UF myIRB

Date: Monday, September 12, 2022 10:25:55 AM

Print Close

ID: IRB201901192

View: Study Title and Staff

Study Title and Staff

All items marked with an orange asterisk ( ) are required. Items without an asterisk may or may not be required depending on whether the items are applicable to this study.*

1.0 * IRB Committee:

IRB-01

* **1.1** Is this a multi-institutional research project where the UF IRB will be the single IRB of record for other participating sites OR are you ceding review to another IRB of record? (IAAs are required between UF and other institutions)

○ **Yes** ● **No**

2.0 * Project Title:

RePEAT Tissue/DNA/Saliva Sample/Data Bank

3.0 Short Title:

RePEAT Tissue/DNA/Saliva Sample/Data Bank

4.0 Provide a summary description or abstract for this study:

Asthma affects 7 million children in the United States, the majority of whom suffer from at least one exacerbation per year. This biobanking protocol will facilitate precision medicine and pharmacogenomics studies for pediatric asthma by collecting tissue/DNA/saliva samples from children with asthma who visit the UF Health Jacksonville Pediatric ED.

* **4.1** Is this a OneFlorida study?

○ **Yes** ● **No**

* **4.2** Is this project a SUS Reciprocity study?

○ **Yes** ● **No**

5.0 * Principal Investigator:

Jennifer Fishe	**JX-EMERGENCY MEDICINE-JAX**	UF	**MD, Assistant Professor of Emergency Medicine**

- [x] **Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects**
- [ ] Performs study related activities but does not interact directly with the study subjects
- [x] **Obtains informed consent**
- [x] **Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]**
- [ ] Enters research related orders into EPIC for subsequent study physician or provider's electronic signature approval
- [x] **Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations**
- [ ] UF Student
- [ ] Volunteer (i.e. you are not staff, student or faculty at UF/Shands/VA)
- [ ] OneFlorida Site PI

6.0 Study Staff:
(HDE-ONLY: SEE IMPORTANT HELPTEXT)

Name	Role	Function	Affiliations	Degree/Title
Viviana Bartlett	Study Coordinator	▪ **Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects** ▪ **Obtains informed consent** ▪ **Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]**	**UF**	**Bachelors of Science in Health**
Brett Baskovich	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects** ▪ **Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or**	**UF**	**MD, Assistant Professor of Pathology**

Name	Role	Function	Affiliations	Degree/Title
		Electronic Medical Record [EMR]		
Andrew Bertrand	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	BSH
Jiang Bian	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Ph.D. Professor
Kathryn Blake	Co-Investigator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for	UF	PharmD Director Center for Pharmacogenomics and Translational Research

Name	Role	Function	Affiliations	Degree/Title
		research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR] ▪ Evaluates any Adverse Events, Unanticipated Events, and Protocol Deviations		
Margaret Carmona	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Bachelor of Science in Health
Megan Curtis Gonzalez	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or	UF	PhD

Name	Role	Function	Affiliations	Degree/Title
		Electronic Medical Record [EMR]		
Kimberly Daly-Crews	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Masters of Science, Biological Scientist I
Amanda Davis	Other	▪ Performs study related activities but does not interact directly with the study subjects ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	BS in Biology
Courtlin Gentry	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for	UF	Bachelor's of Science in Health

Name	Role	Function	Affiliations	Degree/Title
		research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]		
Amber Ginn	Other	▪ Performs study related activities but does not interact directly with the study subjects ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	BS, MB (ASCP), Molecular and Research Technologist
Phyllis Hendry	Co-Investigator	▪ Interacts or intervenes directly (including “remote” interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR] ▪ PI Proxy (Must be a Co-Investigator)	UF	MD
Morgan Henson	Study Coordinator	▪ Interacts or intervenes directly	UF	MPH, CPH, CCRP, CPT Clinical Research Manager

Name	Role	Function	Affiliations	Degree/Title
		(including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]		
Rebecca Higley	Co-Investigator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	MD, BS. Pediatric Emergency Medicine Fellow. Study Staff.
Hui Hu	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or	UF	PhD, Assistant Professor

Name	Role	Function	Affiliations	Degree/Title
		Electronic Medical Record [EMR]		
Dusan Lazic	Other	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Bachelors of Science and Health
Michelle Lott	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Research Coordinator
Reginald Mason	Other	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects	Shands UF	Bachelor's of Science in Public Health

