Chicago Center on Musculoskeletal Pain

Multidisciplinary Translational Research

Application Deadline: October 1, 2024 Notification of Award: October 25, 2024



2024 C-COMP PILOT GRANT ANNOUNCEMENT

This funding opportunity aims to fund pilot and feasibility studies focused on <u>mechanisms</u> <u>underlying pain associated with musculoskeletal and rheumatic diseases</u> (including - but not limited to - osteoarthritis, rheumatoid arthritis, spondyloarthritis, heritable connective tissue diseases, low back pain, intervertebral disc degeneration, fractures). Successful projects should provide the basis for subsequent applications for independent research support from the NIH and other funding agencies.

Proposals may address a broad range of topics related to mechanisms of musculoskeletal pain, and may use human subjects, human tissues, or animal models. We encourage the following topics:

- Proposals that aim to characterize pain behaviors in existing or new animal models of rheumatic and musculoskeletal diseases.
- Proposals aiming to develop new methods to study mechanisms underlying pain associated with rheumatic and musculoskeletal diseases.
- Proposals that aim to study sensory and sympathetic innervation of joints and of the spine.
- Proposals that explore the phenotype of joint-innervating sensory neurons in the course of rheumatic and musculoskeletal diseases.
- Proposals that aim to identify new targets for the management of pain in rheumatic diseases.
- Proposals that explore the role of sex, age, and co-morbidities on the development and mechanisms of pain in rheumatic and musculoskeletal diseases.
- Proposals that aim to develop models of joint pain based on human stem cell technology.

It is expected that applicants will interact with C-COMP core facilities as part of the yearlong pilot project. This can include participation in educational opportunities such as our seminar series/training, and/or use of core facility services. If use of C-COMP core services is proposed, please consult with the core PI about service options and cost estimates.

WHO IS ELIGIBLE TO APPLY?

- Both basic and clinical researchers with an M.D., Ph.D. or equivalent within Rush and Northwestern University are eligible to apply, as well as researchers in other US institutions.
- Before applying, please become a member of C-COMP.
- Investigators need to justify how the proposed studies relate to the broad area of pain in rheumatic and musculoskeletal diseases.
- We encourage interdisciplinary collaborations between musculoskeletal researchers and pain scientists as well as neuroscientists.
- Postdoctoral fellows and PIs at all career stages are welcome to apply. We encourage applications by musculoskeletal researchers who are new to pain research and vice versa.

FUNDING

- Budgets will be approximately \$25,000 (total costs) for a maximum 1-year project period. NO INDIRECTS ALLOWED
- Earliest start date is Jan 1, 2025.

APPLICATION GUIDELINES

Each proposal should use Arial font, size 11, margins no less than 0.5 inches and contain the following:

- Face page (1 page) PHS 398
- Proposal title
- List of Principal Investigator(s) Research and Related Senior/Key Person
- Abstract (300 words max) <u>Continuation Format Page</u>
- Lay language summary (2-3 sentences) <u>Continuation Format Page</u>
- Specific aims (1 page) <u>Continuation Format Page</u>
- Research strategy (significance, innovation, approach); including the following additional information (3-page limit): <u>Continuation Format Page</u>
 - Expected outcomes and plans for subsequent grant submission
 - Statement of how the project will advance the mission of C-COMP
 - Use of C-COMP Core services and facilities (recommended)
- Institutional Assurance that IACUC/IRB forms specific for this project have been submitted to the appropriate committees by the time of application (NOTE: Title and PI must match Pilot Grant Application)
- Human Subject Research
 - Human Subject Education Certification of Training for any individuals on this project who will be involved in HS research.
 - Genomic Data Sharing Plan (required for JIT)

For the NIH GDS policy compliance, we will need an Extramural certificate as well (in addition to the GDS plan that they have submitted).

