REMS SPONSOR GUIDANCE – CAMPUS WRITE ACCESS Quick Guide

<u>Research Enterprise Management System (REMS)</u> is the UCOP application used to track indirect cost exceptions, maintain sponsor codes, and <u>publish sponsor guidance</u>.

Sponsor Guidance Module: The Sponsor Guidance module serves as a <u>repository for information and guidance</u> <u>pertaining to negotiations with various sponsors of research</u>. Sponsor guidance records are derived from several sources, including historical information from retired UCOP databases, RPAC review of policy issues and discussions with the sponsor, and individual campus communications with sponsors. Unless otherwise noted in the record, the RPAC entry under the sponsor guidance is intended to serve as a starting point for a campus's review of sponsor terms. RPAC continues to be available for consultation on policy issues and general questions.

Using the Sponsor Guidance Module for Campus-specific Guidance: Campuses have delegation to negotiate agreement terms with sponsors and accept provisions consistent with their campus's business practices. UCOP is now providing write access to the REMS Sponsor Guidance Module to representatives from each campus so they may create and edit records of campus-specific considerations and practices, and upload guidance when they accept modified terms under their delegated authority. Using REMS for these purposes is optional. All campuses will have access to all REMS guidance, and campus-specific entries will add to the collective information our community can draw upon.

Responsibilities of authorized campus administrators granted REMS write access:

- Can add/edit records of specific sponsor or sponsor category guidance on behalf of *their* campus
- Guidance entered will be made available to <u>all</u> REMS users. The purpose of the repository is for it to be a collective systemwide resource
- Existing RPAC sponsor guidance should *not* be deleted and/or modified. If the RPAC guidance is outdated and/or requires review, please email the <u>RPAC staff member assigned to the subject matter</u>
- If you need to request REMS Sponsor Guidance write access (including for current REMS users), please email: <u>REMS@ucop.edu</u>

Criteria for Campus-specific guidance entry:

- Who: Campus administrator identified by campus leadership
- What: Add/update any sponsor-specific guidance the campus deems appropriate for future reference by them or another campus. Entry titles **must** identify the campus entering the guidance and the date.
- When: Add/update any sponsor-specific guidance whenever deemed appropriate

Step-by-Step Instructions: Creating Campus-specific Sponsor Guidance

- 1) Login to <u>REMS</u>
- 2) Under the Sponsors tab, navigate to 'Sponsor Guidance'. Click on 'Add New'
- 3) Filling out the 'Add/Edit Sponsor Guidance' from the top down
 - a. Select 'Sponsor Code' from the first dropdown menu if providing guidance on a specific sponsor (i.e., has a sponsor code).
 - i. Campuses may also create guidance records for a Sponsor Category, which applies to all sponsors in that Category. Instructions on creating Sponsor Category guidance are in the <u>next section</u>.
 - b. Enter the Sponsor Code into the corresponding field; the sponsor's name will automatically populate.

- i. If you do not know the code for the sponsor you are creating a guidance record for, use the 'Search/Maintain' tool in the Sponsors tab. (If you do not have access to view sponsor codes, email <u>REMS@ucop.edu</u> and we will update your user account.)
- c. Unless the guidance to be added is specifically about Clinical Trials or Material Transfer, select 'General Terms & Conditions' as the Guidance Type from the dropdown menu.
- d. Select 'Yes' if the new guidance subject involves the sponsor's Master Agreement; select 'No' if it does not involve the sponsor's Master Agreement or they do not have one.
- e. Leave the record status as 'Not Published' for now.
- f. Enter the date the new guidance should be considered effective; the field for the end date can be left blank if unknown.
- g. The title should be descriptive of the guidance subject and <u>must</u> include the name of your campus or lab (e.g., UCD, UCSB, LBNL, etc.) first.
 - i. Example: UCSF Indemnification for Komen sponsored clinical trials
 - ii. Example: UCD Alternative language negotiated for 'Use of Name' clause
 - iii. Example: UCSD Campus business decision pertaining to research misconduct reporting on substantiated findings, compliant with CIPA
- h. Add your campus-specific guidance to the Guidance field; you will be able to add uploaded files and links in the following steps.
 - i. If the campus-specific guidance builds on the content from an existing RPAC-created sponsor guidance record, copy and paste the existing guidance into the new record for easy reference and include the existing REMS Sponsor Guidance ID #
- i. In the Tags field, enter various keywords that will allow you and other campuses to easily search for the guidance, such as sponsor name, subject of guidance (e.g., indemnification, patent, etc.), and campus or lab name. Note that the search function in this module does not work well with multiple-word tags (e.g., "intellectual property") so use of individual keywords is recommended.