Name	Role	Function	Affiliations	Degree/Title
		▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]		
Nolan Menze	Study Coordinator	▪ Interacts or intervenes directly (including “remote” interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Bachelor's of Science in Health
Taylor Munson	Study Coordinator	▪ Interacts or intervenes directly (including “remote” interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical	Shands	Bachelors of Science and Health

Name	Role	Function	Affiliations	Degree/Title
		Record [EMR]		
Alexander Parker	Co-Investigator	▪ Performs study related activities but does not interact directly with the study subjects ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	PhD
Edward Swaray	Study Coordinator	▪ Interacts or intervenes directly (including "remote" interactions by phone, internet, etc.) with study subjects ▪ Obtains informed consent ▪ Accesses or obtains, for research purposes, any Protected Health Information [PHI] from a paper or Electronic Medical Record [EMR]	UF	Research Coordinator III, BS

7.0 * Is this study a NIH funded clinical trial?

○ **Yes** ● **No**

8.0 * Is this study related to COVID-19/Coronavirus?

○ **Yes** ● **No**

Date Page Modified:8/3/2022

ID: IRB201901192 View: Researcher Training Summary

Researcher Training Summary

1.0 Researcher Training Summary

1.1 PI Training:
Jennifer Fishe:

Course ID	Name	Completed	Course Due
NIH	**NIH Extramural Education**	**7/5/2017**	**6/28/2047**
GCP200	**Good Clinical Practice: Biomedical Research**	**8/29/2022**	**8/28/2025**
IRB803	**IRB Training**	**7/6/2020**	**7/6/2023**
GCP200	**Good Clinical Practice: Biomedical Research**	**10/14/2019**	**10/13/2022**

1.2 Study Staff Training:
Viviana Bartlett

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	4/27/2020	4/27/2023
IRB803	IRB Training	4/27/2020	4/27/2023

Brett W Baskovich

Course ID	Name	Completed	Course Due
NIH	NIH Extramural Education	7/30/2018	7/22/2048
IRB803	IRB Training	8/2/2021	8/1/2024
GCP200	Good Clinical Practice: Biomedical Research	2/23/2021	2/23/2024

Andrew Bertrand

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	12/10/2021	12/3/2051
H70	CITI Mandatory IRB Trng-Biomed	3/8/2019	2/28/2049
NIH	NIH Extramural Education	7/2/2018	6/24/2048
GCP200	Good Clinical Practice: Biomedical Research	3/4/2022	3/3/2025
IRB803	IRB Training	7/21/2021	7/20/2024

Jiang Bian

Course	Name	Completed	Course

ID			Due
H70	CITI Mandatory IRB Trng-Biomed	12/9/2021	12/2/2051
H70	CITI Mandatory IRB Trng-Biomed	10/8/2018	9/30/2048
H70	CITI Mandatory IRB Trng-Biomed	3/5/2015	2/25/2045
IRB803	IRB Training	2/2/2021	2/2/2024
GCP200	Good Clinical Practice: Biomedical Research	12/3/2019	12/2/2022

Kathryn Vick Blake

Course ID	Name	Completed	Course Due
IRB803	IRB Training	8/2/2022	8/1/2025
GCP200	Good Clinical Practice: Biomedical Research	12/3/2019	12/2/2022

Margaret Carmona

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	12/16/2020	12/16/2023
IRB803	IRB Training	12/15/2020	12/15/2023

Megan Elaine Curtis Gonzalez

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	8/17/2022	8/9/2052
GCP200	Good Clinical Practice: Biomedical Research	8/29/2022	8/28/2025
IRB803	IRB Training	8/15/2022	8/14/2025

Kimberly Baird Daly-Crews

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	3/2/2022	3/1/2025
IRB803	IRB Training	2/8/2022	2/7/2025

Amanda H Davis

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	2/22/2021	2/22/2024
IRB803	IRB Training	6/24/2020	6/24/2023

Courtlin Gentry

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	8/10/2022	8/2/2052

GCP200	Good Clinical Practice: Biomedical Research	5/24/2022	5/23/2025
IRB803	IRB Training	4/27/2022	4/26/2025

Amber M Ginn

Course ID	Name	Completed	Course Due
NIH	NIH Extramural Education	8/3/2018	7/26/2048
IRB803	IRB Training	12/2/2021	12/1/2024
GCP200	Good Clinical Practice: Biomedical Research	3/11/2021	3/10/2024

