[University of New Mexico Health Sciences Center]

Protocol Detail Report Answered Questions Only

Report Comments Protocol Information Version # 5 Reference Number 200420 Protocol Number 16-20042 0-T-HSC Protocol Type: Renewal Principal Investigator: Approval Date: 2/15/2019 Submittal Date: 11/20/2018 Effective Date: 2/15/2019 Author: Renewal Date: 2/15/2020 Status: Approved Next Review Date: 2/15/2020 Inactive Date: Expiration Date: 10/27/2019 **Annual Renewal Section** 1.1 **Continuation Status** Do you wish to continue this protocol? 1.1.1 Yes **Annual Renewal Progress Report** 1.1.1.1 Give a brief summary of progress made during the past year. Include species and number of animals used. We are in the MS preparation phase of this project. We did not use any new animals over the past year. **Expected Progress in Coming Year** 1.1.1.2 Briefly define research goals projected for completion in the upcoming year. We will may be imaging animals later in the year. Our collaborator, has left and is now a Professor at We will amend this protocol to include as a collaboration site. The protocols will be the same. 1.1.1.3 Complications Associated with Animal Procedures Have technical complications occurred with animal procedures in the past year? Yes 1 1.1.1.3.2

No

Funding Status	1.1.1.4
Have there been any changes in funding for this project?	
☐ Yes ✓ No	
	1.1.1.4.2
No	
Current Field Permits	1.1.1.5
Are all your field permits up to date (if applicable)?	
Yes No	
✓ N/A	1.1.1.5.3
N/A	111/11010
Updated or New Animal Handling Training and Medical Clearance	1.1.1.6
All protocol associates must be medically cleared annually and appropriately trained to handle animals.	
Please verify all protocol associates listed on this protocol are up to date on their medical clearance and training.	
Renewal Type	1.1.1.7
Select one. If you wish to make changes at this time (ex: add/remove staff) select "Annual Renewal/Minor Amendment of the control of the cont	nent"
Annual Renewal ONLY Annual Renewal/Minor Amendment	
	1.1.1.7.2
Annual Renewal/Minor Amendment	
Minor Amendment Change(s)	1.1.1.7.2.1
Select ALL that apply.	
Add/Remove Staf: Increase of animals less than 10%	
Minor procedural changes	
	1.1.1.7.2. 1.3
Minor procedural changes	113
Justification for requested changes	1.1.1.7.2. 1.3.1
Briefly summarize the proposed changes if not described above, justify the changes for this amendment, or give reasons for adding new procedures or changing existing procedures.	
Update changes in all appropriate sections of the protocol form.	
We will include new location new location we will need to complete an interinstitutional approval form.	tter, and

Administrative Section	
Reference Number	2.1
This number is automatically populated by the system. 200420	
Protocol Number	2.2
Protocol number is assigned by the Office of Animal Care Compliance (OACC) upon approval. 16-200420-T-HSC	
Title	2.3
Maximum limit is 255 characters, be concise. Note: The title should include reference to procedures and the animal species to be used (e.g. "A Rat Model of Ischemic Stroke.").	
PTSD mouse model animal behavior studies	
Principal Investigator	2.4
PI - individual solely responsible for the protocol, its assurances, and can order animals. Click on the silhouette with the green plus icon below to select the PI. You may type the PI name in the search window. Select the blue information icon to review your contact information. If it needs updating please email	
Department	2.5
Select the appropriate department from the drop down list by clicking the green plus icon to the right. Click the "+" or "-" to expand or collapse the entire list of departments or type the department name in the search window then select "OK". Pathology	
Author	2.6
Someone who fills out or works on the request, and is authorized to order animals. Click on the silhouette with the green plus icon below to select the Author. You may type the Author name in the search window.	
Co-Author	2.7
This person should be someone other than the PI who can access and edit the protocol in the PI's absence. Click on the silhouette with the green plus icon below to select the Co-Author. You may type the Co-Author name in the search window.	

