

HSC Financial Services

Sponsored Projects Office

Understanding a Notice of Award from the National Institutes of Health
A Guide for Faculty and Staff

Notice of Award (NoA) Introduction

The NoA is the legal document issued to notify the recipient that an award has been made and that funds may be requested from the designated Health and Human Services (HHS) payment system or office. The NoA serves as supporting documentation that allows the UNM Health Sciences to move forward with its financial obligations in connection with the awarded project. An NoA is issued for the initial budget period; if subsequent budget periods are approved, the NoA will reference those budgetary commitments and provide an additional NoA releasing the yearly funds. Funding for subsequent budget periods is generally provided in annual increments following the annual assessment of progress. This funding is also contingent on the availability of funds. The NoA includes all applicable *Terms and Conditions specific to* the award by reference or specific statements. It will include reference to additional terms in 2 CFR 200, Uniform Guidance. It provides contact information for the assigned program officer and grants management specialist.

As of October 1, 2020, the NoA is being issued in the Standard HHS Page One (1) Format, used by all HHS agencies to provide universal, streamlined data.. The standard page 1 of the NoA provides consistency for grant recipients and a way to digitally receive or extract NoA data from the Federal grant systems, allowing data to be quickly loaded into grant recipients' systems.

Understanding Your Notice of Award (NoA) from NIH

- The funding agency emails the NoA to UNM Health Sciences SPO (Sponsored Projects Office's central email https://hww.nc.edu). Sometimes, the NoA must be downloaded from the federal systems by the PI/PD or SPO-assigned Authorized Official (AO). If an NoA is sent directly to the PI, the PI must email to https://hww.nc.edu for proper processing.
- Reviewing the Notice of Award at the time of receipt is essential to ensure the faculty and staff understand the sponsor's expectations, the value of the award is what is expected, the indirect costs are accurate, and that the project runs smoothly.
- See Exhibit A See a complete print-out sample of the NoA in connection with this exercise.
- See Exhibit B- Responsibility Chart, throughout the pre-award and award setup process.

Components of the Notice of Award

Page One - Standard Recipient Information

Section I: Award Data & Fiscal Information

- Summary of totals for current and future years
- Fiscal year of the award

Section II: Payment/Hotline Information

- Grant Payment Information
- OIG Hotline Information

Section III: Standard Terms & Conditions

- Grant program legislation and regulations
- Restrictions on the expenditures of funds in appropriations acts
- 45 CFR 74 or 92 as applicable
- NIH Grants Policy Statement
- Carryover automatic or prior approval
- Included/excluded Streamlined Non-competing Award Process (SNAP)
- Reporting Requirements
- Program Income

Section IV: Specific Terms and Conditions

- Revisions
- Cooperative Agreement
- Restrictive Terms
- Staff Contact Information
- Spreadsheet Summary

HEADER – PAGE ONE



The NIH awarding Institute was the "National Institute of Mental Health

Date when the NOA was issued.

FAIN = Federal Award Identification Number

Recipient Information

The Recipient Information fields are populated from the application or mapped from the application.

- 1. Recipient Name details are mapped from the application.
- 2. Congressional District is mapped from the recipient address.
- 3. Payment System Identifier (ID): is displayed
- 4. Your organization's **EIN** is displayed.
- 5. Your organization's **Data Universal Numbering System** (**DUNS**) is displayed.
- 6. Recipient's Unique Entity Identifier (UEI) will contain a value for awards issued after October 29, 2021. If an organization does not have UEI this field will be blank and you will only see the DUNS.
- 7. **Project Director or Principal Investigator** is mapped from the application.
- 8. The **Authorized Official (AO)** listed to receive the NoA via email is shown. If multiple AOs are listed to receive the NoA by email, only one AO will be shown on the NoA. The AO shown is selected by the system as the first AO list (sorted by Ascending Last Name).

Recipient Information

1. Recipient Name

UNIVERSITY OF NEW MEXICO

ALBUQUERQUE, NM 87131

- 2. Congressional District of Recipient 01
- Payment System Identifier (ID) 1856000642A1
- 4. Employer Identification Number (EIN) 856000642
- Data Universal Numbering System (DUNS) 829868723
- 6. Recipient's Unique Entity Identifier G389MFAYJNG9
- Project Director or Principal Investigator, Lobo Louie, MD Professor loboluie@salud.unm.edu 505-272-####
- 8. Authorized Official Marisa Sanchez

Federal Agency Information

The Federal Agency Information contains the contact information for the Awarding Agency and Program Official.

- 9. The **Awarding Agency Contact Information** is displayed. The Grants Management Specialist (GMS) is the individual for all official communications regarding the award. "Official" communications must be submitted through an Authorized Organizational Representive this would be your contact in SPO.
- 10. The **Program Official Contact Information** is displayed.

Federal Agency Information

9. Awarding Agency Contact Information
Jane Z. Lin
Grants Management Specialist
NATIONAL INSTITUTE OF MENTAL HEALTH
linja@mail.nih.gov

301-443-2229

10. Program Official Contact Information
Jovier D Evans
Assistant Professor
NATIONAL INSTITUTE OF MENTAL HEALTH
jevans1@mail.nih.gov
301-443-1369

Award Number and What It Means

The Federal Award Information section contains details on the award such as the Award Number and Award Action Type.

