

General Research Updates

February 25, 2021



UT Health
San Antonio

During the Forum:

- The session will be recorded
- Mute your mics to avoid echoing or background noise
- Do not activate your camera to preserve bandwidth
- In lieu of voicing your questions, use the chat function, a moderator will respond to your question

Overview

ORCA- Accessing Approved Documents

VPR Website

VA Updates

ORCA – Accessing Approved Documents

*Kimberly Summers, PharmD
RPP Director*



[Start Here](#) ➔

ORCA v2.0

Online Research Compliance Assistant

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University of Texas Health Science Center at San Antonio [🔗](#)

Approval Notice Emails

Dear Kimberly Summers,

Your request to conduct this minimal risk research was approved by Expedited Review on 2021-02-25 under the following regulation(s):

The following are included in this approval (see approved application for details):

The IRB has determined that continuing review is not required.

Your UTHSA institutional project update form must be submitted to the Office of Clinical Research 30 days prior to the expiration date. If your study is approved at another institution, confirm submission requirements with the respective research office.

IMPORTANT REMINDER: Even though an IRB continuing review is not required for this study, the study team must still:

- Submit IRB amendments for project changes
- Report possible UPIRSOs and noncompliance to the IRB
- Submit an IRB inactivation form once the project ends, or when personal identifiers are removed from the data- biospecimens and all codes and keys are destroyed.

Institutions which are engaged in this research:

- - University of Texas Health Science Center at San Antonio

NOTE: All approved documents related to this submission will be available from your ORCA dashboard [O.R.C.A.](#) . If you require a formal letter of approval contact the Office of the IRB (OIRB). If your submission requires UTHSA institutional activation, documents will be available after OCR provides this activation. For studies including an affiliate site (VA/UHS), a separate approval is required before beginning your research at the affiliate site.

Accessing Approved Documents

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ORCA Dashboard

Your Protocols				
<div> <div>Active 15</div> <div>Inactive/Expired 7</div> <div>Templates 0</div> </div>				
15 protocols list you as Lead-PI				
Protocol Number	Title	Critical Dates		Reviewing Committee
20210029HU ○	Test Expedited	Regulatory Expiration:	∞	HSC-IRB
20210043TR ○	IIA SNAP	Institutional Expiration:	2023-09-08	HSC-IRB
20210044HR ○	snap 2	Regulatory Expiration:	Pending	HSC-IRB
20210062HU ○	Testing Institutional State	Regulatory Expiration:	∞	HSC-IRB
20210070HU ○	Test for Pam	Regulatory Expiration:	2021-03-16	HSC-IRB
20210117HU ○	Kims Protocol for Regulatory status external IRB	Next Prog Rpt Due:	2021-03-02	HSC-IRB
20210147HU ○	KIMS TEST SITES	Regulatory Expiration:	Pending	HSC-IRB
20210149EX ●	Exempt Protocol No Limited IRB Review	Regulatory Expiration:	∞	HSC-IRB



Study Team Members Access





13 protocols list you as **Study Team Member**

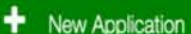


Protocol Number	Title	Critical Dates		Reviewing Committee
20200869HU ○	Test edit site tab	Regulatory Expiration:	Pending	HSC-IRB
20210034HU ○	IRB HU, Exp Review / Continuing Review	Regulatory Expiration: Next Prog Rpt Due:	2025-03-05 2025-02-19	HSC-IRB
20210073HR ○	Mendoza- Test	Regulatory Expiration:	Pending	HSC-IRB
20210075EX ○	Test Protocol - mendoza	Regulatory Expiration:	Pending	HSC-IRB
20210081EX ○	Test protocol - mendoza	Regulatory Expiration: Next Prog Rpt Due:	2022-12-31 2022-12-17	HSC-IRB
20210121HUD ○	cheryl test HUD protocol	Regulatory Expiration: Next Prog Rpt Due:	2022-02-02 2022-01-19	HSC-IRB


Protocol Information







STUDY MANAGEMENT

 Study Personnel

20210255HU | Research Forum Example

Summary

Protocol Number	Title	Type	Status
20210255HU	Research Forum Example	Human Study	Regulatory: ApprovedExpiration: Pending Institutional: --- Expiration: ---:

Contacts

Files & Attachments



Find A Study

Currently Approved Documents Folder

Protocol Documents

 ORCA Current Folder

Documents Available for Download

	0 Current
	19-070X, Summers, CA, 04-23-19, NS.docx
	19-070X, Summers, Form A, 04-23-19, NS.PDF
	19-070X, Summers, Form BB, 04-23-19, NS.pdf
	19-070X, Summers, Form D, 04-23-19, NS.docx
	19-070X, Summers, Form J, 04-23-19, NS.doc
	19-070X, Summers, Form S Aldactone, 04-23-19, NS.pdf
	19-070X, Summers, Form S Eplerenone, 04-23-19, NS.pdf
	19-070X, Summers, Inst B, 04-23-19, NS.docx
	19-070X, Summers, Inst B, 04-23-19, NS.pdf
	19-070X, Summers, Inst CT Form, 06-13-19, AA.docx
	19-070X, Summers, Inst M, 01-09-20, AA.docx
	19-070X, Summers, Medical Release, 04-23-19, NS.pdf
	19-070X, Summers, Modification Request, 06-13-19, AA.docx
	19-070X, Summers, NS LOA INST, 05-22-19.pdf
	19-070X, Summers, WIRB Approval_Site, 04-23-19, NS.PDF
	19-070X, Summers, WIRB Letter, 04-23-19, NS.pdf
	19-070X, Summers,Form MM_recruitment, 04-23-19, NS.pdf
	19-070X, Summers,Form MM, 04-23-19, NS.pdf