Created By	2.8
Creator - the person who initially creates the protocol (auto-populated per the login and cannot be changed) and who may populate documents.	y
Animal Handling Training	2.10
Attachments: OACC Training Page Personnel_Qualifications_Final_9-21-16.docx	
Attach the Personnel Qualifications Form here for the PI and all protocol associates by clicking on the paperclip icon to the right:	
• Personnel Qualifications Form - training for specific hands-on procedures performed on LIVE VERTEBRATE ANIMALS at UNM (this form is NOT needed for collaborative, display, holding, or tissue protocols).	
Protocol associates who are not properly trained may not handle animals and may not be listed on approved protocols.	
Click on the links below to access either the Personnel Qualifications Form (hands-on training) or the website and modules (disable popups on your browser to view attachments).	
3 Year Re-Write	2.11
Does this replace an expiring, expired, or a transfer protocol?	
Yes	
✓ No	
No	.11.2
Associated Protocols	2.12
Select all that apply.	
✓ UNM Protocols	
✓ External Protocols	
None None	
UNM Protocols	.12.1

Related Protocols				2.12.1.
Select UNM protocol(s)	for which you are asso		below.	
Reference #	Protocol #	Status	Title	Туре
200416		Withdrawn	B6.Cg- Tg(tetO_APPSwind) 102Dbo/J Breeding Colony	Amendment
200056	13-100996-T-TR-HSC	Approved	Imaging Brain anatomy and Function Using MRI	
200057	15-101248-B-TR-HSC	Approved	B6.Cg- Tg(tetO_APPSwind) 102Dbo/J Breeding Colony	Original
200058	15-101310-T-TR-HSC	Approved	Live Imaging of Brain Circuitry in Mouse Models (PTSD	Original of
External Protocols				2.12.:
External Related Protocols				2.12.2.
Attachments: 2015 Jan 16 3Yr F		1430.pdf		
Fill in the protocol inforr	nation below.			
For Transfer protocols a	attach all external proto	aal farma and IACI		
	allacii ali external proto	col forms and IAC	JC approval letters.	
·	cols attach IACUC appr	roval letters.		
·		roval letters.		ginal Approval Date
Original Protocol Number	cols attach IACUC appr	roval letters.		ginal Approval Date
Original Protocol Number See Attached Office Use Only	cols attach IACUC appr	roval letters.		ginal Approval Date
For Collaborative protocol Priginal Protocol Number See Attached Office Use Only Scientific Merit Funding	cols attach IACUC appr	roval letters.		ginal Approval Date
Original Protocol Number See Attached Office Use Only Scientific Merit Funding	cols attach IACUC appr	roval letters.		
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Confidentiality Statement Confidentiality St

A1.1.1.1 Grant Information and FP#						
Fill in the following. Click the green plus icon to the right to add rows to the table. Title of grant if different from protocol Fill of grant if different from protocol Grant number/identifier Grant start date Grant end date UNM Identifier (ex: Cayuse#/HSC Pre-Award FP#) 7/1/2012 G/30/2018 PHS Funding 4.2 Is this project Public Health Service (PHS) funded? PHS agencies = National Institutes of Health (NIH), National Science Foundation (NSF), plus the following: ACF, AoA, AHRQ, ATSDR, CDC, CMS, FOH, FDA, HRSA, IHS, SAMHSA Yes Grant Congruency 4.2.1.1 Attachments: 254688 Veit. Animals.pdf Congruency review is required for all PHS agencies = NIH plus the following: ACF, AoA, AHRQ, ATSDR, CDC, CMS, FOH, FDA, HRSA, IHS, SAMHSA *Attach the relevant vertebrate animal section(s) of the grant(s) to document congruency between the animal protocol and the vertebrate animal section(s) of the grant by clicking the paper clip icon to the right. Conflict of Interest 4.3 Has a Conflict of Interest (COI) form been submitted to the Pre-Award Office for grants associated with this protocol? Yes No 4.3.1	NIH/NIMH				4	.1.1.1.1
Click the green plus icon to the right to add rows to the table. Title of grant if different from protocol Grant number/identifier Grant start date Grant end date UNM Identifier (ex: Cayuse#/HSC Pre-Award FP#) 7/1/2012 6/30/2018 PHS Funding Is this project Public Health Service (PHS) funded? PHS agencies = National Institutes of Health (NIH), National Science Foundation (NSF), plus the following: ACF, AoA, AHRQ, ATSDR, CDC, CMS, FOH, FDA, HRSA, IHS, SAMHSA Yes Grant Congruency 4.2.11 Attachments: 254698 Vert. Animals.pdf Congruency review is required for all PHS agencies = NIH plus the following: ACF, AoA, AHRQ, ATSDR, CDC, CMS, FOH, FDA, HRSA, IHS, SAMHSA **Attach the relevant vertebrate animal section(s) of the grant by clicking the paper clip icon to the right. Conflicts of Interest Has a Conflict of Interest (COI) form been submitted to the Pre-Award Office for grants associated with this protocol? Yes No 14.3.11	Grant Information and FP#	£.				4.1.1.2
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	✓ Yes	(p. 5.65001	
						4.3.1