- 11. The **Award Number** is displayed see below a description of each section of this award number.
- 12. The **Unique Federal Award Identification Number (FAIN)** is the unique ID within the Federal agency for each (non-aggregate) financial assistance award.
- 13. **Statutory Authority** is listed from Authorization (Legislation/Regulation).
- 14. The **Federal Award Project Title** Title of Project (or Program) is display, mapped from the application.
- 15. **Assistance Listing Number** is mapped from the application; this is formerly known as the Catalog of Federal Domestic Assistance (CFDA #). A five-digit number that is assigned in the awarding document for all federal assistance award mechanisms, including federal grants and cooperative agreements.
- 16. **Assistance Listing Program Title** is displayed, mapped from the application.
- 17. **Award Action Type** is mapped from the sponsor's award types.
- 18. **Is the Award R&D?** will be marked 'Yes' if the award is designated as a Research and Development award.

Federal Award Information

- 11. Award Number 1R61MH123456-01
- 12. Unique Federal Award Identification Number (FAIN) R61MH123456
- 13. Statutory Authority
 42 USC 241 42 CFR PART 52
- 14. Federal Award Project Title

 How HSC Faculty and Staff Understand their NoA

 from NIH
- 15. Assistance Listing Number 93.242
- Assistance Listing Program Title Mental Health Research Grants
- 17. Award Action Type New Competing
- 18. Is the Award R&D? Yes

Description of the Federal Award Number

Federal Award Information

11. Award Number

1R61MH123456-01

> 1...R61...MH...123456...-01

1= Type of Application

R61= Activity Code

MH= Institute/Center Code

123456 = Unique serial number assigned by the NIH Center for Scientific Review (CSR)-identifying the specific application.

01= Support Year – is a two-digit number that indicates the current year of support (e.g., 01 for year 1) Suffix Code – is an optional code used for supplements, amendments, or fellowship institutional allowances. This example does not have a suffix code.

> Types of Applications and NIH Institutes' Code

Deciphering NIH Application/Grant Numbers

Application	Type	Activity Code	Institute Code (IC)	<u>Serial</u>	<u>Number</u>	Support Year	Other Suf	<u>fixes</u>
1		R01	CA	654	4321	01	A1	
Application Types				NIH Funding	Institutes			
1=New	Reques	t for support of a project that I	nas not yet been funded.	Acronym	Full Name			Code
2=Renewal	Reques	t for additional funding for a	period subsequent to that	FIC	John E. Fogarty	y International Center		TW
2 1101101101		d by a current award.	period subsequent to diat	NCATS	National Cente	er for Advancing Translational Scien	nces (NCATS)	TR
3=Revision	Reques	t for (or the award of) addition	onal funds during a current	NCCIH	National Cente	er for Complementary and Integrat	ive Hea <mark>l</mark> th	AT
			ditional activities that are not	NCI	National Cance	er Institute		CA
			request reflects an expansion of	NEI	National Eye Ir	nstitute		EY
		pe of the grant-approved act peer review.	ivities. Competitive revisions	NHGRI		an Genome Research Institute		HG
		peer review. ninistrative supplement is a re	equest for (or the award of)	NHLBI	National Heart	, Lung, and Blood Institute		HL
			oject period to provide for an	NIA	National Institu	ute on Aging		AG
	increas	e in costs due to unforeseen	circumstances. All additional	NIAAA	National Institu	ute on Alcohol Abuse and Alcoholi	sm	AA
			e peer reviewed and approved	NIAID	National Institu	ute of Allergy and Infectious Disea	ses	Al
4=Extension	project Regues		ort beyond the years previously	NIAMS	National Institu Diseases	ute of Arthritis and Musculoskelet	al and Skin	AR
		d. (Used only for select progr		NIBIB	National Institu	ute of Biomedical Imaging and Bio	engineering	EB
5=Non- competing		the state of the s	budget period within a previously nt does not have to compete	NICHD	Eunice Kenned Human Develo	ly Shriver Nationa <mark>l In</mark> stitute of Chil opment	d Health and	HD
Continuation		her applications.	ne does not have to compete	NIDA	National Institu	ute on Drug Abuse		DA
6=Change of	Process	whereby the rights to and o	bligations under an NIH grant is	NIDCD	National Institu	ute on Deafness and Other Comm	unication Disorders	DC
Organization		, ,	f all of the assets of the grantee	NIDCR	National Institu	ute of Dental and Craniofacial Rese	earch	DE
Status			sets involved in the performance	NIDDK	National Institu	ute of Diabetes and Digestive and	Kidney Diseases	DK
(Successor-In-			tive or other legal action, such as	NIEHS	National Institu	ute of Environmental Health Scien	ces	ES
Interest)	a merge	er or other corporate change.	•	NIGMS	National Institu	ute of Genera <mark>l Medical Sciences</mark>		GM
7=Change of		The state of the s	tive responsibility for a grant-	NIMH	National Institu	ute of Mental Health		MH
Grantee or		The state of the s	ne legal entity to another before d project period (competitive	NIMHD	National Institu	ute on Minority Health and Health	Disparities	MD
Training Institution	segmer		a project period (competitive	NINDS	National Institu	ute of Neurological Disorders and	Stroke	NS
	_	-		NINR	National Institu	ute of Nursing Research		NR
8=Change of Institute or Center		of awarding NIH institute or lation (Type 5).	center for the noncompeting	NLM	National Librar	ry of Medicine		LM
9=Change of	Change	of awarding NIH institute or	center for the renewal (Type 2).	Serial Number	er: Six-digit num	ber assigned within an Institut	e/Center	
Institute or		The state of the s		Support Year	r: Two-digit num	ber indicating segment or bud	get period of a pro	ject.
Center				Other Suffixe	es: 'A' and relate	ed number identifies the amen	dment number (e.	g. A1=
Activity Codes: ht	tp://gran	nts.nih.gov/grants/funding	/funding_program.htm		• •	d number identifies the revisio		_
				year or the a	menument desi	gnation to which additional fur	ius nave been awa	rueu.