* Sponsor Code 🗸						
Sponsor Code •	8739					
Sponsor Name	LEUKEMIA AND LYMPHOMA SOCIETY					
Guidance Information						
Guidance Type-	General Terms & Conditions ✔					
Master Agreement.	⊖Yes ●No					
Status [,]	Not Published 🗸					
Effective Date	12/01/2023 To					
Title-	UCSF - Indemnification					
	228 characters remaining					
Guidance (Please give http:// in the URL when you are adding links or document links)	File - Edit - View - Insert - Format -					
	 ★ ✓ Formats - B I E E E E E E E E 					
	In November 2021, UCSF received the following indemnification clause in an agreement from the Leukemia and Lymphoma Society. UCSF attempted to negotiate inclusion of the proportionality clause, but LLS rejected changes. The following clause is acceptable under DA2239. This REMS entry serves as a blanket exception under which campuses may choose accept this provision in P POWERED BY TINYMCE at the provision in P P POWERED BY TINYMCE at the provision in P P POWERED BY TINYMCE at the provision in P P POWERED BY TINYMCE P P P P P P P P P P P P P P P P P P P					
Tags						
	Note: Separate tags with commas.					
Links						
You may only upload up to ten documents. The maximum allowed file size for	or each uploaded document is 20 MB.					
Do no use symbols or spaces when naming files to upload into REMS. Symbol	ols, such as percentage or dollar signs, may cause an error when attempting to retrieve the					

Choose File No file chosen

Add/Edit Sponsor Guidance

1/25/2024

record once it is activated. Document Title 1

- 4) In the Links section, click 'Choose File' to upload any documents that may be helpful when this guidance is used in the future
 - a. Only PDF, Word, or Excel files may be uploaded. Other files must be converted to PDFs before uploading
- 5) Do not modify the Contact Information section
- 6) Click 'Save' at the bottom of the page. Click <u>here</u> to see an example of a completed Guidance record
- 7) The Guidance ID number will be automatically assigned to the guidance
- 8) Click 'Edit' at the bottom of the page
- 9) If the guidance is ready for use and you did not upload any files, you may change the status to 'Published' and click 'Save' at the bottom of the page. Note: Once 'Published', the entry is visible to all REMS users
- 10) To give users access to an uploaded file, click 'View' next to the name of the uploaded file
- 11) Copy the URL of the window that opened the uploaded file
 - a. If your browser uses an extension to open the file (e.g., Adobe Acrobat), only copy the part from "https://rems.ucop.edu..." to the end of the URL on the right
- 12) Return to the window with the REMS Sponsor Guidance
- 13) Select the text that you want to turn into a link for the uploaded file; with that text still selected, type Ctrl+K or click the link icon in the upper right corner of the Guidance
 - a. The text should describe or name the file that will be opened by the link (e.g., signed agreement, reply email from sponsor, etc.)
- 14) Paste the uploaded file URL into the corresponding field of the Insert Link pop-up window and click 'Ok'
- 15) If you have finished linking to the uploaded files and the guidance is ready for use, you may change the status to 'Published' and click 'Save' at the bottom of the page

Sponsor Category Guidance

In REMS, sponsors are organized into ten numbered <u>Sponsor Categories</u> that describe their entity type (see image below), with some categories being further organized into subcategories (in REMS, referred to as Agency Codes and Sub Agency Codes). Campuses may create a Sponsor Category guidance record <u>only</u> if the guidance is applicable to all sponsors that are and may be assigned to that Category. The process for creating a Sponsor Category guidance record is identical to the process described above for Sponsor Guidance, with the exception of Steps 3a and 3b.

- 3) Filling out the 'Add/Edit Sponsor Guidance' from the top down
 - a. Select 'Sponsor Category' from the first dropdown menu if providing guidance on all sponsors of a certain Category
 - b. Select the Sponsor Category and, if applicable, the Agency/Sub Agency Code, to which the guidance will apply

After completing these steps, you may continue using the instructions in the previous section for creating a record starting with <u>Step 3c</u>.