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Scientific Abstract/Project Overview	4.4
Include aims/hypotheses/objectives. The PI may choose to add a link to their NIH Biosketch, Researchgate, research page, or other summary of relevant publications by clicking on the paperdip icon to the right or embedding a link in the text below.	
This is one component of a newly funded 5 year study that will explore possible anatomical and biological alterations in brains of Post-Traumatic Stress Disorder (PTSD). We will link genetics, fear responses, and functional and structural MRI information in this study. The anxiety tests and MRI components will be done by collaborators at post-mortem tissue will be prepaded either at post-mortem or UNM and microscopic and biochemical analyses performed. High end miicroscopy will be performed at the components will be prepaded to the components will be done by collaborators at the components will be done by collaborators at the components will be prepaded to the components will be done by collaborators at the components will be done by collaborators.	
We will use in vivo mouse models of PTSD in a collaborative "tissue" protocol where tissues are collected at either at UNM or at the standard of the standard	.
We will do standard mouse behavior studies to test anxiety behavior at each institution. Prior to and at various intervals after a traumatic event exposure to predator odor), mice will be videotaped in a light/dark box and the videos analyzed. Th higher the anxiety, the longer the time they spend in the dark. Then they will be anesthetized, cardiac perfused, and their brains will be fixed by standard protocols and tested for biological and anatomical differences.	е
Our hypothesis is that fear evokes neuronal activity that in some individuals continues long after the traumatic event resolves, leading to the changes we will be looking for. Our aim is to map neuronal responses, to correlate them to SERT variability and to determine fear circuitry in these model animals.	
Using the information we gain from these mice, we hope to be able to look at human PTSD in a more critical and hopefully more biologically useful way. We should be able to identify susceptibilities and possible windows for therapy (immediately after the trauma, before the anatomical changes occur would be one possibility). We hope that these mice can tell us which of the human SERT gene variants are more protective against PTSD, and which might make people more susceptible.	h
All live animal experimentation is concluded as of January 2016 and the project is now at the stage of tissue analysis by microscopy either at UNM or at where where the has a Visiting Associate appointment and can use high-end laser-light sheet microscopy not available at UNM to image these precious brains. The subaward to from 2012-2016 was in place with all appropriate approvals and assurances at during the subaward. Now the project has moved into analysis mode which will be performed at both and UNM. Because has a Visiting Associate appointment at a no subaward is necessary for the tissue analysis on the advanced microscopy equipment there which she will perform. We will include the new location approval form.	
Lay Summary	4.5
Address species or taxon of animal(s) using common names, goals, a list of animal procedures, and benefits of the study. Use non-scientific words. Eliminate or define abbreviations, technical terms, and jargon.	

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Using the information gained from these mice we hope to be able to look at human PTSD in ways that are more biologically and dinically useful. We hope to better identify windows for therapy. We hope that these mice can tell us which of the human SERT gene variants are more protective against the clinical problems caused by PTSD. And which might make people more at risk to PTSD. All live experimentation has been concluded since Janaury 2016 and this project is now in the

analysis and microscopy stage.

Scientific Merit Review				4.6	
	to independent peer revie	ew?			
Yes No					
Vac				4.6.1	
Yes					
Scientific Reviewing Entity				4.6.1.1	
List the scientific reviewi	• •				
Center for Scientific Rev	iew, NIH				
Collaborative or Tissue Info	rmation				
Protocol Type	······································			5.1	
Select all that apply.					
Animal Tissue					
Collaborative (place holder for	funding - ALL vertebrate research un	der this UNM funded project conducted	d at an external institution)		
Animal Tissue				5.1.1	
Reason for Tissue Collection	1			5.1.1.1	
Will tissue be collected from live vertebrate animals or will animals be euthanized solely for the purpose of this study? If not, then this qualifies as a tissue protocol and you will fill out the details of your study by selecting "No". Examples of Tissue Protocols: Tissues obtained from a retail source Shared tissues obtained from animals utilized under a separately approved protocol					
Bird or Reptile embryos	obtained prior to hatching		p. 6.666		
Embryos (e.g. ∠ebraīisn Yes No	up 72 hours post fertilizat	ion)			
				5.1.1.1.2	
No					
Animal Tissue				5.1.1.1.2.1	
Fill in the following. Click the green plus icon	to the right to add rows to	o the table.			
Species of Origin	Tissue Type	Quantity Requested	Source (e.g. research facility or retail)	UNM Protocol # for tissue origin (if applicable)	
mouse	brain	100			