<u>1. Genomic Data Sharing Plan</u>

Genomic Data sharing plan should address the following elements:

- a) Data Type
- *b)* Data Repository- Please note GEO is a public repository that will distribute the data via unrestricted access- anyone can access the data (not limited to research)
- c) Data Submission and Release Timeline
- d) IRB Assurance of the Genomic Data Sharing Plan
- e) Appropriate Uses of the Data

More complete guidance for developing a genomic data sharing plan is available at <u>National Institutes of Health Guidance for Investigators in Developing Genomic</u> <u>Data Sharing Plans</u>, and the <u>Supplemental Information to the NIH Genomic Data</u> <u>Sharing Policy</u>

2. Institutional Certification

The templates can be found at: <u>https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form#step-0</u>. Genomic Summary Results (GSR- page 2, middle) refer to summary (aggregate) level data and NIH employs an unrestricted access model

for GSR from most studies. However, it is possible that privacy and confidentiality risks related to unrestricted access to GSR may be heightened for study populations, from isolated geographic regions or with rare traits. These studies may be considered as "sensitive" and the access to GSR would be provided through controlled-access procedures. Please note the data use limitations and access of the **individual level data (page 2 top and page 3 bottom)** must be consistent with the consent obtained from the patients.

<u>3. OPTIONAL- Information for dbGaP Study Registration (see attached file)</u> We recommend that you share a draft of the Genomic Data Sharing Plan and the Institutional Certification with us, and before approaching institutional officials to make the final submission. The final Genomic Data Sharing Plan and the Institutional Certification should be submitted to the NIAMS Grants Management Branch with a copy to NIAMS Genomic Data Sharing, through an Authorized Organizational Representative for your institution.

Additional information to accompany the application (but outside the above page limits) should include:

- Investigator biosketch (please use the most recent NIH template and follow NIH style) (NF) Biosketch Format Page
- Project timeline <u>Continuation Format Page</u>
- Bibliography
- Budget (1 year) PHS 398 Detailed Initial Budget
 - Permitted budget categories include: PI salary support (not to exceed 10% of total direct costs including fringe benefits), supplies, salary support for other personnel (e.g., study coordinator, technician), animal purchase and housing, core service usage. Indirect costs are not permitted and will not be funded. Applicants should confirm your institution's acceptance of these terms prior to submission. Exceptions will not be made at the time of award.
 - o Budget categories not permitted: Equipment and Travel
 - <u>PHS 398 Budget Page 4</u>
 - Budget justification (1 page)

REVIEW AND POST-AWARD REQUIREMENTS

Anticipated award date: January 1, 2025

C-COMP will manage the review process following NIH guidelines. Proposals will be reviewed by a multidisciplinary committee comprised of leading experts in pain and rheumatic diseases.

Awardees must deliver:

- An interim progress report six months after receiving funding (about one page) submitted by email to <u>ccomp@rush.edu</u> due July 1, 2025; along with a Request for a No-Cost Extension
- A final report describing the study's findings, related publications, and any other outcomes or subsequent grant submissions within two months of the project's conclusion (two pages);
- Publications and other products from the award must acknowledge the P30 funding.
 - *e.g.* Acknowledgements: We would like to thank NIH/NIAMS P30AR079206 and acknowledge the Chicago Center on Musculoskeletal Pain Research Core Center for support.
- A presentation of findings at the annual C-COMP Symposium after the conclusion of the pilot study.

DEADLINE

Send the full proposal as a single PDF file to ccomp@rush.edu with the subject line "FY2024 C-

COMP P&F Application" by October 1, 2025, 11:59pm.

Please send questions about the application process to <u>ccomp@rush.edu</u>



The J.I.T will require:

- Other Support Checklist
- Other Support Format Pages: PI and any other Co-Investigators
- Recipient Commitment Form
- IACUC / IRB Approval (PI and Title must match Pilot Grant Application)
- <u>Statement of Work</u>
- Human Subject Research (if applicable)
 - Human Subject Education Certification of Training for any individuals on this project who will be involved in HS research.
 - Genomic Data Sharing Plan (required for JIT) For the NIH GDS policy compliance, we will need an Extramural certificate as

well (in addition to the GDS plan that they have submitted). <u>1. Genomic Data Sharing Plan</u>

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How to Submit a Carryover Request (Carryover Unobligated Funds (nih.gov)

All carryover requests must be made in writing (or via email) to the GMS assigned to the project and signed by the Authorized Organization Representative from the grantee institution (submitted by RUSH on your behalf). Requests should be submitted in a timely manner, within one year of the end of the budget period from which the funds were unexpended, and must include the following information:

Grant number and PI name.

