

ISMMS Grants and Contracts Office Application Submission Checklist Instructions

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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

All sponsored project applications and a subset of research applications are prepared in <u>InfoEd</u> and routed for approval through the department(s) in which there are key personnel each year of the project. For an understanding of the terms used in the process, please refer to GCO's <u>Glossary of Common Terms</u>, which is organized in the following sections: Application Types, Award Instruments, Software Terms, Personnel Types, and Other Basic Terms.

All sponsored projects must be submitted through InfoEd and reviewed by the GCO prior to submission to an external funding agency, even those that do not require an institutional signature.

Refer to GCO's <u>Submission, Review, and Approval Process Pictorial</u>, <u>Workflow Submission Diagram</u>, and the corresponding <u>Application Submission Checklist</u> as additional resources. Also, please refer to the <u>InfoEd training requirement policy</u>.

## Sponsored Project Applications

All sponsored project applications are submitted to the GCO. A sponsored project is defined as an externally-funded activity in which a formal written agreement, i.e., a grant, contract, or cooperative agreement, is entered into by Mount Sinai and the extramural funding agency generally after a competitive peer review process.

Other types of projects that are submitted to the GCO are industry sponsored projects in which there typically is no competitive peer review process. Effective 1/1/2024, <u>new</u> industry sponsored clinical trials with no competitive review process are no longer submitted to the GCO. Re: industry sponsored clinical trials with no competitive review process that have already been <u>submitted</u> to the GCO, please <u>do</u> continue submitting the non-competitive applications to the GCO through close out. Industry funding where MSIP signs the agreement and <u>all</u> industry funding that is peer reviewed, including but not limited to SBIR/STTR subawards, continues to require GCO submission and review.

Exception to InfoEd Submission – Do not submit the project to the GCO if this is a Cooperative Research Group project.

Cooperative research group projects are studies where the overall funding is provided by the NIH either directly or through a subaward and then the Institution is asked to carry out multiple individual clinical studies, which do not have separate applications or budgets. The overall funding continues to go through GCO, but the *individual clinical studies* do not require GCO submissions.

### **ISMMS Projects**

These are research projects in which the Icahn School of Medicine at Mount Sinai (ISMMS) is not receiving external sponsored project funding to carry out the associated activities.

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.

All ISMMS projects that do not involve human subjects or vertebrate animals must be submitted to the GCO.

### Exception to InfoEd Submission:

Do not submit the project to the GCO if this is an ISMMS project involving human subject or vertebrate animal research. However, if an ISMMS project requires an endorsement by the GCO (e.g., Data Use Agreement, Study Drug Donation, Confidentiality Disclosure Agreement, etc.), do submit the project to the GCO.

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 <u>all Federal electronic</u> 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.

# InfoEd Proposal Development (PD) and Proposal Tracking (PT): Submission and Sponsored Project 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 <u>single project</u> 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.

# eDisclosure Management System (eDMS) and Conflict of Interest (COI) Disclosures

eDMS is the electronic software system that is required for personnel to create and sign off on COI disclosures. eDMS replaces the Sinai Central IF and COI system beginning April 10, 2023. Investigators update their COI "Disclosure Profile" on an annual basis. All investigators answer "Research Trigger Questions," which are particular questions for the GCO submission. The COI Disclosure profile is then updated with answers for a specific GCO submission.

Answering these "Research Trigger Questions" for all GCO project submissions is required except final reports regardless of funding source. Federal COI regulations require that all Investigators must submit these 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 financial conflict of interest that may compromise the research enterprise.

## Technical (InfoEd) Instructions

Required Course (<u>Peak</u> > Online Courses > Functional > Research > InfoEd Proposal Development: Demo

 and <u>Training Policy</u>
 Did the person(s) preparing the InfoEd application attend the required 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 <u>InfoEd Ticket</u> 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 Administration IT (RAIT) can support the delegate (i.e., obtain assistance via the RAIT 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 participating in your project. 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 Administration IT (RAIT) can support the delegate (i.e., obtain assistance via the RAIT ticket system) but cannot support the PI until the PI has attended the class."