NIH National Institutes of Health
Office of Extramural Research

Download this document at https://era.nih.gov/about_era/nih_day.cfm

> Activity Codes

For this example, an R61 activity code is a Research Project, Phase I Exploratory / Developmental Grant, as part of a bi-phasic approach. For a complete list of Activity Codes, please visit https://grants.nih.gov/grants/funding/funding_program.htm

Summary Federal Award Financial Information

The Summary Federal Award Financial Information section contains information on the Budget and Project Periods.

- 19. **Budget Period Dates** are displayed, representing period which funding was approved or "awarded" period.
- 20. **Total Amount of Federal Funds Obligated by this Action** (Direct Cost Amount and Indirect Cost Amount will be displayed. Depending on the action of the NoA, sometimes these amounts will be blank, as only cumulative amounts will show). For example, when you receive an NOA with '\$0' it could be an administrative NOA, such as NCE approvals, change of PI, lifting or adding spending restrictions.
- 21. The **Authorized Carryover:** this amount would typically be displayed on page 1 of the NoA, when applicable. Unobligated funds from previous periods, that may be used in the current period.
- 22. The **Offset**: this amount would typically be displayed on page 1 of the NoA, when applicable. Offset would generally be unobligated funds from previous budget periods, that would reduce the anticipated amount of the current period.
- 23. Total Amount of Federal Funds Obligated in the Budget Period: shows the funds obligated in the current budget period.
- 24. The **Total Approved Cost Sharing or Matching, where applicable:** this amount would typically be displayed on page 1 of the NoA, when applicable. Amount recipient is responsible for contributing to the project.
- 25. **Total Federal and Non-Federal Approved This Budget Period:** shows the funds obligated in the current budget period.
- 26. **Project Period Dates** shows the project period start date of when the project period would end. (The anticipated funding period for the entire project).
- 27. **Total Amount of Federal Award Including Approved Cost Share or Matching this Project Period** will show the cumulative amount of Federal funds awarded to date, as well as the non-federal share.
 - 28. Authorized Treatment of Program Income is displayed.
- 29. **Grants Management Officer Signature** will show the GMO name and date of signature on the award.

Summary Federal Award Financial Information	
19. Budget Period Start Date 02/04/2021 – End Date 01/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	\$756,111
20 a. Direct Cost Amount	\$521,547
20 b. Indirect Cost Amount	\$234,564
21. Authorized Carryover	\$0
22. Offset	\$0
23. Total Amount of Federal Funds Obligated this budget period	\$756,111
24. Total Approved Cost Sharing or Matching, where applicable	\$0
25. Total Federal and Non-Federal Approved this Budget Period	\$756,111
26. Project Period Start Date 02/04/2021 – End Date 01/31/2023	
27. Total Amount of the Federal Award including Approved Cost	\$756,111
Sharing or Matching this Project Period	

- 28. Authorized Treatment of Program Income Additional Costs
- Grants Management Officer Signature Maggie C. Paolini

Remarks

drawn.

30. The **Remarks** section shows any comments added to the NoA, which would also include special restrictions/requirements and/or explanations of Administrative (\$0 dollar) NOAs

Why the NoA was issued, 1st Paragraph: In this example, the first paragraph demonstrates how much has been awarded for the current budget period for the specifically mentioned grant.

Acceptance, 2nd Paragraph: One thing to keep in mind is if there are issues with the Terms and Conditions, they should be resolved before spending and drawing down funds. Acceptance of Terms happens when funds are

Standard NIH Policies, 3rd, and 4th Paragraphs: (1) NIH Acknowledgement (2) NIH Public Access Policy (PubMed) (3) Conflict of Interest. NIH's Public Access Policy P.L. 110-161 requires that the PI/PD submit manuscripts for publication in the PubMed Central System no later than 12 months after the official publication date. All publications must acknowledge the NIH award support and include the award number.

Prior to accepting the award, Conflict of Interest's (COI) for participants must be completed. The COI disclosure forms are included in all research proposals/protocols submissions to the following offices: UNM Sponsored Projects Office (SPO), Human Research Protections Program (HRPP), Research Allocation Committee (RAC), and the Office of Animal Care and Compliance (OACC). The faculty engaged in research much comply with all COI requirements of Policy E110. For questions or guidance, please visit the HSC Conflict of Interest and Commitment Office at: https://hsc.unm.edu/research/compliance/coi/

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Notice of Award



Phase 1 Exploratory/Developmental Grant Department of Health and Human Services National Institutes of Health

NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I - AWARD DATA - 1R61MH123456-01

Principal Investigator(s):

Award e-mailed to: HSC-Preaward@salud.unm.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$756,111 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced. incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R61MH123456. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

Authorized the Award, last Paragraph and Signature:

Grants Management Officer who processed the award.

If you have any questions about this award, please direct questions to the Federal Agency

Sincerely yours,

Maggie C. Paolini Grants Management Officer NATIONAL INSTITUTE OF MENTAL HEALTH

Award Data: Includes Budget Period and itemized totals for the amount authorized. Not all NIH NOA's include a detailed budget breakdown (i.e. if a Modular Budget was submitted) and may only include Total Direct and Indirect Costs).

Salaries and Wages	\$255,309
Fringe Benefits	\$84,974
Personnel Costs (Subtotal)	\$340,283
Equipment	\$61,242
Materials & Supplies	\$5,000
Travel	\$6,000
Other	\$59,433
Subawards/Consortium/Contractual Costs	\$49,589
Federal Direct Costs	\$521,547
Federal F&A Costs	\$234,564
Approved Budget	\$756,111
Total Amount of Federal Funds Authorized (Federal Share)	\$756,111
TOTAL FEDERAL AWARD AMOUNT	\$756,111
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$756,111

Anticipated Total Funding, Funding Estimates for each year: The anticipated amounts for future years of the the project, which typically may change throughout the course of a competitive period as the NIH's budget and policies change, with also a possibility of change in the project scope..