Amount of funds to be carried over.

Explanation for the unobligated balance.

Plan for expenditure, including a description of activities to be carried out during the carryover period, and how the activities relate to the aims of the project.

Detailed budget in PHS 398 format (Form Page 4) and justification for all items, including detailed budget pages for any subcontract costs.

When preparing a justification for a carryover request, grantees should answer the following questions:

•Why were the funds not spent in the past year?

•What additional work will be done during the current grant year that is not possible with the budget currently allotted to this year? Thought must be given to how the work will be accelerated; for example, will more staff be hired, effort increased or more assays run?

•Is the request essential? Are costs reasonable, allowable, necessary and in line with the existing budget? Are there new costs that were previously unforeseen? How will the work be impacted if the funds are not carried over?

Given the current limited period of performance we recommend having this documentation to us no later than July 1st. The request must be approved and released by our Research Office. A NIH response is expected withing 30 days of receipt of the request.

Form Approved Through	02/28/2023					OMB No. 0925-0001
Depa	rtment of Health and Hum	an Services	LEAVE BLANK—FOR PHS USE ONLY. Type Activity Number			
	Public Health Service		Type Acti Review Group	vity	Number Formerly	
Grant Application		•				
Do not exc	eed character length restr	ictions indicated.	Council/Board (Month	n, Year)	Date Rece	eived
1. TITLE OF PROJECT	Oo not exceed 81 chara	cters, including spaces and p	unctuation.)			
2 RESPONSE TO SPE		PPLICATIONS OR PROGRA				
(If "Yes," state numb				ONCOOLIGHT		
Number:	Title:					
3. PROGRAM DIRECT	OR/PRINCIPAL INVESTIC	GATOR				
3a. NAME (Last, first, m	iddle)		3b. DEGREE(S)		3h. eRA Co	mmons User Name
3c. POSITION TITLE			3d. MAILING ADDRE	SS (Street, c	ity, state, zip	code)
			-			
3e. DEPARTMENT, SEF	RVICE, LABORATORY, C	REQUIVALENT				
3f. MAJOR SUBDIVISIO						
3g. TELEPHONE AND F	AX (Area code, number	and extension)	E-MAIL ADDRESS:			
TEL:	FAX:					
4. HUMAN SUBJECTS	RESEARCH	4a. Research Exempt	If "Yes," Exemption N	0.		
🗌 No 🗌 Yes		No Yes				
4b. Federal-Wide Assura	ance No.	4c. Clinical Trial	4	d. NIH-define	d Phase III Cl	inical Trial
		No Yes		No	Yes	
5. VERTEBRATE ANIM	IALS 🗌 No 🗌 Yes	;	5a. Animal Welfare A	ssurance No.		
6. DATES OF PROPOS SUPPORT (month,	SED PERIOD OF day, year—MM/DD/YY)	7. COSTS REQUESTED BUDGET PERIOD	FOR INITIAL		REQUESTED OF SUPPOF	FOR PROPOSED
From	Through	7a. Direct Costs (\$)	7b. Total Costs (\$)	8a. Direct Cos	sts (\$) 8b.	Total Costs (\$)
9. APPLICANT ORGAN			10. TYPE OF ORGA	NIZATION		
Name			Public: \rightarrow	Federal	State	Local
Address			Private: →	Private Non	profit	
			For-profit: →	General	Small B	usiness
			Woman-owned		_	ally Disadvantaged
			11. ENTITY IDENTIF		MBER	, ,
					1	
			DUNS NO.		Cong. Distric	ct
12. ADMINISTRATIVE C Name	OFFICIAL TO BE NOTIFIE	ED IF AWARD IS MADE	13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name			
Title			Title			
		Address				
Tel: FAX:		Tel:		FAX:		
E-Mail:			E-Mail:		an 0 0 0	
the statements herein are tr accept the obligation to com is awarded as a result of this	ue, complete and accurate to pply with Public Health Service	D ACCEPTANCE: I certify that the best of my knowledge, and es terms and conditions if a grant any false, fictitious, or fraudulent administrative penalties.	SIGNATURE OF OFI (In ink. "Per" signatur			DATE
PHS 398 (Rev. 03/2020)		Face Page				Form Page 1