3. Delegate New User: 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.

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 <u>how to instructions</u> on completing the Personnel tab. They are meant to clarify the personnel that the GCO requires on this tab.

- a. Determining Personnel to Data Enter on Personnel Tab
  - 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</u>

<u>Instructions for Sponsored Projects with Subawards When ISMMS is the Prime</u> <u>Institution</u> for further instructions.

- 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.
- For non system to system applications, you can omit non key personnel positions. For example, if you have a named research coordinator or a TBN technician, do not data enter these lines on the Personnel tab. Please review section "<u>17. Budget tab on InfoEd</u> for budget tab data entry instructions.
- 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. <u>New Personnel at ISMMS</u> After clicking on link, select "InfoEd / New Personnel Request" from the "Help Topic" drop down menu, and complete form.
- [ ] ii. <u>New Personnel at Sub-Awardee Institution</u> After clicking on link, select "InfoEd / New Subaward/Consultant Request" from the "Help Topic" drop down menu, and complete form.
- [ ] iii. <u>New Consultant</u> 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 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 <u>New Funding Agency Request</u>. 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 ISMMS supported projects) 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 updated COI <u>Disclosures in eDMS as appropriate</u>, by these deadlines. Routing the application through the departments for approval occurs before GCO receipt.

Application Type	Deadline	Other			
Federal Applications	5 Business days prior to extramural funding agency deadline by 11 am	See important note below.			
All Other Applications	1 Business Day prior to extramural funding agency deadline	See important note below.			
<u>Note</u> : 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., program projects, application with many subawards, international extramural funding agency application with nonstandard budget forms).					
<u>Note</u> : Only a small subset of ISMMS projects must be submitted to the GCO. Click <u>here</u> for more information.					

## 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 <u>Overview</u> section for including a person who is <u>non</u>-key and faculty on your InfoEd submission.

# <u>Forms</u>

- 8. InfoEd eForm: Have you added the eDMS Triggering Event (TE) # to the eForm entitled "New/Comp Renew/Resub" or "Non Comp/Supp/NCE"? See following checklist item for TE creation instructions.
  - Copy the TE # from <u>eDMS</u>
  - ... and paste it into the "Eform" in your <u>InfoEd</u> application.

Setup Questions     Briel Lay Summary     Research or     Program Plan     Personnel     Budget	Setup Questions     Progress Report     Personnel     Classification Codes	Page 1 General Information Section Effective 4/10/23 All Conflicts of interest disclosures will be created and submitted via the new eDisclosure Management System (eDMS).
Classification Codes	Non-Compete Cont / Supplement	Please click eDMS.mountsinal.org to generate a TE Number and enter the newly created TE Number below.
Renewals /	Internal Documents	TE Number (Triggering Event)Effective 4/10/23
Internal Documents	Finalize	IMPORTANT: Enter the TE # exactly as TE####### (TE w/8 digits ex. TE00000000)
Finalize		

9. Creating eDMS COI Triggering Event (TE) and Tracking Investigator Responses
 <u>eDMS Log In Site</u> | <u>Instructions</u> | <u>Training Videos</u> > Online Courses > Functional > Research > eDMS

eDMS - Create and Manage Triggering Events eDMS - Update Your Disclosure Profile: Research, Faculty, and Staff eDMS - Disclosure Overview

The GCO instructions provided here are quick reference only. "Updating COI Disclosures" and "Answering Triggering Questions" are used synonymously. Please review the link to the eDMS instructions and training videos above for complete information.

a. Creating: Have you created the Triggering Event?
 To create a new TE, go to:
 Log In Site > COI > Triggering Events > Create Triggering Event

When a new Triggering Event is created, it will be given a "TE". Please insert this TE # into the "General Information Section" located at the top of the eForm in InfoEd.