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)				
YR	THIS AWARD	CUMULATIVE TOTALS		
1	\$756,111	\$756,111		
2	\$687,658	\$687,658		

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information: Shows the funds committed during the federal NIH Fiscal Year , which runs from October $1^{\rm st}$ – September $30^{\rm th}$.

Fiscal Information:

IC	CAN	2021	2022	
MH	8472591	\$756,111	\$687,658	

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: A4-GPX / OC: 41021 / Released: Paolini, Maggie 01/27/2021

Award Processed: 02/04/2021 12:10:38 AM

SECTION II – PAYMENT / HOTLINE INFORMATION

Payment information: No action is required by the Principal Investigator or research staff. UNM HSC Contract and Grant Accounting Office is responsible for drawing down funds in accordance with NIH fiscal requirements and University policy."

You may find specific information regarding the Office of Inspector General Hotline (OIG) for any fraud reporting at: https://grants.nih.gov/grants/policy/awardconditions.htm

OIG Telephone: 1-800-447-8477 (1-800-HHS-TIPS)

E-mail: HHSTips@oig.hhs.gov

It is recommended that any information that you share with the OIG's office is kept confidential, or you can also submit this information anonymously.

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R61MH123456-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.cov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS

Standard Terms and Conditions: These terms apply to NIH's awards across the board. This section may also include terms that are specific to your project such as **reporting requirments**. It is imperative for the PI/PD to ensure that the Research Performance Progress Report (RPPR) is submitted: (1) Annually to report scientific progress (2) Interim to submit renewal (for Type 2 Applications) and (3) Final – to submit project outcomes and closeout process. NIH Award Conditions and Information can be accessed at:

https://grants.nih.gov/grants/policy/awardconditions.htm

Research and Development (R&R): Under <u>Uniform</u> <u>Guidance</u>, a non-Federal entity that expends \$750,000 or more in Federal awards during the non-Federal entity's fiscal year must have a single audit conducted. At UNM, Financial Services, Office of the University Controller, is responsible for ensuring compliance with all financial policies, rules, & regulations, including state and federal audit requirements.

Carry-forward Authorization (Carryover): You have "carryover amounts" when you did not spend part of the budget allocation during a previous budget period, and you may "carry it" over into the next budget cycle. In this example, you do not need prior approval from the sponsor, but another example can be "Carry forward of an unobligated balance into the next budget period requires Grants Management Officerpriorapproval", so you will need to work with your SPO Specialist to request approval by preparing a budget, a budget justification and a formal letter asking for approval to use unobligated balances. Note: Carryover approval requests are not to be included in the RPPR submissions. This type of request needs to be submitted separately to be considered for approval by NIH.

SECTION III - STANDARD TERMS AND CONDITIONS - 1R61MH123456-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
 Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75
- National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget neriod
- Federal Award Performance Goals: As required by the periodic report in the RPPR or in
 the final progress report when applicable.
- the final progress report when applicable.

 f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval. SNAP Authorization: SNAP awards include Ks & Rs (except R35): RPPR is due approximately 45 days before the next budget period start date; Carryover authority and happens automatically. The RPPR does not require a detailed budget, but it does require "other support" to submit any changes in level effort >25% from key personnel, changes in personnel; the RPPR also needs to include any unobligated balance greater than 25% of the previous budget period, provide a brief description on the future use of funds. The FFR is due at the very end of the competitive segment.

Non-SNAP awards (include Ts, Us, Ps, R35, clinical trials): RPPR is due approximately 60 days before the next budget period start date. All prior approval requests must NOT be submitted with the RPPR; these must be addressed separately. Carryover prior approval requests require a detailed budget, budget justification, IRB & IACUC approvals, and annual FFR; no-cost extensions require prior approval. The FFR must be submitted and accepted in the system before a carryover request is considered.

Additional Special Terms and Conditions -Research and Development (R&D) (including Treatment of Program Income, if applicable)

UEI/DUNS/SAM: The UNM HSC Sponsored Projects Office is responsible for keeping this information up-to-date as required by the federal government to accept awards. No action is required by the PI/PD or research personnel.

FAIN Documentation: The UNM HSC Sponsored Projects Office is responsible for issuing all consortium agreements to other entities, and the FAIN information is included in each executed sub-award agreement as required. No action is required by PI/PD or research personnel..

Public Access Policy: The RPPR is also used to comply with NIH's Public Access Policy P.L. 110-161 – The PI/PD must submit compliant manuscripts for publication in the PubMed Central System no later than 12 months after the official publication date. It is recommended that this is done before submitting the annual RPPR Report; if this is not done, the sponsor may delay your funding for the subsequent year of the project. You do not want to wait until the RPPR is due. All publications must acknowledge the NIH award support and include the award number.

NIH Policy on Dissemination of NIH-Funded Clinical Trial Information: All NIH-funded clinical trials are required to be registered, with reported results submitted to Clinicaltrials.gov. As such, the "responsible person" (which is the PI/PD) must ensure "applicable clinical trials" and studies are registered on this website.