Phyllis Hendry

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	5/5/2022	4/27/2052
NIH	NIH Extramural Education	5/4/2013	4/27/2043
GCP200	Good Clinical Practice: Biomedical Research	12/12/2019	12/11/2022
IRB803	IRB Training	11/10/2019	11/9/2022

Morgan Henson

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	12/3/2021	11/26/2051
H70	CITI Mandatory IRB Trng-Biomed	1/18/2018	1/11/2048
NIH	NIH Extramural Education	5/19/2014	5/11/2044
IRB803	IRB Training	12/11/2020	12/11/2023
GCP200	Good Clinical Practice: Biomedical Research	12/3/2019	12/2/2022

Rebecca Krista Higley

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	11/14/2019	11/13/2022
IRB803	IRB Training	11/13/2019	11/12/2022

Hui Hu

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	5/28/2020	5/21/2050
H70	CITI Mandatory IRB Trng-Biomed	6/27/2017	6/20/2047
H70	CITI Mandatory IRB Trng-Biomed	4/27/2013	4/20/2043

IRB803	IRB Training	1/27/2022	1/26/2025

Dusan Lazic

Course ID	Name	Completed	Course Due
IRB803	IRB Training	4/7/2021	4/6/2024
GCP200	Good Clinical Practice: Biomedical Research	4/1/2021	3/31/2024

Michelle Lott

Course ID	Name	Completed	Course Due
NIH	NIH Extramural Education	1/7/2016	12/30/2045
H64	NSF Responsible Conduct of Res.	4/13/2014	4/5/2044
IRB803	IRB Training	6/2/2022	6/1/2025
GCP200	Good Clinical Practice: Biomedical Research	9/24/2019	9/23/2022

Reginald Gladstone Mason

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	8/16/2022	8/15/2025
IRB803	IRB Training	8/2/2022	8/1/2025

Nolan Menze

Course ID	Name	Completed	Course Due
GCP200	Good Clinical Practice: Biomedical Research	12/9/2021	12/8/2024
IRB803	IRB Training	11/16/2021	11/15/2024

Taylor Munson

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	6/8/2022	5/31/2052
H70	CITI Mandatory IRB Trng-Biomed	3/24/2019	3/16/2049
IRB803	IRB Training	3/25/2022	3/24/2025

Alexander S Parker

Course ID	Name	Completed	Course Due
CITI	CITI Mandatory IRB Trng-Spec Mods	11/14/2018	11/6/2048
IRB803	IRB Training	11/29/2021	11/28/2024
GCP200	Good Clinical Practice: Biomedical Research	5/12/2020	5/12/2023

Edward Michael Swaray

Course	Name	Completed	Course

ID			Due
H70	CITI Mandatory IRB Trng-Biomed	10/6/2020	9/29/2050
GCP200	Good Clinical Practice: Biomedical Research	10/6/2020	10/6/2023
IRB803	IRB Training	10/5/2020	10/5/2023

Date Page Modified:

ID: IRB201901192 View: Requested Review Type

Requested Review Type

1.0 * Requested Review Type:

- ○ Non-Human
- ○ Data/Chart Review
- ● **Banking Only**
- ○ Exempt
- ○ Expedited
- ○ Full Board
- ○ Humanitarian Use Device [HUD]/ Humanitarian Device Exception [HDE]-Only

2.0 * Will you be using Clinical and Translational Science Institute [CTSI] resources (including, but not limited to RedCap, CTSI Biorepository, Healthstreet)? Please see link provided in the help text for a complete list.

● **Yes** ○ **No**

3.0 Full Board Agenda Group: *(choose one, if applicable)*
Indicate if submissions related to study should be reviewed in a Full Board group category

4.0 * Will information gained from this project result in publication in an ICMJE member Journal?

● **Yes** ○ **No**

5.0 * Is this research considered "classified"?

○ **Yes** ● **No**

Date Page Modified:

ID: IRB201901192 View: Oncology SRMC Determination

Oncology SRMC Determination

1.0 * Does this study require that patients have a known diagnosis (current or previous) or suspected diagnosis of cancer as part of the eligibility criteria?

○ **Yes** ● **No**

2.0 * Is this study looking at cancer relevant aims, endpoints or outcomes (including any studies involving tobacco use, cessation or prevention) (i.e. related to cancer treatment, supportive care, control, diagnosis, screening, prevention, risk factors or other cancer specific research)?