**b.** Answering TE questions: Do the investigators who you added know how answer the research trigger questions?

Training Video on Updating Disclosure Profile

Once the PI/Designee enters investigators on the TE, each person listed is automatically sent an e-mail notification asking the investigator to update their "Disclosure Profile" as a function of the research project and to answer the "Research Trigger questions.

To answer the COI research trigger questions, investigators can click on the link provided in the e-mail or access from the eDMS site.

Log In Site > COI > Disclosures > Complete Disclosure Profile Update > Update button

Mount Sinai	eDisclosure Management System	Hello, Rebecca Simms (pi	•	Update Disclosures
Dashboard	COI			Complete Disclosure Profile Update
Disclosures Requests	Certifications Plans Triggering Events Reports	Meetings Help Center		By completing your disclosure profile update you are verifying that all disclosure information is accurate and current to the best of your knowledge.
Action Required	Disclosure Profile for Rebecca Simms (pi)			<ol> <li>Open Research Thiggers: When you are listed as an investigatorico-investigator on a submitted research project. It will display below as an "open research thigger". As part of the review process, you will need to update age.<sup>1</sup> Open research thigger "listed in the table below by clicitory <u>updater</u>. This will bring you to a series of project-specific questions related to disclosed outside financial interests; you answers to these questions are mandatory and will hap determine whether there reserves the provide questions are mainted or the protect the transmitter there </li></ol>
Profile Update	Action Required	Reason		Research Event Type Sconsor Related
	Review disclosure information in the disclosure profile When all disclosure information is current and accurate, click on the Complete Disclosure Profile Update button.	Discloser manually updated the disclosure profile		In the second se
	Review disclosure information in the disclosure profile. When all disclosure information i current and accurate, click on the Complete Disclosure Profile Update button.	<ul> <li>Discloser was added to a research project</li> </ul>		$^{\rm o}$ By checking this box, I certify that all open research trigger information has been updated and provided. All open research triggers must be completed before clicking OK. $_{\rm O}$
	Edit Disclosure Profile			
		3	-	OK Cancel

Once updated, the investigator's profile will be in the No Action Required state.

No Action Required	Disclosure Profile for F	Rebecca Simms (pi)	
Disclosure profile last		Instruction Center	
<b>completed:</b> 3/2/2023	Action Required No actions need to be taken at this time	Reason Discloser's disclosure profile is up-to-date and requires no action	Γ
	Edit Disclosure Profile		

c. Tracking: Are you tracking to make sure all the investigators answered their research trigger questions so your project is not delayed at the GCO?

The person who created the TE and added the investigators can track if the persons added answered the three research trigger questions: 1. Fin. Interest; 2. Inst. Interest; and 3. Foreign Influence. See screenshot below. *Ignore the "Review Status" column. That is for the COI Office.* 