Program Income: If Program Income is generated from a grant, the revenue realized from the provision of services is subject to the administrative requirements, cost principles, and audit requirements that govern Federal monies associated with the award. If applicable, the HSC Contract and Grant Accounting Office will issue a separate index to track revenue and expense in connection with the Program Income and ensure all reporting requirements are completed and submitted to the sponsor.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See

http://grants.nih.gov/grants/policy/awardcond/fions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R61MH123456. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.ini.gow/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of <u>Public Law 110-85</u>), the "responsible party" must register "applicable clinical trials" on the <u>ClinicalTrials gov Protocol Registration System Information Website</u>. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see

http://grants.nih.gov/grants/funding/women_min/quidelines_amended_10_2001.htm)

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships

Treatment of Program Income: Additional Costs

SECTION IV – MH SPECIFIC AWARD CONDITIONS

Specific Award Conditions: these terms and conditions are associated with the funding Institute, specific grant mechanism or specific action or terms to your particular project. It is very important to review this section since they are more restrictive terms for your project. Terms may include "Information" sections referencing adjusted requested levels of support, funded through a Continuing Resolution (CR). It also may reference the RFA terms in connection with the award.

Specific Award Conditions- Personnel Cost: this section includes restrictions on the salary cap for Executive Level II on the Executive Pay Scale and it also may stipulate that no salary increases will be provided on the grant for the remainder of the project period. This needs to be monitored closely to ensure salaries are allocated at the Federal cap level and updated as needed. This section may also list Key Personnel.

Note: Salary cap policy applies even if not specified in the NoA. The policy is updated every year and can be found: https://grants.nih.gov/grants/policy/salcap_summary.htm

Specific Award Conditions -Consortium / Contractual

Costs: In this example, there are three (3) itemized Consortium/Contractual participants. (Not all NOAs will itemize and list subawardees); UNM Health Sciences, as the prime recipient, needs to make sure all supporting documentation is in place for each subawardee. The Principal Investigator's home department is responsible for initiating a Click record and submitting all supporting documentation to the Sponsored Projects Office to initiate the subcontracting process. Note: UNM Health Sciences as the prime recipient of the award, retains budgeting authority. For questions or guidance regarding sub-awards, contact SPO at https://hsc.unm.edu/about/finance/sponsored-projects/grants-contracts-clinical-trials/sub-awards.html.

Specific Award Conditions - Human Subjects Research:

It is the PI/PD's responsibility to ensure that certification of IRB approval is obtained by all (as prime recipient of the NoA, this includes making sure our consortium partners also comply). For guidance and questions on Human Subject Research, you can contact the HSC Human Research Protection Program (HRPO) at hsc-hrpo@salud.unm.edu or visit their website at:

https://hsc.unm.edu/research/compliance/hrpo/.

SECTION IV - MH SPECIFIC AWARD CONDITIONS - 1R61MH123456-01

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:

This award has been made in response to the application submitted under the Funding Opportunity Announcement RFA-MH-18-702 which can be referenced at: https://grants.nih.gov/grants/quide/ffa-files/RFA-MH-18-702 html.

PERSONNEL COSTS:

As detailed in the NIH Guide Notice on "Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2020" (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-065.html), the Executive Level II on the Federal Executive Pay Scale has increased. Salaries requested in the application at a rate in excess of the salary cap have been reduced and future year recommended levels have been adjusted accordingly. In the event of future salary cap level changes, no salary increases will be provided on this grant for the remainder of this project period.

CONSORTIUM / CONTRACTUAL COSTS:

This award includes funds for consortium activity with following organizations.

- 1. Research Entity #1
- 2. Research Entity #2
- 3. Research Entity #3

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/hihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health

HUMAN SUBJECTS RESEARCH:

This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

Participant Recruitment – Milestones: Additional project reporting requirements – must meet participant recruitment milestones, of which the sponsor can and will withhold future funding if recruitment falls significantly. The PI/PD is responsible for the recruitment, tracking, and reporting of participants.

PARTICIPANT RECRUITMENT - MILESTONES:

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on #####20##. It is expected that ## of the ## total projected participants will be recruited by #####20##. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at:

http://wwwapps.nimh.nih.gov/mr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

Data Sharing Plan: This is part of the NIH reporting requirements, which must be included in the Research Performance Progress Report (RPPR) and currently, in initial applications.

The RPPR report is submitted via eRA Commons by the PI/PD. eRA Commons Website can be accessed at: https://commons.era.nih.gov/commons/index.jsp

For assistance with Data Sharing Plans, visit the HSC Library & Informatics Center at: https://libguides.health.unm.edu/dataplanning

This award is subject to the data sharing guidance outlined in NOT-MH-14-015 and can be found at https://grants.nin.gov/grants/guide/notice-files/NOT-MH-14-015.html. recipient agrees to adhere to the resource and data sharing plan negotiated with NIMH Program staff. Dissemination of study data will be in accord with the Recipient's accepted data sharing plan as stated in the lefter dated https://disservices.nih.grant/ with the plan in page(s) #### of the application. Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing." Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIHIC may result in Enforcement Actions as described in the NIHI Grants Policy Statement

Complete NIMH data sharing terms and conditions can be found at https://nda.nih.gov/contribute/sharing-regimen.html, Instructions are available at https://grants.nih.gov/grants/rppr/index.htm. Complete guidelines on data sharing are available at https://grants.nih.gov/grants/policy/data sharing/index.htm.

Good Clinical Practice (GCP): The PI/PD is responsible for ensuring that all faculty and staff involved in the research project comply with Good Clinical Practice and that all required training and certification are completed. To access GCP training, please visit the Collaborative Institutional Training Initiative (CITI Program) at: https://about.citiprogram.org/.

GCP TRAINING:

DATA SHARING PLAN:

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) as stated in NOT-OD-16-148.

Clinical Trial Dissemination Plan: The PI/PD must ensure that the study is registered on Clinicaltrials.gov no later than 21 days after the first participant has enrolled in the research study.