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator				
Prefix: * First Name:	Middle Name:			
* Last Name:	Suffix:			
Position/Title:	Department:			
Organization Name:	Division:			
* Street1:				
Street2:				
* City:	County/ Parish:			
* State:	Province:			
* Country: USA: UNITED STATES	* Zip / Postal Code:			
* Phone Number:	Fax Number:			
* E-Mail:				
Credential, e.g., agency login:				
* Project Role: PD/PI	Other Project Role Category:			
Degree Type:				
Degree Year:				
*Attach Biographical Sketch	Add Attachment Delete Attachment View Attachment			
Attach Current & Pending Support	Add Attachment Delete Attachment View Attachment			
	PROFILE - Senior/Key Person 1			
Prefix: * First Name:	Middle Name:			
* Last Name:	Suffix:			
Position/Title:	Department:			
Organization Name:	Division:			
* Street1:				
Street2:				
* City:	County/ Parish:			
* State:	Province:			
* Country: USA: UNITED STATES	* Zip / Postal Code:			
* Phone Number:	Fax Number:			
* E-Mail:				
Credential, e.g., agency login:				
* Project Role:	Other Project Role Category:			
Degree Type:				
Degree Year:				
Attach Biographical Sketch	Add Attachment Delete Attachment View Attachment			
Attach Current & Pending Support	Add Attachment Delete Attachment View Attachment			
Delete Entry	Next Person			

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

Click for More Info on This Form

Name of Applicant (Last, First, Middle):

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
A. Personal Statement	2		

- B. Positions, Scientific Appointments, and Honors (in reverse chronological order)
- C. Contributions to Science

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY

THROUGH

FROM

List PERSONNEL (Applicant organization only) Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested (*omit cents*) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	3	TOTAL
	PD/PI								0
									0
									0
									0
									0
									0
									0
S	UBTOTALS				→	0		0	0
CONSULTANT COSTS									I
EQUIPMENT (Itemize)				X					
SUPPLIES (Itemize by category)	C								
TRAVEL		-						+	
INPATIENT CARE COSTS									
OUTPATIENT CARE COSTS								<u> </u>	
ALTERATIONS AND RENOVATIONS (Itemize by categ	jory)							
OTHER EXPENSES (Itemize by catego	ry)								
CONSORTIUM/CONTRACTUAL COST	S					DIRE	CT COSTS	 	
SUBTOTAL DIRECT COSTS F		BUDGE		DD (Item 7	'a, Face Page)			\$	0
CONSORTIUM/CONTRACTUAL COSTS FACILITIES AND ADMINISTRATIVE COSTS					т 				
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD					\$	0			

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OMB No. 0925-0001 Form Page 4

BUDGET JUSTIFICATION

PERSONNEL

First Name Last Name, MD/Ph.D., Principal Investigator – XXX will serve as the Principal Investigator.

XXX will devote X% effort or X.X calendar months each year of the project.

XXX will lead/direct/oversee...

XXX is board certified/is an expert in/has X years of experience with...

XXX will also be responsible for data integrity/data analysis/writing of publications/training of...

First Name Last Name, MD/Ph.D., Co-Investigator – XXX will serve as Co-Investigator.

XXX will devote X% effort or X.X calendar months each year of the project.

XXX will lead/direct/oversee...

XXX is board certified/is an expert in/has X years of experience with...

XXX will also be responsible for data integrity/data analysis/writing of publications/training of...

First Name Last Name, Research Coordinator– XXX will serve as the primary research coordinator.

XXX will devote X% effort or X.X calendar months each year of the project.