Add/Edit Sponsor Guidance

* Sponsor Category ➤	
Sponsor Category*	Select 🗸
Guidance Information	Select 01 - US Federal Government Agency
Guidance Type	02 - State Of California Government Agency
Master Agreement.	03 - Other, Inter, Non-Governmental Organization 04 - Business/For-Profit/Sole Proprietor
Status•	06 - Foundation/Charitable Trust
Effective Date	07 - Charitable Organization
Title-	08 - Higher Education 12 - Agriculture Marketing Board 14 - UC Campus, Location, or Program

Step-by-Step Instructions: Editing Campus-specific Guidance

- 1) Login to <u>REMS</u>
- 2) Under the Sponsors tab, navigate to 'Sponsor Guidance'. Click on 'Search/Maintain'
- 3) Search by either Sponsor Code, Sponsor Name, or Tag (keyword) for the record you wish to modify
 - a. Searching for your campus (e.g., UCSB) in the Tags field should bring up all records pertaining to your campus
 - b. Searching for a broad term (e.g., indemnification) in the Tags field should bring up all records pertaining to that keyword. Please note that many RPAC created records do not have tags and will not appear in search results

Но	me	Sponsors - In	direct Cost Exceptions 👻	Maintenance - Ca	mpus REMS Directory	Contact Us	Logout		
Sear	rch Տլ	ponsor Guida	ance						
	Sponsor	r Code							
	Sponsor	r Name							
	Record I	ID							
	Tags						Search		
Spe	unsor Guir	dance List							
- opc	ID 🗘	Sponsor Code 🗢		Sponsor 🗢	Guidance Typ	e ≑	Master 🗢	Title 🗢	Sta
1	440	1424	QUALCOMM INCORPOR	ATED	General Terms & Con	ditions Y		UC-Qualcomm Master Confidential Disclosure Agreement	Publishee
2	438	Category	US FEDERAL GOVERNME	INT AGENCY	General Terms & Con	ditions N		Prohibition on a ByteDance Covered Application - FAR 52.204-27	Publishee
3	437	9953	HOWARD HUGHES MED	ICAL INSTITUTE	General Terms & Con	ditions Y		Freeman Hrabowski Scholars	Publishee
4	435	VC74	INTERNATIONAL CANCE	R GENOME CONSORTIUN	General Terms & Con	ditions N		Indemnification clause in data transfer agreements from the International Cancer	Publishe

- 4) Click on the row of the record you wish to modify
 - a. Be certain that you are modifying a record that belongs to your campus or lab
- 5) At the bottom of the 'Sponsor Guidance View' window, click the 'Edit' button

Sponsor Guidance View

Sponsor:	r: 9953 - HOWARD HUGHES MEDICAL INSTITUTE		
Title:	:: Freeman Hrabowski Scholars		
Effective Date:	: Start: 10/24/2023		
Guidance:	e: This is an amendment to the HHMI master agreement. The master agreement is available in REMS guidance ID 103.		
	Freeman Hrabowski Scholars ("Scholars:) are outstanding early career faculty in science who have the potential to become leaders in their research fields and create diverse and inclusive lab environments in which everyone can thrive. HHMI wishes to expanded its medical research program to include laboratories supervised by the Scholars. Scholars are expected to have a five-year term, renewable one time, for an expected ten-year term in total. The Scholars will be expected to spend at least 80 percent of their professional time on research (in contrast to the 75 percent requirement for HHMI Investigators). Outside of those two distinctions, the Scholars will be similarly situated to other HHMI Investigators. Link to the signed agreement letter.		
GuidanceType:	General Terms & Conditions		
Master Agreement:	Yes		
Tags:			
Guidance ID:	437		
Created By:	Sean Mayuga on 10/24/2023		
Last Modified By:	Felice Lu on 10/31/2023		
RPAC Contact:	Felice Lu		
Status:	Published		
Edit Close			

- 6) Edit the text in the Guidance field as needed. If adding additional text to the guidance, it is recommended that the new text be labeled with "Updated" and the date. The original text in the guidance should be labeled as "Initial" and the date it was published or went into effect.
 - a. If uploading a file, use the instructions from the Creating Campus-specific Sponsor Guidance section starting at <u>Step 4</u>
- 7) Once you have completed your entry, click 'Save' at the bottom of the page

Example of an updated Sponsor Guidance entry:

Sponsor Guidance View

Sponsor: 1636 - SUSAN G. KOMEN BREAST CANCER FOUNDATION, INC.