CLINICAL TRIAL DISSEMINATION PLAN:

The clinical trial(s) supported by this award is subject to the plan submitted on #####20## and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. It is required that the clinical trial(s) funded by this award will be registered in ClinicalTrials gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

Clinical Trial Requirements: The Research Performance Progress Report (RPPR) is required annually to document the recipient's accomplishments and compliance with the terms of the award. The RPPR describes scientific progress, identify significant changes, report on personnel, and describe plans for the subsequent budget period or year. As part of the clinical trial requirements, the PI/PD is responsible for submitting the RPPR in a timely manner. Please visit the following link to access the NIH RPPR Guide:

https://grants.nih.gov/sites/default/files/rppr_instruction_guide.pdf

Data and Safety Monitoring: The NIH has launched a series of initiatives to enhance the accountability and transparency of clinical research and in particular clinical trial research. The Data & Safety Monitoring requires that our institution and the PI/PD include all reports from the Data and Safety and Monitoring Boards (DSMB) in the Research Performance Progress Report. For more information about this NIH Policy, you visit:

https://grants.nih.gov/grants/guide/notice-files/not98-

084.html

Spreadsheet Summary: This is the complete breakdown of the anticipated budget for the project period that was funded. You will see all years, itemized costs, applied indirect rate, and indirect cost with all the totals. It is good practice to review the proposal budget that was submitted against the awarded budget listed here to ensure your budget is adjusted

according to the approved amounts.

CLINICAL TRIAL REQUIREMENTS:

This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

DATA AND SAFETY MONITORING:

This grant is expected to involve a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards cited in NOT-MH-19-027. Each RPPR submitted should include copies of all DSMB reports in RPPR Section G.1 since the last annual award. The recipient is also reminded of required reporting pursuant to NIHGPS 4.1.15.3 and the NIMH Reportable Events Policy cited in NOT-MH-19-027, as appropriate.

SPREADSHEET SUMMARY AWARD NUMBER: 1R61MH123456-01

INSTITUTION: UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR

Budget	Year 1	Year 2
Salaries and Wages	\$255,309	\$255,309
Fringe Benefits	\$84,974	\$84,974
Personnel Costs (Subtotal)	\$340,283	\$340,283
Equipment	\$61,242	
Materials & Supplies	\$5,000	\$5,000
Travel	\$6,000	\$6,000
Other	\$59,433	\$59,853
Subawards/Consortium/ Contractual Costs	\$49,589	\$52,992
Publication Costs		\$6,000
TOTAL FEDERAL DC	\$521,547	\$470,128
TOTAL FEDERAL F&A	\$234,564	\$217,530
TOTAL COST	\$756,111	\$687,658

Facilities and Administrative Costs	Year 1	Year 2	
F&A Cost Rate 1	51.5%	51.5%	
F&A Cost Base 1	\$455,464	\$422,388	
F&A Costs 1	\$234 564	\$217.530	

Recipient Information

1. Recipient Name

UNIVERSITY OF NEW MEXICO

ALBUQUERQUE, NM 87131

- 2. Congressional District of Recipient
 01
- 3. Payment System Identifier (ID) 1856000642A1
- 4. Employer Identification Number (EIN) 856000642
- 5. Data Universal Numbering System (DUNS) 829868723
- 6. Recipient's Unique Entity Identifier G389MFAYJNG9
- 7. Project Director or Principal Investigator,

Lobo Louie, MD Professor loboluie@salud.unm.edu 505-272-####

8. Authorized Official

Marisa Sanchez

Federal Agency Information

9. Awarding Agency Contact Information

Jane Z. Lin

Grants Management Specialist NATIONAL INSTITUTE OF MENTAL HEALTH linja@mail.nih.gov 301-443-2229

10. Program Official Contact Information

Jovier D Evans Assistant Professor NATIONAL INSTITUTE OF MENTAL HEALTH jevans1@mail.nih.gov 301-443-1369

Federal Award Information

11. Award Number

1R61MH123456-01

12. Unique Federal Award Identification Number (FAIN)

R61MH123456

13. Statutory Authority

42 USC 241 42 CFR PART 52

14. Federal Award Project Title

How HSC Faculty and Staff Understand their NoA from NIH

15. Assistance Listing Number

93.242

16. Assistance Listing Program Title

Mental Health Research Grants

17. Award Action Type

New Competing

18. Is the Award R&D?

Yes

Summary Federal Award Financial Information		
19. Budget Period Start Date 02/04/2021 – End Date 01/31/2022		
20. Total Amount of Federal Funds Obligated by this Action	\$756,111	
20 a. Direct Cost Amount	\$521,547	
20 b. Indirect Cost Amount	\$234,564	
21. Authorized Carryover	\$0	
22. Offset	\$0	
23. Total Amount of Federal Funds Obligated this budget period	\$756,111	
24. Total Approved Cost Sharing or Matching, where applicable		
25. Total Federal and Non-Federal Approved this Budget Period	\$756,111	
26. Project Period Start Date 02/04/2021 – End Date 01/31/2023		
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	\$756,111	

28. Authorized Treatment of Program Income

Additional Costs

29. Grants Management Officer - Signature

Maggie C. Paolini

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.