○ **Yes** ● **No**

3.0 * Do you plan to exclusively enroll patients with a known diagnosis (current or previous) or suspected diagnosis of cancer?

○ **Yes** ● **No**

For more information on studies that require SRMC review, click here

NOTE: If you answered yes to any of the questions above, the UFHCC Scientific Review and Monitoring Committee (SRMC) will need to review this study to determine if SRMC review is required. To

submit for SRMC review and determination, please complete the new submission request form found at: https://sharepoint.ahc.ufl.edu/research/cro/Intake/SitePages/Home.aspx

If SRMC review is required, please ensure that the IRB application requests collection of all SRMC required datapoints based on the SRMC level of review assigned. More information can be found at: https://cancer.ufl.edu/wordpress/files/2019/05/ADM-004-V3-2019-02-20.pdf

Date Page Modified:

ID: IRB201901192 View: Individual COI and Affiliation Summary

Individual Conflict of Interest [COI] and Affiliation Summary

This page is to show you whether or not all Study Staff have "Agreed to Participate" on the project (as indicated in the "Agreed" column below).

It will also provide you with information as to whether or not the study staff have a conflict of interest [COI] or are considered an unaffiliated investigator [Affiliations/UIA].

Be sure that you send an email to your study staff to notify them to execute the "Agree to Participate" activity. Use the **Send Email to Study Team** activity to notify them.

1.0 Individual Conflict of Interest [COI] and Affiliation Summary

Name	Role	Agreed	COI	COI Compliance Doc	Affiliation	UIA Doc
Viviana Bartlett	Study Coordinator	yes	no		UF	
Brett Baskovich	Co-Investigator	yes	no		UF	
Andrew Bertrand	Study Coordinator	yes	no		UF	
Jiang Bian	Co-Investigator	yes	no		UF	
Kathryn Blake	Co-Investigator	yes	no		UF	
Margaret Carmona	Study Coordinator	yes	no		UF	
Megan Curtis Gonzalez	Study Coordinator	yes	no		UF	
Kimberly Daly-Crews	Study Coordinator	yes	no		UF	
Amanda Davis	Other	yes	no		UF	
Courtlin Gentry	Study Coordinator	yes	no		UF	
Amber Ginn	Other	yes	no		UF	
Phyllis Hendry	Co-Investigator	yes	no		UF	
Morgan Henson	Study Coordinator	yes	no		UF	
Rebecca Higley	Co-Investigator	yes	no		UF	
Hui Hu	Co-Investigator	yes	no		UF	
Dusan Lazic	Other	yes	no		UF	
Michelle Lott	Study Coordinator	yes	no		UF	
Reginald Mason	Other	yes	no		Shands UF	

Name	Role	Agreed	COI	COI Compliance Doc	Affiliation	UIA Doc
Nolan Menze	Study Coordinator	yes	no		UF	
Taylor Munson	Study Coordinator	yes	no		Shands	
Alexander Parker	Co-Investigator	yes	no		UF	
Edward Swaray	Study Coordinator	yes	no		UF	

2.0

PI Conflict of Interest and Affiliation Summary

	PI Name	Agreed	COI	COI Compliance Doc	Affiliation	UIA Doc
View	**Jennifer Fishe**	**yes**	**no**		**UF**	

Date Page Modified:

ID: IRB201901192 View: Risk Benefit Assessment - Banking Only

Risk & Benefit Assessment - Banking Only

1.0 * Risk classification for this study. *(select one)*

- (●) **No more than Minimal Risk or No Risk**
- ( ) Greater than Minimal Risk

NOTE:

Minimal Risk: A probability and magnitude of harm or discomfort (physical, psychological, or social) that are no greater, in and of themselves, than those in daily life or in a routine physical or psychological examination or test.

Expedited Review: Reviewed outside of the full Board and approved under certain categories defined by the federal regulations.