Title: UCSF Indemnification for Komen sponsored clinical trials

Effective Date: Start: 01/08/2024

Guidance: Updated REMS Entry: 1/8/2024

Since Komen rejected inclusion of the proportionality clause and any other edits, one path forward is for UC campuses to notify Komen via email that UC interprets "to the full extent permitted by law" to include our Standing Orders. We are relying on the phrase "to the full extent permitted by law" in making the determination that the clause is within the Standing Orders because the University is self-legislating under the California Constitution. This means that UC is in effect only indemnifying to the extent allowed by The Regents Standing Orders.

Campuses should carefully consider this position since it could involve costly litigation if it is ever challenged. If your campus accepts Komen's Indemnification clause, as a best practice, you should notify Komen via email that as a public institution, the University considers its Standing Orders as applicable law for the purpose of interpreting the Indemnification clause.

Initial REMS Entry: 12/4/2023

During negotiations with UCSF in mid-2021, SUSAN G. KOMEN BREAST CANCER FOUNDATION, INC. rejected requests to include the proportionality clause, or any other edits, in the following indemnification provision:

III. Indemnification

 The Sponsoring Institution acknowledges and agrees that the work to be performed pursuant to this award is the responsibility of the Sponsoring Institution; that the Sponsoring Institution shall be responsible for any and all claims that may arise out of or in connection with such work; that Komen shall have no responsibility for or to the subjects involved; and, to the full extent permitted by law, that the Sponsoring Institution shall indemnify and hold Komen harmless from and against any and all claims, liabilities and/or expenses arising from or related to this award and the work performed pursuant thereto. The Sponsoring Institution represents that it has and agrees to maintain insurance in a sufficient amount to cover its responsibilities and liabilities under this Agreement. Upon Komen written request, the Sponsoring Institution shall promptly provide Komen with a copy of the applicable certificate(s) of insurance.

GuidanceType: General Terms & Conditions Tags: UCSF, Indemnification Guidance ID: 441 Created By: Sean Mayuga on 01/08/2024 Last Modified By: Sean Mayuga on 01/09/2024 RPAC Contact: Sean Mayuga Status: Not Published

Example of a completed new RPAC Sponsor Guidance entry:

Add/Edit Sponsor Guidance	
* Sponsor Code 🛛 🗸	
Sponsor Code •	F4A7
Sponsor Name	HYUNDAI HOPE ON WHEELS
Guidance Information	
Guidance ID	443
Guidance Type-	General Terms & Conditions 💙
Master Agreement-	⊖yes ®No
Status-	Published V
Effective Date	01/05/2024 To
Title-	UCSF Alternative language negotiated for Publicity/Use of
	Name clause
Guidance (Please give http:// in the URL when you are adding links or document links)	File - Edit - View - Insert - Format -
	♠ Formats- B I E E E I I I A
	Update: 01/05/2024 UCSF Alternative language negotiated for Publicity/Use of Name clause
	The Hyundai Hope on Wheels (HHOW) terms and conditions have been problematic because of how HHOW would like to use the University's logo, images, etc. in its promotional campaigns. UCSF's most recent HHOW award provided the opportunity to further negotiate their publicity/use of name clause. HHOW has approved the following alternative version to their Publicity/Use of name clause. A copy of their acceptance is attached for reference.
	Initial REMS Entry Sponsor Guidance ID 413: December 03, 2021
	The Hyundai Hope on Wheels terms and conditions have been problematic in the past because of how HHOW would like to use the University's logo, images, etc. in its promotional campaigns. Campuses receiving HHOW awards should review the terms carefully. The Office of Communications at each campus have the delegated authority to accept non-standard publicity clauses. Please consult with your Office of Communications prior to
	P » SPAN » EM POWERED BY TINYMCE
Tags	UCSF, alternative language
	Note: Separate tags with commas
Links	
You may only upload up to ten documents. The maximum allowed file size fo	or each uploaded document is 20 MB.
Do no use symbols or spaces when naming files to upload into REMS. Symbo	ols, such as percentage or dollar signs, may cause an error when attempting to retrieve
the record once it is activated.	
Document Title 1	UCSF Email 01052024_Proposed revision HHOW use of name clause.pdf UCSF Email 01052024_Proposed revision HHOW use of name clause.pdf Delete View
Document Title 2	Choose File No file chosen
Contact Information	
Responsible RPAC Contact-	Hilds Vasquez 🗸
Created By-	Hilde Vesquez 💙
Created Date-	01/10/2024
Last Modified By	Sean Mayuga on 01/10/2024
Save Cancel Delete	