Phase 1 Exploratory/Developmental Grant Department of Health and Human Services National Institutes of Health



NATIONAL INSTITUTE OF MENTAL HEALTH

SECTION I – AWARD DATA – 1R61MH123456-01

Principal Investigator(s):

Lobo Louie, MD

Award e-mailed to: HSC-Preaward@salud.unm.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of \$756,111 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR PART 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Mental Health of the National Institutes of Health under Award Number R61MH123456. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Maggie C. Paolini Grants Management Officer NATIONAL INSTITUTE OF MENTAL HEALTH

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars) Salaries and Wages	\$255,309
Fringe Benefits	\$84,974
Personnel Costs (Subtotal)	\$340,283
Equipment	\$61,242
Materials & Supplies	\$5,000
Travel	\$6,000
Other	\$59,433
Subawards/Consortium/Contractual Costs	\$49,589
Federal Direct Costs	\$521,547
Federal F&A Costs	\$234,564
Approved Budget	\$756,111
Total Amount of Federal Funds Authorized (Federal Share)	\$756,111
TOTAL FEDERAL AWARD AMOUNT	\$756,111
AMOUNT OF THIS ACTION (FEDERAL SHARE)	\$756,111

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)			
YR THIS AWARD CUMULATIVE TOTALS		CUMULATIVE TOTALS	
1	\$756,111	\$756,111	
2	\$687,658	\$687,658	

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier: 1856000642A1

Document Number: RMH123456A

PMS Account Type: P (Subaccount)

Fiscal Year: 2021

IC	CAN	2021	2022
MH	8472591	\$756,111	\$687,658

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: A4-GPX / OC: 41021 / Released: Paolini, Maggie 01/27/2021

Award Processed: 02/04/2021 12:10:38 AM

SECTION II - PAYMENT/HOTLINE INFORMATION - 1R61MH123456-01

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III - STANDARD TERMS AND CONDITIONS - 1R61MH123456-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- c. 45 CFR Part 75.
- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in

the final progress report when applicable.

This award notice. INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R61MH123456. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials fdaaa/

This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see

http://grants.nih.gov/grants/funding/women min/guidelines amended 10 2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV - MH SPECIFIC AWARD CONDITIONS - 1R61MH123456-01

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

AWARD NOTICE:

This award has been made in response to the application submitted under the Funding Opportunity Announcement RFA-MH-18-702 which can be referenced at: https://grants.nih.gov/grants/guide/rfa-files/RFA-MH-18-702.html.

INFORMATION:

This grant is awarded with the understanding that project delays and challenges may occur due to COVID-19. It is NIMH's intention to ensure the ultimate success of each project: to that end, we will work with recipients on a case-by-case basis to identify flexibilities and find solutions. You are encouraged to refer to the NIH Guide (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html, and updates referenced therein) and to the regularly updated Frequently Asked Questions (https://grants.nih.gov/faqs#/covid-19.htm) for guidance on delays in research progress, delays in financial and RPPR reporting, costs, and other relevant issues, and contact your grants specialist and/or program officer with questions.

The NIH is concerned about the safety and welfare of human subject participants and research staff and has issued <u>Guidance for NIH-funded Clinical Trials and Human Subjects Studies</u>

<u>Affected by COVID-19</u>. For the purposes of RMR reporting, the NIMH requests that study teams continue to enter their anticipated recruitment milestones and actual recruitment numbers and succinctly indicate in the comments box if and how COVID-19 has impacted study recruitment efforts. NIMH staff will continue to monitor and work with you as <u>additional guidance and</u> information becomes available.

PERSONNEL COSTS:

As detailed in the NIH Guide Notice on "Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2020" (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-065.html), the Executive Level II on the Federal Executive Pay Scale has increased. Salaries requested in the application at a rate in excess of the salary cap have been reduced and future year recommended levels have been adjusted accordingly. In the event of future salary cap level changes, no salary increases will be provided on this grant for the remainder of this project period.

CONSORTIUM / CONTRACTUAL COSTS:

This award includes funds for consortium activity with following organizations.

- 1. Name of Research Entity #1
- 2. Name of Research Entity #2
- 3. Name of Research Entity #3

Each consortium is to be established and administered in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/index.htm). No foreign performance site may be added to this project without the written prior approval of the National Institute of Mental Health.

HUMAN SUBJECTS RESEARCH:

This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and collected data and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

PARTICIPANT RECRUITMENT - MILESTONES:

Future NIMH support for this study is contingent upon adequate participant recruitment based on projected milestones as approved in the Recruitment Milestone Reporting system (RMR) on ##/##/20##. It is expected that ## of the ## total projected participants will be recruited by ##/##/20##. This tri-yearly recruitment report should be submitted electronically to NIMH after each milestone period of April 1, August 1 and December 1 at:

http://wwwapps.nimh.nih.gov/rmr/displayHome.action. In the event that actual recruitment falls significantly below projected milestones, NIMH may consider withholding future support and/or negotiating an orderly phase-out of this study. Information regarding the NIMH Policy for the Recruitment of Participants in Clinical Research is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-MH-19-027.html.

DATA SHARING PLAN:

This award is subject to the data sharing guidance outlined in NOT-MH-14-015 and can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-MH-14-015.html. recipient agrees to adhere to the resource and data sharing plan negotiated with NIMH Program staff. Dissemination of study data will be in accord with the Recipient's accepted data sharing plan as stated in the letter dated ##/##/20##, and the plan in page(s) ### of the application. Please note that a statement of progress on the Sharing Plan must be included in the Research Performance Progress Report (RPPR) under section C.5 "Other Products and Resource Sharing." Failure to adhere to the sharing plan as mutually agreed upon by the Recipient and the NIH/IC may result in Enforcement Actions as described in the NIH Grants Policy Statement.

Complete NIMH data sharing terms and conditions can be found at https://nda.nih.gov/contribute/sharing-regimen.html. Instructions are available at http://grants.nih.gov/grants/rppr/index.htm. Complete guidelines on data sharing are available at http://grants.nih.gov/grants/policy/data_sharing/index.htm.

GCP TRAINING:

NIH expects that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) as stated in NOT-OD-16-148.