Destroyerd	IACUC	IRB		COI	Sat	fety						
Disclosures R	equests Certifications	Plans Triggering E	vents Reports	Meeting	s Help Center							
OI > Triggering Events > FCO	H Walkthru 1/19/23											
Open	TE1000012	Q. ECOI Wall	thru 1/10	2/23								
	111000012	9.1 COI Wall	(III u 1/13	5/25								
/26/2023	Primary contact: P				55 A1	signed coordinator: P	Medicine at 1	Acunt Sinai				
stimated end date: 1/26/2024	Associated entities:				At	ssociated internal depl	artment or di	vision:				
Created date: 1/19/2023 12:43 PM												
Last modified date: 3/22/2023 11:05 AM					M	anagement Plan:	and an and finance					
Next Stens					1.4	S ruly squee mana	Accelor Later	COND IEN	A series part	0.02)		
Edit Triggering Event	Ogen -	Closed										
Edit Triggering Event	<b></b>	Closed								>		
Edit Triggering Event Activities  Manage Certifications	Open +(	Closed Historical Certifications	History Read-C	Only Certification	a Project Level B	eview				2		
Edit Traggering Event Activities Activities Anage Certifications Assign Coordinator	Current Certifications Project-Level Review	Closed Historical Certifications	History Read-C	Daly Certification	a Project Level R	eview				2		
Edit Triggering Event Activities  Manage Certifications Assign Coordinator Close Triggering Event	Current Certifications Project-Level Review Name	Closed Historical Certifications	History Read-C	Daly Certification Life Number	Role	eview Review Status	Fin, Interest	Inst. Interest	Foreign	2	BIR Smartform Conflic	ts Execute Activity
Edit Traggering Event Activities  Activities  Analyse Centifications  Assign Coordinator  Close Traggering Event	Current Certifications Current Certifications Project-Level Review Name Research centrication for E	Closed Historical Certifications Date	History Read-C Modified Fob 13 17 24 39 EST	Life Number 2110067	s Project Level R Role Human Subjects PI	eview Review Status Clarifications Requested	Fin. Interest Yes	Inst. Interest Yes	Foreign Influence Yes		BIR Smartform Conflic Complete	ts Execute Activity y Activite
Edit Tragaring Event Activities  Activities  Activities  Activities  Coordinator  Close Traggering Event	Current Certifications Current Certifications Project-Level Review Name Research certification for P RE	Closed Historical Cettifications	History Read-C Modified Feb 13 17 24 39 EST Jan (3 13 33 36 EST 2	Life Number 2110067	Role Project Level B Human Subjects PI Principal Investigator	Review Status Clarifications Requested Under Review	Fin. Interest Yes	inst. Interest Yes	Foreign Influence Yes No		BiR Smartform Conflic Complete Incomplete	s Execute Activity y Activite Activite

To track, go to COI tab > Triggering Events > [Search by TE #] > Project-Level Review

Investigators not answering the Research Trigger Questions cause delays in InfoEd application review at the GCO. Create the Triggering Event in eDMS as soon as possible to allow time for investigators to update their Disclosure Profile (i.e., answer the research trigger questions). See the training video links for additional information.

10. CITI COI Education Training: Have you checked in eDMS to make sure all the investigators completed the COI training?

Completion of the COI Training is mandatory for all ISMMS investigators.

Go to COI > Triggering Events > [Search by TE#] > Read-Only Certifications > COI Training Complete

Dastibualu	IACUC	IND	COI	Salety				
Disclosures Req	uests Certifications	Plans Triggering Events	Reports Meetings	Help Center				
COI > Triggering Events > FCOI V	/alkthru 1/19/23							🚱 Help
Open	TE10000129	: FCOI Walkth	ru 1/19/23					
Estimated start date: 1/26/2023 Estimated end date: 1/26/2024 Created date: 1/19/2023 12:43 PM Last modified date: 3/22/2023 11:05 AM	Event type: New or Transfer Primary contact: / Associated entities:			Sponsor Assigned Associat Managen	: Icahn School of Medicine at d coordinator: ed internal department or d nent Plan: v Signed - Management Plan	Mount Sinai	2)	
Next Steps					, eignes management ram	obino tost possitisticipal(e.e		
Edit Triggering Event	Open	Closed						
Activities								
Manage Certifications	Current Certifications	Historical Certifications Histor	y Read-Only Certifications	Project Level Review				
Assign Coordinator	Read-Only Certificatio	ns						
Close Triggering Event	Name	Date Modifi	ed Discloser First Name	Discloser Last Name	Last COI Profile Update	COI Training Complete	Review Status	Determination
	Research certification for	9 Mon Feb 13 2023	17:24:39 EST		Tue Jan 24 21:25:34 EST 2023	Incomplete	Clarifications Requested	
	Research certification for TE10000129	Thu Jan 19	13:33:36 EST 2023 P		Tue Jan 24 21:25:34 EST 2023	Thu Sep 10 11:01:02 EDT 2020	Administrative Review	
	Research certification for NTE10000129	Thu Jan 19	13:09:38 EST 2023 N	No. of Concession, Name	Tue Jan 24 21:25:34 EST 2023	Wed Jul 15 09:18:04 EDT 2020	No Review Required	No Review Required
					√ e	ompleted	X Inco	mplete