Select all that apply. Itssues will be used in invitro assays Itssues will be used for invitro assays Itssues will be used for invitro assays Itssues will be used for invitro assays Itssues will be incutaled into other laboratory animals 2.4		
Itssues will be used in a wet lab as training specimens Itssues will be inoculated into other laboratory animals Other Specify Tissue Use - Other Specify Tissue Use - Other Specify Tissue Use - Other Specify Other use of tissue not listed in the above selection choices. Brains are perfused and fixed and imaged post-mortem for microscopy or harvested after euthanasia and quick frozen for biochemistry. The project is now in analysis stage. All live imaging was completed in prior for January 2016. Microscoopy will be performed both at an and UNIM. We will include new location will new location. Agente and Occupational Risks Occupational Risks Associated with Animals or Tissues Prior to Research Manipulation 6.1 Some naive animals or animal tissues pose intrinsic occupational risks to personnel since they may harbor naturally endogenous zoonoses or animals may pose threat of physical injury. If applicable, please indicate any specific occupational risks associated with animals or animal tissues used under this project and indicate methods to be utilized that will minimize such risks. The occupational risks associated with these animals are the usual ones; being bitten and clawed, and exposure to animal allergens. Biological, Chemical or Radiological Agent Use 6.2 Will you be using biological, chemical, or radiological agents of any kind (both hazardous and non-hazardous)? Yes Will you be using biological, chemical, or radiological agents of any kind (both hazardous and non-hazardous)?	Tissue Uses	5.1.1.1.2.2
Other Specify Tissue Use - Other Specify Tissue Use - Other Specify other use of tissue not listed in the above selection choices. Brains are perfused and fixed and imaged post-mortem for microscopy or harvested after euthanasia and quick frozen for biochemistry The project is now in analysis stage. All live imaging was completed in prior for January 2016. Microscoopy will be performed both at	Tissues will be used in a wet lab as training specimens	
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Biological, Chemical or Radiological Agent Use Will you be using biological, chemical, or radiological agents of any kind (both hazardous and non-hazardous)? Yes No	endogenous zoonoses or animals may pose threat of physical injury. If applicable, please indicate any specific occupational risks associated with animals or animal tissues used under this	i
Will you be using biological, chemical, or radiological agents of any kind (both hazardous and non-hazardous)? ☐ Yes ✓ №		nimal
Yes✓No	Biological, Chemical or Radiological Agent Use	6.2
_	Yes	
No		6.2.2

Assurance Statement

7.1 PI Assurances Read and select all. The PI must agree to all provisions contained herein. Once selected and saved, this program will require an electronic signature by the PI that will signify the Principal Investigator's agreement with the following conditions and assurances. The PI must be logged in and must save the checkboxes in order to generate the login that creates the e-signature. No one else may sign. Animals are essential for this project and the study does not UNNECESSARILY duplicate previous experiments. **V** The minimum number of animals will be used to support the goals of this study. **✓** All procedures are conducted in a manner to minimize discomfort, distress and pain. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending ✓ veterinarian and/or the IACUC. All personnel par icipating in animal activities on this protocol are adequately trained in the procedures in which hey are involved. ✓ All personnel are aware of ethical responsibilities associated with animal research activities and procedures for repor ing animal welfare concerns. **✓** The PI and all personnel associated with this study will follow procedures under the approved protocol and comply with all pertinent institutional, state and federal rules regarding the use of animals in research, testing or education. I understand that if this protocol expires, all animal work under the protocol must cease until a replacement protocol is approved and all remaining animals must be transferred to a holding protocol All individuals associated with this protocol that will have contact with live animals or with animal tissues or body fluids have been informed of the requirement for participation in the Institution's Employee Occupational Health and Safety Program. 7.1.1 Animals are essential for this project and the study does not UNNECESSARILY duplicate previous experiments. 7.1.2 The minimum number of animals will be used to support the goals of this study. 7.1.3 All procedures are conducted in a manner to minimize discomfort, distress and pain. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and/or the IACUC. 7.1.4 All personnel participating in animal activities on this protocol are adequately trained in the procedures in which they are involved. 7.1.5 All personnel are aware of ethical respons bilities associated with animal research activities and procedures for reporting animal welfare concerns. 7.1.6 The PI and all personnel associated with this study will follow procedures under the approved protocol and comply with all pertinent institutional, state and federal rules regarding the use of animals in research, testing or education. 7.1.7 I understand that if this protocol expires, all animal work under the protocol must cease until a replacement protocol is approved and all remaining animals must be transferred to a holding protocol.

All individuals associated with this protocol that will have contact with live animals or with animal tissues or body fluids have been informed of the requirement for participation in the Institution's Employee Occupational Health and Safety Program.

7.1.8