CLINICAL TRIAL DISSEMINATION PLAN:

The clinical trial(s) supported by this award is subject to the plan submitted on ##/##/20## and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. It is required that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

CLINICAL TRIAL REQUIREMENTS:

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In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

DATA AND SAFETY MONITORING:

This grant is expected to involve a Data and Safety Monitoring Board (DSMB). The recipient and Principal Investigator(s) should review the <u>NIMH Policy Governing Independent Safety Monitors and Independent Data and Safety Monitoring Boards</u> cited in NOT-MH-19-027. Each RPPR submitted should include copies of all DSMB reports in RPPR Section G.1 since the last annual award. The recipient is also reminded of required reporting pursuant to NIHGPS 4.1.15.3 and the <u>NIMH Reportable Events Policy cited in NOT-MH-19-027</u>, as appropriate.

SPREADSHEET SUMMARY

AWARD NUMBER: 1R61MH123456-01

INSTITUTION: UNIVERSITY OF NEW MEXICO HEALTH SCIS CTR

Budget	Year 1	Year 2
Salaries and Wages	\$255,309	\$255,309
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(Subtotal)		
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Other	\$59,433	\$59,853
Subawards/Consortium/	\$49,589	\$52,992
Contractual Costs		
Publication Costs		\$6,000
TOTAL FEDERAL DC	\$521,547	\$470,128
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TOTAL COST	\$756,111	\$687,658

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F&A Cost Base 1	\$455,464	\$422,388
F&A Costs 1	\$234,564	\$217,530

Exhibit B



Financial Services Sponsored Projects Office

Research Administration Roles and Responsibilities Matrix August 2023

The Roles and Responsibilities Matrix for Research Administration at UNM HSC seeks to identify commonly encountered activities and to provide guidance regarding the responsible parties for each within sponsored research.

Note that this Matrix is not meant to be prescriptive or exhaustive and is subject to change.

	ROLE DESIGNATION LEGEND								
Research Administration Roles and Responsibilities Matrix August 2023	Primary Responsibility for action/implementation of tasks: P= PRIMARY currently PF= PRIMARY in FUTURE				Support/Consult, as necessary: S= SUPPORT currently SF= SUPPORT in FUTURE				
RESEARCH ADMINISTRATION PROCESS	Principal Investigator (PI)	Sponsored Projects Office (SPO)	Contract & Grant Accounting (CGA)	Department Administrator, Department Accountants, Study Support Staff, Department Acesarch Administrator	Technology Transfer Office (TTO), Rainforest Innovations	Clinical & Translational Science Center (CTSC) (For industry research only)	Research Compliance Offices: Office of Research- Export, COI, IRB, OACC, IBC	Property Accounting Office (PAO), Inventory Control	Purchasing Department, Accounts Payable
	Pre Award								
Preparing to Submit a Proposal									
Locate funding opportunity	Р	s				s	Τ		
Read and interpret proposal guidelines	Р	S		S		S	S		
Prepare Non-Disclosure Agreements, as needed	S	Р							
Prepare Teaming Agreements, as needed		Р							
Proposal Development									
Obtain and understand sponsor instructions for proposal preparation	Р	P	T	s		Т	Τ	Т	
Identify Cost Sharing in proposal and obtain cost share approval from Department	Р	S		s					
Identify and indicate approvals needed for proposal		Р		S					
Completion of Proposal in Sponsor's Submission Portals, and Internal Click eRA record		S		Р					
Provide quidance to PI on proposal preparation		Р		s		s			
Develop and revise technical narrative, Bio sketches, Current and Pending				S					
Complete and/or Confirm administrative/institutional requirements of proposal		Р	S	S					
Ensure required Effort available, if awarded				S					
Identify subcontractors/collaborators	Р								
Request and collect necessary Subcontractor Budget, Statement of Work (SOW), Commitment Form and Sole Source Justification	Р	s		P					
Notify CTSC of proposal with Industry Clinical Trials, if Department needs support with budget	Р			s		s			
Draft Budget [Use the latest version of the Internal Budget Worksheet (ibw) in SPO website]	S/ PF			P/SF					
Review Budget	P/ SF	S/PF		s		s			
Revise Budget in partnership with PI	s	s		Р					

ROLE DESIGNATION LEGEND Research Administration Roles and Responsibilities Matrix Primary Responsibility for action/implementation of tasks: Support/Consult, as necessary: August 2023 P= PRIMARY currently S= SUPPORT currently PF= PRIMARY in FUTURE SF= SUPPORT in FUTURE RESEARCH ADMINISTRATION PROCESS Proposal Review and Approval Review proposal package, including cost-share requirements, before sending proposal and completed Click record to SPO at least 10 Business Days in advance of electronic submission deadline Ρ Р Provide institutional review and approval of proposal and budget within 3 days of receipt. Р Review proposed Cost Sharing commitment for compliance with University policy and sponsor terms S Ρ s s Identify non-standard F&A (Indirect Cost) rate requiring an F&A Waiver Р Р Initiate/Submit to SPO F&A (Indirect Cost) rate waiver approval requests P s Review subcontractors' proposals and check for their institutional approval s Р S Make revisions and corrections to proposal after institutional review s Р Identify export control issues, if any Р s S Obtain necessary export control review Р s S Initiate Institutional Review Board (IRB) approvals Р s s Initiate Institutional Animal Care and Use Committee (IACUC) approvals Р S s Initiate Technology Control Plan Р s s s Initiate biosafety reviews Р s s **Proposal Submission** Submit proposals to sponsors (SPO must be involved in all proposal submissions.) S Р Record proposal submission in Click eRA, after information has been entered - see above. P s **Pre-award Activities** Prepare/collect additional paperwork for sponsor (i.e., Just In Time (JIT)) s Review and submit additional paperwork to sponsor (JIT) s Р s Request pre-award spending index (RTSF) if needed, including Budget and Period of Performance s Approve pre-award spending account request (RTSF) Ρ Set up pre-award spending account (new index) Р Communications with Grants Management Office on behalf of PI/PD