Please see the screenshot above. Please review training date. If the COI training is within 4 years of completion, the training is up to date. If the COI training is not up to date or "Incomplete" investigators, please remind investigator to complete at this site:

<u>CITI</u> > Log in through my Institution > View Courses > Add a Course > Choose FCOI > Submit > Start Now

Additional CITI instructions from the COI Office are here.

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 not expired, you do not need 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.

11. Annual COI Disclosure Profile: Have you checked to make sure all the investigators have complete their annual disclosure?

Go to COI > Triggering Events > [Search by TE#] > Read-Only Certifications > Last COI Profile

Dashboard		IACUC		IRB		COI	Safety				
Disclosures	Requests	Certifications	Plans Trig	gering Events	Reports	Meetings	Help Center				
COI > Triggering Events > FC	COI Walkthru 1	/19/23									😯 Helj
Open	T	E1000012	9: FCOI V	Valkthr	u 1/19,	/23					
Estimated start date: 1/26/2023 Estimated end date: 1/26/2024 Created date: 1/19/2023 12:43 PM Last modified date: 3/22/2023 11:05 AM	Eve Prir Ass	ent type: New or Transfe mary contact: sociated entities:					Sponsor Assigne Associat Manager Participation	: Icahn School of Medicine at I d coordinator: ted internal department or dr ment Plan: y Signed - Management Plan -	Vount Sinai	)	
Next Steps								y orgined - inditagement r ian -	como reat pocument par(o.oz	1 000	
Edit Triggering Event		Open	Closed		_						
Manage Certifications	CL	irrent Certifications	Historical Certificat	ions History	Read-Onl	ly Certifications	Project Level Review				
Assign Coordinator	Re	ad-Only Certificati	ons								
O Close Triggering Event	Nar	me		Date Modified		Discloser First Name	Discloser Last Name	Last COI Profile Update	COI Training Complete	Review Status	Determination
	Res	search certification for		Mon Feb 13 17 2023	24:39 EST			Tue Jan 24 21:25:34 EST 2023	Incomplete	Clarifications Requested	
	Res	search certification for P 10000129		Thu Jan 19 13	33:36 EST 202	31		Tue Jan 24 21:25:34 EST 2023	Thu Sep 10 11:01:02 EDT 2020	Administrative Review	
	Res	search certification for N		Thu Jan 19 13	09:38 EST 202	3		Tue Jan 24 21:25:34 EST 2023	Wed Jul 15 09:18:04 EDT 2020	No Review Required	No Review Required
								🗸 Completed			

Please see the screenshot above. Please review last profile update date. Investigators receive an e-mail notifying them to update their "Disclosure Profile" annually. However, if you see it is out date or incomplete, please inform them to update their profile:

To answer the COI research trigger questions, investigators can click on the link provided in the e-mail or access from the eDMS site.

Log In Site > COI > Disclosures > Complete Disclosure Profile Update > Edit Disclosure Profile button

Completion of the COI Disclosure Profile is mandatory on an annual basis for all ISMMS investigators. Resource: <u>Training Videos</u> > Online Courses > Functional > Research > eDMS

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 "Documentation and Instructions for Sponsored Projects with Subawards When ISMMS 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</u> <u>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 <u>instructions</u> 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 (Non-S2S)</u> 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 key personnel line individually with % effort, base salary, salary requested, and fringe benefits.

For non-key personnel costs (e.g., post doc, technician, research coordinator, etc.) enter cumulative dollar amounts as specified below in the "Non-Personnel Costs" section.

## - Non- Personnel Costs

If you have non-key personnel costs, enter the <u>cumulative</u> total of non key personnel salaries in the "Salaries & Wages" line and the <u>cumulative</u> total of non key personnel fringe in the "Fringe Benefits" line.

