

Office of Sponsored Programs

Research Administration

How to confirm the In Case of Injury (ICOI) Option # with OSP

1. Log in with your Emory NetID to the Electronic Contracts Tracking System (eCTS): <u>https://osp.emory.edu/index.html</u> (click on the middle tile).

2. In the Search field to the right, enter the EPEX proposal ID.

 \rightarrow If no record appears, it may not have routed in EPEX to OSP yet OR check under the "Search Contracts Not Pending" tab at the top left because the record may be in On-hold, Withdrawn, or Completed status.

→If you do not know the EPEX proposal ID, you can also try searching using the PI's name or Sponsor name in the Search field.

	EMORY Research Administration WEB SOLUTION													
ORA Web Servic	ces - Main Menu	OSP - Electronic C	ontract Tracking §	System										Logout
Search Pendin	ng Contracts	Search Contracts No	t Pending											
					How	To Sear	ch Per	nding Contra	icts					
				(The informatio	n below n	epresents the statu	s of Contracts	s as of the close of busines	s on the previous day.)					
Search Contracts: In the search field below, type any word or number related to a Contract.														
		Sort Data Columns	Click the arrow syr	nbols just to the right of	each colu	mn heading.								
		View Contract Deta	ils: On the far-left :	ide of the data table, cli	ck a Contr	act's Proposal ID n	umber.							
		Contact Analysts: C	On the far-right side	of the data table, click a	n Analyst'	s name, type a me	ssage and clic	ck Send Email.						
Search Pending Contracts														
											Sear	ch: 67050		
	Proposal	ID	>	Title	÷	Investigator	÷	Sponsor	\$	School/Department	\$	Status	Analys	st 🔅
000006705	50			ase 2, Multicenter, Open- Ib (AMG 510) in Subje	label	Steuer, Conor Ernst	AMGEN		SOM: HMO: Med Onc Pending		Pending	Daniella Lo	pez	
Showing 1 to from 613 tot	o 1 of 1 entries (f tal entries)	iltered												

This initial page will show you who the assigned OSP Contracts analyst is on the far right.

3. Click on the hyperlinked Proposal ID and a window will pop up with status details and the confirmation status of the ICOI.

A. If confirmed at the time*, the ICOI will be indicated in two places—in the middle of the pop-up window with a "Yes" under Option 1, 2, or 3 and in the Details area in caps with the date confirmed.



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Proposal ID):	School/Department	t:	Award Setup Request ID:					
0000067050		SOM: HMO: Med Onc	AS0000000						
Sponsor:	Title				Status	5:			
AMGEN	20190288: A Ph	ase 2, Multicenter, Op	en-label Study of Sotorasil	o (AMG 510) in	Pendin	g			
Injury Option 1:		Inju	ry Option 2:						
No		No			Yes				
IMPORTAN	T DATES:								
Received by Contract Group:		First Revision Sent	Negotiations Completed	Signed Sent to Sponsor		Fully Executed	File Sent for No	ОA	
25th January, 2022		27th January, 2022	27th January, 2022 -			-	-		
DETAILS:									
Internal contact: legan Sponsor contact: Linda Myers, Imyers02@amgen.com STUDY00003690 01/27/22: SUBJECT INJURY OPTION is #3, Section 11.2 of MCTA 01/27/22: no changes required. Pending budget and IRB approvals and completed eCOI.									

B. If the ICOI has not been confirmed at the time, it is pending confirmation with the sponsor.

-When a contract initially routes to OSP in EPEX, if it is with a sponsor with whom we have a Master Agreement, the OSP Contracts Analyst can confirm the ICOI in eCTS upon completion of their initial intake.

-If the contract is with a sponsor with whom we do *not* have a Master Agreement and the subject injury language in the sponsor's contract template falls within Emory's Subject Injury Policy Options 1, 2, or 3, the OSP Contracts Analyst is able to confirm the ICOI in eCTS upon completion of their initial intake.

-If the contract is with a sponsor with whom we do *not* have a Master Agreement and the subject injury language in the sponsor's contract template does *not* fall within Emory's Subject Injury Policy Options 1, 2, or 3, the OSP Contracts Analyst must redline and negotiate that language with the sponsor until the language falls within one of the options per the Policy and then can confirm in eCTS when they have reached an agreement with the sponsor on that language. If the language must be negotiated, OSP Contracts Analysts generally try to edit the language to conform with Option 2 on the initial redlines to the sponsor.

Emory's current Subject Injury Policy can be found here: https://irb.emory.edu/_includes/documents/sections/subjectinjuryct.pdf

*****The data in eCTS does not update in real time, but rather, refreshes every day at 5am.

C. When the ICOI is confirmed in eCTS, the study team representative may take a screenshot of the eCTS window and upload it to the eIRB record as sufficient confirmation by OSP for IRB.



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Potential Causes for Delay of Confirmation of ICOI by OSP

1. When the Sponsor has engaged a Contract Research Organization (CRO) and there is a middleman in the negotiations.

-If the counterparty to the contract is the CRO instead of the Sponsor, the subject injury language will be found in a separate agreement called the Letter of Indemnification (LOI). Generally, an LOI template is not initially included in the EPEX routing package and the OSP Contracts Analyst must request it from the CRO contact on the initial contact, wait to receive it, and then review, redline, and negotiate the subject injury language.

-Contract negotiations generally take longer if a CRO is involved because they often must seek approval from the sponsor on revisions before responding back to Emory.

2. For Sponsor-initiated protocols, the subject injury language is usually a hybrid of Options 2 and 3 and the OSP Contracts Analyst must edit the language to conform with one of the two options. The OSP Contracts Analysts generally include a link to Emory's Subject Injury Policy so that the counterparty can see their options directly. Sometimes there are a few rounds of back-and-forth to finalize the subject injury language into Option 2 or 3.

3. Sometimes, there is no subject injury language in the template contract at all so the OSP Contracts Analyst will add Option 2 language and negotiate with the counterparty until both sides agree.

4. Sometimes, it becomes apparent that the subject injury language in the contract and the ICOI language in the ICF are not aligning via communications between OSP, IRB, and the study team, in which case, it may take additional time to align between Emory and the sponsor.

How OSP Receives a Contract Assignment

1. Contracts with funding that need to be reviewed, negotiated, and executed by OSP must be submitted to the appropriate Research Administrative Services (RAS) Unit for routing in EPEX. This includes, without limitation, an editable Word version of the draft contract template, sponsor contract contact information, the Protocol/Research Plan/Scope of Work, the draft ICF, and the eCOI form.

2. Once the EPEX proposal routes to OSP, a record is created in eCTS and assigned to the OSP Contracts Analyst assigned to the department. The assigned OSP Analyst by department can be found here: <u>https://osp.emory.edu/about/dept-listing.html</u>

3. Based on the agreement type, OSP has target turnaround times for when the initial redlines should be sent to the sponsor contact and it is within this time that the confirmation of the ICOI is evaluated.