VPR Website

Kimberly Summers, PharmD
RPP Director

Navigating the Research Lifecycle

Office of the Vice President for Research

The Office of the Vice President for Research provides resources and services to support researchers throughout the "lifecycle" of the research. Our aim is to foster a research culture that drives innovation, collaboration and recognition of our researchers.

[Where do I start? »](#)

[COVID Related Information »](#)

[Frequently Asked Questions »](#)



We're with you at every stage of the research lifecycle

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Quicklinks


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President for Research

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"cycle" of the research. Our aim is to foster a research culture
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Development

Logistics

Approval

Initiation

Management

Close Out

We're with you at every stage of the research lifecycle

Quicklinks

Human Study Submissions

- Clinical Trial
- UTHSA IRB Review
- External IRB Review
- Amendment/Modifications
- Progress Report/Update Report
- Prompt Report
- Exception Request

Logins

- ORCA
- Velos
- iDisclose
- CITI

Events

- Upcoming Events

Find

- Training for Animal Studies
- Training for Human Studies
- Glossary
- Forms
- Guidance & Policies
- Trending Information

Contact Us

- IRB
- OCR
- CTO
- COI
- IACP
- LAR

More

- Investigator Registry
- Find-A-Study

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Supporting the Research Lifecycle

Vice President for Research

The Office of the Vice President for Research provides resources and services to support the "research lifecycle" of the research. Our aim is to foster a research culture of collaboration and recognition of our researchers.



Quicklinks

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Events

- Upcoming Events

Find

- Training for Animal Studies
- Training for Human Studies
- Glossary

Questions?

VA Updates

Polly Hitchcock Noël, PhD

Assistant ACOS for Human Research

South Texas Veterans Health Care System

VA Innovation Research Review System (VAIRRS)

VA's enterprise instance of IRBNet

Research software management platform for all VAMCs with research program – intended benefits:

- Support all committee work & institutional tracking of all research / innovation projects

- Improve transparency of protocol tracking

- Reduce administrative load on R&D staff, committee members, & researchers

- Provide dashboard reporting of key metrics

VA Innovation Research Review System (VAIRRS)

IRBNet/VAIRRS features include:

- Separate “workspaces” for researchers, R&D admin, & committee/subcommittees
- Automated reminders for continuing reviews
- Library of core documents
- Training / credentials tracking
- Committee minutes / agendas

VA Innovation Research Review System (VAIRRS)

With VAIRRS, VA ORD hopes to standardize R&D processes:

- All project submissions (except FCOIs), reviews, & approvals* occur within VAIRRS
- “Submission” pathway for new projects (all administrative / institutional reviews completed prior to IRB/IACUC submission)
- Feasibility, Alignment, & Scientific Reviews

VA Innovation Research Review System (VAIRRS)

With VAIRRS, VA ORD hopes to standardize R&D processes & forms:

- Two required “wizards” or smart forms:
 - Project Cover Sheet (required for all projects)
 - Information Sheet (required for all projects submitted to either internal / external IRB or IACUC)
 - (IRB Info Sheet is available; IACUC Info Sheet is pending)

VA Innovation Research Review System (VAIRRS) – Next Steps

- Local training sessions March 4th & March 11th
- IRBNet currently setting up committee structure and registering admin staff & committee members
- Once completed (date TBD), R&D admin can start working with administrative tools
- Researchers can register, but cannot submit projects/packages until Go Live date

VA Innovation Research Review System (VAIRRS) – Next Steps

- Submission of data conversion sheet to IRBNet by March 12th
- IRBNet will create “shells” for existing projects
- VAIRRS Go-Live date tentatively scheduled for March 19th

VA Innovation Research Review System (VAIRRS) – Next Steps

After Go-Live date, researchers can begin submitting new projects or “packages” to existing projects

- If they have registered (including submission of most current training records)
- Completed required forms for new & existing project (i.e., Project Cover Sheet & Information Sheet)

VA Innovation Research Review System (VAIRRS)

Basic information about VAIRRS available at:
(<https://www.research.va.gov/programs/orppe/vairrs/>)

Detailed training materials (including webinars & demos) can also be accessed on the VA Intranet [VA Innovation and Research Review System \(VAIRRS\) - Home \(sharepoint.com\)](#)

Questions?

Upcoming Forum and Concierge Dates

Forum scheduled for

- Thursday, March 25, 2021
- 1:00 pm – 2:00 pm
- Zoom

Concierge Dates Meetings are through Microsoft Teams

- Tuesday, March 2, 2021
Timeslots available from 1:00 pm – 4:00 pm
- Wednesday, March 10, 2021 & March 24, 2021
Timeslots available from 9:00 am – 12:00 pm