

AnSRS4U Project Administration

*Topic: Compliance
Animal Welfare Office
Biosafety
Human Subjects Protection Program*



Presenters

- Shelly Grassinger, SR. Project Administrator
- Deanna Hawley, SR. Project Administrator
- Andi Mitchell, Director Animal Welfare Office
- Christine McFarland, Director Biological Safety Office
- Aliese Seawright, Director Human Subjects Research Protection Program



Welcome to Our First Step of Project Administration

- AASET Ansr4u Refresher
- At this phase of the set up, What is compliance? ...
- This step affects interim funding as well as any action with funding tied. Compliance does expire so frequent review is required.



Types of Compliance Protocols

Forms of Compliance:

- Human Subjects with Human Research Protection Program (HRPP)
 - <https://rcb.tamu.edu/humansubjects/hrpp>
- Biosafety Occupational Health Program with Office of Biosafety (OBS)
 - <https://rcb.tamu.edu/bohp>
- Animals with Animal Use Protocol & Institutional Animal Care and Use Committee (IACUC)
 - <https://rcb.tamu.edu/animals/resources/animal-use-protocol>



Example of Pending HRPP (Human Subjects)

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Home Proposal **Project** Account Definition NSF Reporting

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 - Proposal
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 - Anticipated Fund
 - Actions
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 - Deliverables
 - Indirect Cost
 - Cost Sharing
 - Limitation of Cos
 - Reporting Code
 - Location
 - Abstract & Keywc
 - Data Managemer
 - IDC Distribution
- Control
 - Integrity Check
 - FCOI Status

PI Compliance Statement

Current ID (M1903002)

Short Title	Sponsor Name	Sponsor Award Number	PI	Lead Organization
Influences of Virtual Window Views on Ho	Houston Methodist Research Institute	AGMT00003750	Zhipeng Lu	TAMU - Architecture

Compliance Items

Action View Format Complete Detach Wrap

Compliance Items	Value	Required Additional Data	Definition
Human Subjects	<input checked="" type="radio"/> Yes <input type="radio"/> No		Human subject/human participant research is applicable when the proposed research involves development, te...
Protected Health Information	<input type="radio"/> Yes <input checked="" type="radio"/> No		Individually identifiable health information transmitted or maintained in electronic or any other form or medium t...
Human Embryonic Stem Cells	<input type="radio"/> Yes <input checked="" type="radio"/> No		Pluripotent stem cells derived from early stage human embryos, up to and including the blastocyst stage, that a...
Animals (Vertebrates)	<input type="radio"/> Yes <input checked="" type="radio"/> No	Edit	Vertebrate animals used for research, testing, and teaching. This includes: live vertebrates, animal tissue, bloo...
Recombinant DNA and Transgenic Organisms	<input type="radio"/> Yes <input checked="" type="radio"/> No		In the context of the NIH Guidelines, recombinant DNA molecules are defined as either: (i) molecules that are c...
Biohazards	<input type="radio"/> Yes <input checked="" type="radio"/> No		Any pathogens or potential pathogens of human, animals or plants; materials potentially containing human pat...
Select Agents	<input type="radio"/> Yes <input checked="" type="radio"/> No	Edit	Select agents are pathogens or biological toxins which have been declared by the U.S. Department of Health an...
Involves use of Biosafety Level 3 (BSL-3) Facility BSL3 non-select agent/ABSL3	<input type="radio"/> Yes <input checked="" type="radio"/> No		Work with infectious agents that require biosafety level 3 facilities.
Renovations to Facility	<input type="radio"/> Yes <input checked="" type="radio"/> No	Edit	As defined in TAMUS Policy 51.01, Capital Planning (http://policies.tamus.edu/51-01.pdf) .
Planned Environmental Release of Infectious, Hazardous or Genetically Modified Organism	<input type="radio"/> Yes <input checked="" type="radio"/> No		Release into the environment of infectious material, hazardous chemicals, radioactive material or genetically m...

Continued Example of HRPP

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 - IDC Distribution

Project Compliance

Current ID (M1903002)

Short Title	Sponsor Name	Sponsor Award Number	PI	Lead Organization	Performance Period
Influences of Virtual Window Views on Ho	Houston Methodist Research Institute	AGMT00003750	Zhipeng Lu	TAMU - Architecture	15-Nov-2019 - 31-Dec-2021

Project Compliance

Action View Format + X [Icons] Detach Wrap

Compliance Item	Additional Data	Status Date	Expiration Date	Status	Authorization Number	Approvals	Compliance PoC	Created On	Created By	Updated
Human Subjects		23-Sep-2020		Acknowledged		View	Denise Puga, Heather Cline, Jane Sea...	03-Oct-2019	Pauline Recek	
Export Control - International Collaboration	Xiaosai Hao,China	19-Feb-2020	19-May-2020	Active		View	Amber Oehlke, Griselle Hernandez, Les...	04-Feb-2020	David Lytle	
Export Control - Project Performed at a Non-US Location	Beijing University of Civil Engineering & Architecture,China	19-Feb-2020	19-May-2020	Active		View	Amber Oehlke, Griselle Hernandez, Les...	04-Feb-2020	David Lytle	
Export Control - Items to be Shipped to a Non-US Destination	TAMU,China	19-Feb-2020	19-May-2020	Active		View	Amber Oehlke, Griselle Hernandez, Les...	04-Feb-2020	David Lytle	



Example of Completed Biosafety (OBS)

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PI Compliance Statement

Current ID (M1902271)

Short Title	Sponsor Name	Sponsor Award Number	PI	Lead Organization
Cy-KIs As Potential Glioblastoma Theranos	Texas A&M University Health Science Center	M1900579-23-439481-01001	Kevin Burgess	TAMU - Chemistry

Compliance Items

Action View Format Complete Detach Wrap

Compliance Items	Value	Required Additional Data	Definition
Human Subjects	<input type="radio"/> Yes <input checked="" type="radio"/> No		Human subject/human participant research is applicable when the proposed research involves development, te...
Protected Health Information	<input type="radio"/> Yes <input checked="" type="radio"/> No		Individually identifiable health information transmitted or maintained in electronic or any other form or medium t...
Human Embryonic Stem Cells	<input type="radio"/> Yes <input checked="" type="radio"/> No		Pluripotent stem cells derived from early stage human embryos, up to and including the blastocyst stage, that a...
Animals (Vertebrates)	<input type="radio"/> Yes <input checked="" type="radio"/> No	Edit	Vertebrate animals used for research, testing, and teaching. This includes: live vertebrates, animal tissue, bloo...
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Renovations to Facility	<input type="radio"/> Yes <input checked="" type="radio"/> No	Edit	As defined in TAMUS Policy 51.01, Capital Planning (http://policies.tamug.edu/51-01.pdf) .



Continued Example of Biosafety (OBS)

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Project Compliance

Current ID (M1902271)

Short Title Cy-KIs As Potential Glioblastoma Theranos	Sponsor Name Texas A&M University Health Science Center	Sponsor Award Number M1900579-23-439481-01001	PI Kevin Burgess	Lead Organization TAMU - Chemistry	Performance Per 31-Aug-2018 - 21
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Project Compliance

Action

Compliance Item	Additional Data	Status Date	Expiration Date	Status	Authorization Number	Approvals	Compliance PoC	Created On
Biohazards		19-Apr-2019	18-Apr-2022	Active	IBC2019-029	View	Anne-Sophie Hieke, Beatriz Velez, Christine McFarland, Je...	19-Apr-2019



Kicking off to the Compliance Officers...