For example if the cumulative total of your research coordinator and post doc salary is 100,000, enter 100,000 in "Salaries and Wages." If the cumulative total of the fringe is 30,000, enter 30,000 in "Fringe Benefits."

All other direct costs can be added in a <u>cumulative 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: 2<sup>nd</sup> 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. c. <u>Federal Competitive Detailed Budget/Non Modular (S2S)</u> 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

- You must enter the complete detailed budget for each year as per the budget instructions in the <u>SF424 Guide</u> for NIH applications. 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, both key and non key, with % effort, base salary (for key personnel only), salary requested, and fringe benefits.
- iii. Enter one <u>cumulative</u> 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 <u>not</u> 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 individually, 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).
- vii. Data Enter Modular Budget tab. See <u>InfoEd Instructions</u> > Slide 15 and 16.
- e. <u>Federal Competitive /NIH ASSIST Projects</u> (non-S2S) Projects Examples: new P01 grant, competitive renewal P50 grant
  - 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 see instructions on last page of InfoEd's <u>Non S2S Set Up instructions</u>.
- 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. <u>Federal Non-Competitive</u> (non-S2S) Projects
   Examples: Y2 of NIH R21, Y3 of NIH P01, Y4 of NIH R01
   Enter budget for the upcoming year.
   For Personnel costs, follow instructions in 17.a.ii.
   For Non-Personnel costs, follow the instructions in 17d. iii vi. above.
- g. ISMMS as the Subawardee: All (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> <u>Instructions: ISMMS as a Subaward on a Sponsored Project Application</u>" (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 <u>cost sharing policy</u> for complete information.

Upload the *signed* <u>form</u>, if applicable into the Internal Documents tab of your InfoEd proposal.

### b. Documenting VA Effort Commitment

Please read GCO's memo "<u>Budgeting for an ISMMS Faculty Member with a VA Appointment</u>" 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**

### Competitive Sponsored Projects

20. For <u>non-NIH</u> 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.

21. For <u>NIH</u> 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.

<u>ISMMS Supported Projects and All Transfer, Non-Competitive, and No Cost Extension Projects</u> 22. For all <u>ISMMS</u> projects in which a GCO submission is required and for <u>all</u> transfer, non-competitive, no cost extension projects, have you submitted the corresponding compliance application to the appropriate compliance office?

Failure to submit your compliance application to these offices in accordance with their due dates will result in delays of review of your InfoEd application at the GCO.

<u>Additional Information for Non-Competitive and No Cost Extension Projects</u> Regarding submitting a compliance application to the PPHS and/or the IACUC, check whether you are submitting every year or every three years to these offices.

If your project requires PPHS/IRB or IACUC approval for the <u>upcoming</u> year, please submit the applications to these respective offices prior to InfoEd submission. Many projects share the same yearly start and end dates as the GCO / InfoEd submission. In other cases, the PPHS yearly start and end dates are different from the GCO / InfoEd yearly submission dates. In the case that they are not in sync, submission of an upcoming year's PPHS application may be premature. Please check when your IRB approval ends. IRB submissions are submitted generally 8 weeks prior to expiration.

## **Helpful Links**

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

Application Submission Process: Which Applications and Forms Do I Complete First: Sponsored Projects CITI COI Education Module Instructions

<u>eDMS Log In Site</u> I <u>Instructions</u> I <u>Training Videos</u> > Online Courses > Functional > Research > eDMS External Electronic Submission Systems that Require User Registration through the GCO GCO Project Submission Workflow Diagram Grant Application Resource Center Grants and Contracts Office (GCO) InfoEd Log In Site I Instructions I Ticketing System Institutional Animal Care and Use Committee Program for the Protection of Human Subjects Research Roadmap