XXX will lead/direct/oversee...

XXX is has X years of experience with...

XXX will also be responsible for data integrity/data analysis/writing of publications/training of...

EQUIPMENT Not applicable

TRAVEL_Not Applicable

OTHER DIRECT COSTS

Materials and Supplies – These costs are requested to cover

<u>Publication Costs</u> – These costs are requested to help to defray publication costs of scientific articles in various peer-reviewed journals as a result of this research.

Consultant Services -

First Name Last Name, MD/Ph.D. – XXX will serve as a consultant. XXX will lead/direct/oversee... XXX is board certified/is an expert in/has X years of experience with... XXX will be compensated \$ per year.

<u>Computer Services</u> – These costs are requested for....

Equipment or Facility Rental/User Fees – These costs are requested for....

Alterations and Renovations – These costs are requested for....

Other -

FRINGE BENEFIT RATE [Insert institution name] federally negotiated fringe benefit rate for full-time employees is X.X% and for part-time employees is X.X%.

Just-In-Time (JIT) is a standard notice and request for information from Applicant Organizations and Principal

Investigators.

PI Name:		PI Email:	
Admin Name:		Admin Email:	
Department:		ORA#:	20032404
		Grant #	
JIT Due Date	November 8, 2024	Type of Award	Pilot Grant

KEY PERSONNEL REQUIREMENTS					
Item		Notes			
Key Personnel (other than PI) included on the project?	YES/NO				
If yes, how many Key Personnel?					
Other Support Uploaded for ALL Key Personnel? If not, please provide an explanation in notes field	YES/NO				
Recipient Commitment Form included?	YES/NO				

IRB AND IACUC DOCUMENTATION				
Item	Yes	No	Notes	
Does this project involve Human Subjects?				
If yes, please attach/upload approval letter and enter IRB approval date.				
Does this project involve Animals?				
If yes, please attach approval letter and enter IACUC approval date				

Other Support Checklist

Please fill out this checklist as you review Other Support for all Senior/Key Personnel involved in the grant. Please complete only **ONE** checklist per submission.

Other Support documents must be completed for ALL senior/key personnel on a grant except:

- Program Directors, training faculty, and other individuals involved in the oversight of training grants
- Individuals categorized as Other Significant Contributors

Other Support					
	All items to be included in an Other Support Document:				
	Are all active projects within the 12 person month limit listed?				
	Is Other Support document organized by "Active", "In-Kind" and then "Pending"?				
	Are all budgets and dates updated based on the most recent award notice?				
	Are all pending projects, including the one under JIT review, listed?				
	Note: Projects under JIT must be listed as Pending with the proposed effort listed.				
	Have you verified that the effort commitments (including the proposal under JIT review) do not exceed 12 months?				
	If the effort commitment is over the 12 person month limit, is a detailed Overlap Statement explaining how effort will be adjusted included?				
	Do all projects have a grant number provided?				
	Are all activities, foreign or domestic, listed which 1) are conducted within the scope of an investigator's appointment at their institution of employment and/or 2) provides funding or requires a commitment of time/effort.				
	Note: Commitments are regular obligations of time (part of an investigator's regular activities), not short-term obligations, such as attending a meeting or making a presentation. All activities where the investigator has a commitment (effort), but is not receiving salary support from the commitment, is reported under "In-Kind.".				

