored project is competitive, follow instructions 17a. above. For non-competitive applications, follow instructions 17b. above.

When the funding source is federal and the sponsored project is competitive, follow 17c., d., or e. as appropriate. For non-competitive applications, follow instructions 17f. above.

Budget entry instructions are also included in the GCO memo entitled "<u>Documentation and</u> Instructions: ISMMS as a Subaward on a Sponsored Project Application" (p.7).

18. Base Salary Verification for all Personnel: Did you verify base salaries with a departmental administrator prior to finalizing your budget?

Please check with a departmental administrator or assigned contact person in your department for additional information.

Including incorrect base salaries on your budget will lead to delays in departmental InfoEd approval.

19. Cost Sharing and Documenting VA Effort Commitment: Will there be cost sharing? Are there VA employees working on the project for which you need to document VA effort commitment?

a. Cost-sharing

Cost sharing occurs when a departmental or unrestricted fund account covers a project cost rather than the sponsored project budget. Examples of cost sharing are: 1. An ISMMS investigator contributing effort but his/her salary will be charged to an unrestricted account rather that the grant budget; 2. a piece of equipment that a department purchases in order for the PI to conduct the study rather than the PI requesting the equipment funds on the grant budget. Please consult the cost sharing policy for complete information.

Upload the signed form, if applicable into the Internal Documents tab of your InfoEd proposal.

b. Documenting VA Effort Commitment

Please read GCO's memo "Budgeting for an ISMMS Faculty Member with a VA Appointment" for complete information. If applicable, please obtain approval from the appropriate JJPVAMC administrative officer confirming that VA funds will cover the cost of employees' effort or other than personnel expenses rather than the sponsored project budget.

Sample VA administration approval: I approve Dr. Smith working 5% effort on Dr. White's NIH study entitled "Multigenerational Effects of Undernutrition."

Please upload this approval into the Internal Documents tab of your InfoEd Application.

Compliance (PPHS and IACUC) Instructions

20. Regarding submitting your compliance application to the PPHS and/or IACUC, check whether you are submitting every year or every three years to these offices. Failure to submit your compliance application will result in delays of review of your InfoEd application at the GCO.

Sponsored Projects

21. For non-NIH new, competitive renewal or resubmission projects, have you submitted the compliance application to the appropriate compliance office <u>or</u> completed the <u>compliance waiver</u> and attached it in the Internal Documents tab of your InfoEd proposal?

Projects that involve human subjects and/or animals require PPHS/IRB or IACUC approval respectively.

If you choose <u>not</u> to submit the internal compliance application prior to submitting your InfoEd application, you must complete this <u>compliance waiver form</u> instead.

22. For NIH new, competitive renewal or resubmission projects, the NIH has a "Just in Time" policy and you do not need to submit a compliance application or a waiver at this time. You will need to complete compliance paperwork "Just in Time" at a later date only if the NIH notifies you that your project is in the fundable scoring range after peer review. The waiver form is <u>not</u> required for NIH competitive grants.

If this a non-NIH new, competitive renewal or resubmission project funded by an agency that has a policy like the NIH's, this means that the funding agency that has a two-step review process that allows for a "just in time" review by the ISMMS compliance committees at a later date. You do not need to submit a compliance application or a waiver at this time.

Submitting a compliance waiver to the GCO with your InfoEd application is not an option for the following projects.

- ISMMS Sponsored (i.e., no external funding source)
- Industry Sponsored Projects (unless it is a competitive, peer reviewed application)
- Transfer, non-competitive and no cost extension applications

Also, for delayed on-set studies where human subject or animal activities are scheduled to begin after a period of funded protocol development please include a memo explaining the timeline rather than the waiver with your InfoEd application.

Helpful Links

<u>Administrative Information Sheet</u> includes budgeting and other institutional information

Application Submission Checklist

External Electronic Submission Systems that Require User Registration through the GCO

Grant Application Resource Center

Grants and Contracts Office (GCO)

InfoEd Log In Site | Instructions | Ticketing System

Institutional Animal Care and Use Committee

Program for the Protection of Human Subjects

Research Roadmap

<u>Sinai Central Log In Site</u> | Instructions for Completing | F -- COI -- S&D Forms |

Highlights of Significant Changes to this Document from Previous Versions

Section	Description of Change	Other
6/20 version		
10. CITI COI Education module	As of 5/18/20, the COI training education	
	module has moved from PEAK to CITI.	