#### **Highlights of Significant Changes to this Document from Previous Versions**

Section	Description of Change	Other
1/24 version		
All relevant sections	InfoEd instructions and FAQs moved to SharePoin	t
12/23 version		
Overview	Clinical Trials Workflow Process Change	
9. and 11. eDMS	eDMS Training Videos moved to PEAK	
Document-wide	RAIT InfoEd Ticketing System moved to	
	ServiceNow platform	
5/23 version		-
8. eDisclosure Management System	Added eDMS written instructions link	
17d. Modular Budget	Added InfoEd instructions to Modular budget	
	tab.	
4/23 version		
Overview and 8. – 11.	Updated COI software system from Sinai Central	
eDisclosure Management System	to eDMS	
1/22 version		
17. Budget	Added to Federal NCC Non S2S	
	Data enter non key personnel cumulative total on	Non
	S2S submission in the "Salaries & Wages" line and	i
	"Fringe" line in the "Non Personnel" costs section	•
10/21 version	1	1
19. Cost sharing	Updated link	
6/21 version		1
4. Personnel	Data entry of non key personnel on NonS2S	
	submissions is not required.	
17. Budget	Data enter non key personnel cumulative total	
	on Non S2S submission in the "Salaries &	
	Wages" line and "Fringe" line in the "Non	
	Personnel" costs section.	
4/21 version	1	I
7. Deadlines	Updated deadlines	
11/20 version	1	1
Addendum – COI Education Module	Removed and replaced with link to instructions.	
CITI Instructions		

9/20 version		
Overview	Added new GCO submission policy eff. 9/23/20	
	for ISMMS projects.	
20 – 22. Compliance (PPHS and	Updated this section in accordance with new	
IACUC) Sections	GCO submission policy for ISMMS projects.	
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	1	
Overview	Added new GCO submission policy for expedited	
	human subject research projects without external	
	funding (i.e., ISMMS, industry clinical trials	
	negotiated by FACTS, and cooperative trial	
	research projects).	
7. Deadlines	Incorporated above policy.	
20 – 22.Compliance sections	Updated due to new GCO and PPHS submission	
	policies.	
6/18 version		
Overview	Renumbered document steps.	
2. PI Access	Added PI access step separating it from the previous	
	step.	
11. Sinai Central Annual COI	Added Sinai Central Annual COI Requirement.	
Requirement		
10/17 version		
Overview	Clarified BRANY projects in GCO submission policy.	
1. InfoEd Training Requirement	Removed language regarding super-user and	
	delegate	
15. Budget Tab on InfoEd	Added language regarding projects funded by	
	milestone payments not requiring InfoEd budget	
	data entry.	
8/17 version		
3. Personnel	Revised section on data entry shortcuts.	
8/16 version		
9. Sinai Central COI Education Module	Updated certification process as per current COI	
C/1C version	Office policy.	
6/16 Version	Added electrification of "DDANN projects" in	
Uverview > GCO Application	Added clarification of BRAINY projects in	
2 Derconnol	Applications that are submitted to the GCU.	
17 Cost Sharing / Decumenting VA	Revised section on data entry shortcuts.	
offort commitment	"Pudgoting for an ISMMS Equilty Mombor with a VA	
	Appointment"	
19 Applications that require a	Added more application types	
corresponding PPHS or IACLIC	Added more application types	
submission		
300111331011		

12/15 version			
15.d.iv. Budget Tab on InfoEd for NIH	Changed unit cost from \$500 to \$1,500 for	r	
Modular (S2S) Competitive Projects	equipment software.		
7/15 version			
Overview > InfoEd Proposal	Removed "New NSF grant" as an example of	While PIs c	an
Development (PD) and Proposal	other federal projects that PIs submit S2S.	submit nev	v NSF
Tracking (PT): Submission and		grants S2S,	GCO
Sponsored Project Management		recommen	ds NSF
Software System		Fastlane ar	nd
		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)	<ul> <li>Added "transfer" applications as a type of</li> </ul>		
Instructions	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.		