Are all applicable Consulting Activities listed? You must list all consulting projects
wherein the investigator will be involved in the design, conduct, and/or reporting of research as part of the consulting activities. If a consulting agreement does <u>NOT</u>
involve research activities, it does not need to be included in Other Support. Note
consulting activities do not count toward effort limits. The total being paid to the
consultant should be listed for that project with no effort noted.
Is all participation/collaboration in, or affiliation with, a foreign talent or similar-type
program listed?
Are all clinical trials included?
Note: Estimate senior/key personnel effort on the clinical trial in person months.
If applicable, is the appropriate Supporting Documentation attached?
Note: For all Foreign appointments, affiliations, and/or employment with a foreign
institution, you must include accompanying foreign contracts, grants or any other
agreements specific to the foreign appointment listed? Copies must be provided as
part of the PDF following the Other Support format page.
If they are not in English, you must provide translated copies.
Are all projects in No-cost Extension (NCE) included, with the Project Period End date of the NCE?
Are all incoming subawards included?
Note: For subawards, the total subaward amount, the project number of the prime grant, Name of PD/PI on the prime grant, and source of Support for the overall project is included.
Are all applicable In-Kind Contributions listed? You must list all In-Kind Contributions
from any entity (either domestic or foreign) in support of any of an investigator's research endeavors including, but not limited to:
• Personnel (e.g., visiting scholars, visiting students, supported by a non-UCI entity)
• Space
• Equipment
Materials
• Supplies
For in-kind resources with no time commitment, list zero effort, but provide estimated dollar value. The effort and dollar value cannot both be zero.
Has the Senior/Key Person reviewed the Other Support document and demonstrated their approval via Digital Signature?
Note: A typed name is not an electronic signature and is not acceptable.
Note: Wet (ink) signatures are not acceptable.
Has the document been saved as a flattened PDF?

Items NOT to be included:
Projects that have expired (project end date is in the past)
 Awards resulting from internally-funded competitions. Examples include: Training awards Gifts, prizes, endowments
In-kind contributions intended for use on the project/proposal that was submitted to NIH and that have no associated time commitment. (Report instead in Facilities and Other Resources)
Start-up packages from the researcher's home institution. You MUST include start-up packages from other entities.
One-time travel to present at a conference at an international organization
Consulting or professional services where no research is performed
Home institution salary
Unfunded research collaborations conducted as part of an investigator's home institution appointment. This comment does not refer to projects that are pending.
I confirm that the above items are NOT included in the Other Support document for any Key Personnel.

By checking this box, I,

, confirm the following:

- 1. I have reviewed all Other Support documents for each individual Senior/Key Personnel involved in this project.
- 2. All Other Support documents have been completed in compliance with the above checklist.
- 3. All Other Support documents for all Senior/Key Personnel have been combined into ONE continuous, flattened PDF.

PHS OTHER SUPPORT For All Application Types – DO NOT SUBMIT UNLESS REQUESTED

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.

*Name of Individual: Commons ID:

Other Support – Project/Proposal

 $\langle \rangle$

*Title:

*Major Goals:

*Status of Support:

Project Number:

Name of PD/PI:

*Source of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

* Total Award Amount (including Indirect Costs).

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##.##)
1. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

Name of Individual: Commons ID:

IN-KIND

*Summary of In-Kind Contribution:

*Status of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (##.##)
1. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

*Estimated Dollar Value of In-Kind Information:

*Overlap (summarized for each individual):

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature:

Date:



Checklist to Determine Recipient or Contractor Classification

Name of RUMC PI: Anne-Marie Malfait, MD, PhD

ORA Number: 20032404

Name of Outside Entity:

SECTION 1 - RECIPIENT Description : A subaward is for the purpose of carrying out a portion of a Federal award and creates a Federal assistance relationship with the subrecipient. Characteristics which support the classification of the non-Federal entity as a subrecipient include when the contractor: Determines who is eligible to receive what Federal assistance; 1. Has its performance measured in relation to whether objectives of a Federal program were met; 2. Has responsibility for programmatic decision making; 3. In accordance with its agreement, uses the Federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of the pass-through entity. 4 Entities that include these characteristics are responsible for adherence to applicable Federal program requirements specified in the Federal award. SECTION 2 - CONTRACTOR/Vendor Description : A contract is for the purpose of obtaining goods and services for the non-Federal entity's own use and creates a procurement relationship with the contractor. Characteristics indicative of a procurement relationship between the non-Federal entity and a contractor are when the non-Federal entity receiving the Federal funds: 1. Provides the goods and services within normal business operations; 2. Provides similar goods or services to many different purchasers; 3. Normally operates in a competitive environment; Provides goods or services that are ancillary to the operation of the Federal program. 4. Entities that include these characteristics are not subject to compliance requirements of the Federal program as a result of the agreement, through similar requirements may apply for other reasons.