2/20 version				
Overview		Added new GCO submission policy for		
		expedited human subject research projects		
		without external funding (i.e., ISMMS,		
		industry clinical trials negotiated by I	FACTS,	
		and cooperative trial research project	cts).	
7. Deadlines		Incorporated above policy.	,	
20. – 22.Compliance sections		Updated due to new GCO and PPHS		
		submission policies.		
6/18 version		- Commission positions	I	
Overview		Renumbered document steps.		
2. PI Access		Added PI access step separating it from	the	
		previous step.		
11. Sinai Central Annual COI Requiren	nent	Added Sinai Central Annual COI Require	ment.	
10/17 version			1	
Overview		Clarified BRANY projects in GCO submiss	sion	
		policy.		
1. InfoEd Training Requirement		Removed language regarding superuser and		
		delegate		
15. Budget Tab on InfoEd		Added language regarding projects fund	led by	
		milestone payments not requiring InfoEd		
		budget data entry.		
8/17 version		1	ı	
3. Personnel		Revised section on data entry shortcuts.		
8/16 version			•	
9. Sinai Central COI Education Module	9	Updated certification process as per current		
		COI Office policy.		
6/16 version		T		
Overview > GCO Application Submissi	ion	Added clarification of "BRANY projects" in		
Process		applications that are submitted to the GCO.		
3. Personnel	·r .	Revised section on data entry shortcuts.		
17. Cost Sharing / Documenting VA ef	fort	Renamed and added link to GCO's Memo		
commitment		"Budgeting for an ISMMS Faculty Member with a VA Appointment"		
19. Applications that require a		Added more application types		
corresponding PPHS or IACUC submis	sion	Added more application types		
12/15 version	31011	1		
15.d.iv. Budget Tab on InfoEd for NIH		Changed unit cost from \$500 to \$1,500 for		
Modular (S2S) Competitive Projects		equipment software.		
7/15 version		-4. 1	<u> </u>	
·		oved "New NSF grant" as an example of	While PIs can	
Development (PD) and Proposal		federal projects that PIs submit S2S.	submit new	
Tracking (PT): Submission and		• •	NSF grants S2S,	
Sponsored Project Management			GCO	
Software System			recommends	
			NSF Fastlane	

		and submitting non-S2S.
Administrative Instructions > Sinai	Added links to the IF, COI, and S&D	
Central IF and COI and S&D Forms	Instructions	
Compliance (PPHS and IACUC) Instructions	 Added "transfer" applications as a type of submission where the compliance waiver cannot be used. Changed "Industry Sponsored Clinical Trials to all "Industry Sponsored Projects (unless it is a competitive, peer reviewed application)" as a type of submission where the compliance waiver cannot be used. Added new information about 1) agencies with a two-step review process 2) delayed onset studies. 	

^{*}For purposes of application and registration with the GCO, research is defined as systematic investigation designed to develop or contribute to generalizable knowledge. Activities meet this definition, even when the overall purpose is not primarily research, but may include training, demonstration, or service programs.

^{**}Please contact your assigned Grants Specialist in advance regarding any additional time the GCO may need in the review and approval process if you are applying for a sponsored project with complex budgetary and/or administrative requirements (e.g., non-federal application with many subawards, international extramural funding agency application with nonstandard budget forms).

CITI Instructions

As of May 18, 2020, the Financial Conflicts of Interest in Research training course has transitioned from PEAK to CITI Program (www.citiprogram.org). In the CITI Program site, be sure to add your **Mount Sinai email address** and **life number** to your institutional profile so that your certification date gets added to your project in Sinai Central. For any questions or concerns, please contact the Office of Industry Engagement and Conflicts of Interest at Conflicts.of.Interest@mssm.edu or (212) 241-0845.

How to Sign In?

Visit: https://www.citiprogram.org

If you need to create a new account:

- 1. Click **Log In** (top right of the window)
- 2. Click "LOG IN THROUGH MY INSTITUTION"
- 3. Scroll and select "Icahn School of Medicine at Mount Sinai"
- 4. Type in your Mount Sinai Email Address and Password
- 5. Select "I don't have a CITI Program account and I need to create one."
- 6. Click "Create a New CITI Program Account"
- 7. Watch video

If you already have a CITI account:

- 1. Click **Log In** (top right of the window)
- 2. Click "LOG IN THROUGH MY INSTITUTION"
- 3. Scroll and select "Icahn School of Medicine at Mount Sinai"
- 4. Type in your Mount Sinai Email Address and Password
- 5. Select "I already have a CITI Program account."
- 6. Enter your existing Username and Password to link your account to your Mount Sinai Credentials.
- 7. Watch video

To add a new course:

On your Profile page, in the "My Learner Tools for Icahn School of Medicine at Mount Sinai" section:

- 1. Click "Add a Course"
- 2. Scroll to select the relevant topic/course (example: Financial Conflict of Interest in Research)
- 3. Click "Submit"
- 4. Watch video

Important Note:

Please use your Mount Sinai email address, your name recognized by HR, and your Life Number in your Institutional Profile. You can find this by clicking your name on the top right hand corner of your CITI page and by selecting "profile." Under Member Profile, please edit your profile to include your Mount Sinai email address. Scroll down to find the Icahn School of Medicine at Mount Sinai under your "Institutional Profiles." Please select "edit" and ensure your Life Number is associated with this profile.

This is essential to ensure that your record of completion electronically populates into your Sinai Central profile. If Icahn School of Medicine at Mount Sinai does not appear under your institutional profiles, please select "add an affiliation" to add this at this time.