FINAL DETERMINATION:





(If Contractor/Vendor, please contact the RUMC Pl about procuring your organization's products and service as a Contractor)

OPTIONAL - SECTION 3 - USE OF JUDGMENT (use only when the determination cannot clearly be made using the above criteria)

Description: In determining whether an agreement between a pass-through entity and another non-Federal entity casts the latter as a subrecipient or a contractor, the substance of the relationship is more important than the form of the agreement. All of the characteristics listed above may not be present in all cases, and the pass-through entity must use judgment in classifying each agreement as a subaward or a procurement contract.

Explanation of Use of Judgment Determination:

Commitment Form				
Any organization planning to enter into a collaborative subrecipient relationship with Rush University Medical Center (RUMC) must complete this form at the proposal stage. This form will be considered valid for one year from the date of signature by your organization's Authorized Official.				
Section A: RUMC Informat	ion			
^{Rush PI:} Anne-Marie Malfait, MD, PhD		ORA #: 20032404		
Prime Sponsor: NIH - National Institute of Health NIAMS				
Proposal Title: C-COMP P30 Pilot Grant				
Proposed Dates:	Start Date: 12/1/2024	End Date: 11/31/2025		
Section B: Recipient Institutional Information				
PI Name:				
Subrecipient Legal Name:				
EIN Number: UEI Number:				
Address:		City: State:		
Country:	Zip+4:	Congressional District:		
Proposal Title (if different than above):				
PROJECT COSTS	Initial Year Budget	Total Project Budget		
Total Direct Costs:	\$ 25,000.00	\$ 25,000.00		
Total Costs	\$ 25,000.00	\$ 25,000.00		
Human Subjects: Yes	No Vertebrate	e Animals: Yes No		

Section C: Recipient Proposal Documents				
The following documents are included with this completed and signed commitment form:				
Statement of Work (Required)	~	Biosketch and Other Support		
Budget and Budget Justification	(Required)	Other		
Section D: Official Signing for Recipient				
The information, certifications and representations above have been read, signed and made by an authorized official of the Subrecipient named herein. The appropriate programmatic and administrative personnel involved in this application are aware of agency policy in regard to subawards and are prepared to establish the necessary inter-institutional agreements consistent with those policies. Any work begun and/or expenses incurred prior to execution of a subaward agreement are at the Subrecipient's own risk. No work involving human subjects and/or animals may begin until the subrecipient has obtained registered Institutional Review Board and/or Animal Care and Use Committee review and approval. [This form is in lieu of an institutionally endorsed letter of intent].				
Signature:				
Name and Title of Authorized Official:				
Date:				
Email:				

Statement of Work Instructions and Sample

Statement of Work Statement

Every subcontract must include a statement of work statement. The SOW statement should provide sufficient detail about the proposed work to allow someone reviewing the statement and who was familiar with the project to determine whether or not the work agreed to was delivered/performed. While the exact experimental or procedural information is not necessary. The following elements are typically included under "statement of work," however these are not all-inclusive:

- 1. Project title
- 2. Princpial Investigator name at each institution
- 3. Timetable or schedule of work to be performed/start&end dates,
- 4. Project description
 - i. Purpose or objective(s) of the work to be performed;
 - ii. An explanation of the work to be performed inclusive of special personnel, supplies, materials, equipment or travel needed;
 - iii. Specification of how the work's progress or results are to be measured;
 - iv. Identification of deliverables, products or expected outcomes.
 - v. Explain the intellectual expertise that the SUBAWARDEE will provide to the research project that distinguishes this work form a bid for services or a purchase order.

Statement of Work Sample

Project Title: Primary Site PI:

Primary Site Institution: Subaward Site PI: Subaward Site Institution:

Project start/end date:

Project Description:

Objectives

Explanation of work to be performed- *special personnel, supplies, materials, equipment or travel needed*

Tasks- Specification of how the work's progress or results are to be measured Deliverables- Identification of deliverables, products or expected outcomes

Insert – dbGap Study Registration (reference only)