Date Page Modified:

ID: IRB201901192 View: Study Locations

Study Locations

1.0 * Where are you going to conduct this project? *(choose all that apply)*

- [ ] UF and/or UF Health
- [x] **UF and/or UF Health Jacksonville**
- [ ] VA
- [ ] Baptist/Wolfson
- [ ] Sacred Heart
- [ ] Nemours
- [ ] Florida Department of Health
- [ ] Halifax
- [ ] Community Health Northwest Florida (Escambia Clinic)
- [ ] Other sites in the USA
- [ ] Other sites outside the USA

2.0 Are you getting any data or tissue from international locations?

○ **Yes** ● **No**

3.0 Name a lead site investigator if any of the following is true:

More than one (1) UF location is selected
OR
One (1) UF location is selected in combination with a non-UF location and the PI for the study is not at both locations

Date Page Modified:

ID: IRB201901192 View: Study Funding

Study Funding

1.0 * Indicate appropriate **funding types** for this project:

- [x] **DHHS, including NIH and NCI or NSF**
- [ ] Federal Grant (other than DHHS or VA)
- [ ] Veteran Affairs (VA)
- [ ] State or Local Government
- [x] **Non-Profit Organization**
- [ ] Industry
- [ ] Internally Funded, CTSI
- [ ] Internally Funded, Other
- [ ] No Funding required to initiate or complete this study

NOTE: Industry authored/sponsored, multisite, FDA regulated research in the College of Medicine is required to be submitted to WIRB.
If you wish to submit to IRB-01 and your study is required to be submitted to WIRB, per the above criterion, you must receive written approval from Michael Mahoney.

DO NOT proceed with your submission until approval is received. If Michael Mahoney approves IRB-01 review, attach a copy of the approval to the 'Miscellaneous Attachments' page of this myIRB submission.

Date Page Modified:

ID: IRB201901192 View: Government Funding Sources

Government Funding Sources

1.0 * Add information about each **Government Funding Source** here:

ID	Source Name	Other	Grant Number	UFIRST Project	Deadline
ID00053218	**NATL INST OF HLTH NCATS**		**2UL1TR001427-05**		

1.1 If you are getting funding from the **Department of Defense**, you must attach **Addendum U**.

Date Page Modified:9/13/2019

ID: IRB201901192 View: External Funding Sources

External Funding Sources

1.0 * Add information about each **External Funding Source** here:

ID	Source Name	Other	UFIRST Project	Deadline
ID00053217	SCOTT R MACKENZIE FOUNDATION			

Date Page Modified:2/13/2020

ID: IRB201901192 View: Funding Summary

Funding Summary

1.0 Funding Sources:

Government Funding Sources:

ID	Source Name	Other	Grant Number	UFIRST Project	Deadline
ID00053218	NATL INST OF HLTH NCATS		2UL1TR001427-05		

External Funding Sources:

ID	Source Name	Other	UFIRST Project	Deadline
ID00053217	SCOTT R MACKENZIE FOUNDATION			

Internal Funding Sources:

ID	College	Dept	Unit	UFIRST Project	Deadline

There are no items to display

1.1 Upload Additional Funding documentation/attachments here:

	Document	Description
View	award letter.pdf(0.01)	

Date Page Modified:

ID: IRB201901192 View: Conflict of Interest - Institutional

Conflict of Interest - Institutional

1.0 * Does the institution (University of Florida, Shands , or NF/SG VHS) hold a patent or license for any material, object, or process used in this project?

○ **Yes** ● **No**

2.0 * Is a patent or license pending or under consideration or is there any intention to file a patent application at a later date?

○ **Yes** ● **No**

3.0 * Does the institution (University of Florida, Shands, NF/SG VHS) own stock in the company sponsoring the project?

○ **Yes** ● **No**

NOTE: **If the answers to any of these questions change from "No" to "Yes" you must inform the IRB IMMEDIATELY.**

This includes any new investigators who are added to the study at a later date.

Date Page Modified:

ID: IRB201901192 View: Study Billing: RAC Review Determination

Study Billing: Research Billing Compliance Review Determination

1.0 * Does this study involve a **UF Principal Investigator** and activities conducted in a **Gainesville Health Science Center (HSC) facility**?

Examples of **Gainesville** HSC facilities include, but are not limited to:

- Shands Hospital
- Shands Ancillary Departments (e.g. lab, radiology, etc.)
- Shands/UF Clinic Space
- UF Core Labs
- HSC Communicore Building
- HSC Medical Science Building
- HSC Academic Research Building
- HPNP
- CTRB Building (includes Aging and CTSI)
- McKnight Brain Institute
- CTSI Clinical Research Centers (e.g. UF CRC)

○ **Yes** ● **No**

1.1 If "Yes, does this project involve any of the following:

- the use of any **IND drugs** or **IDE devices**
- any **services that generate a charge** in a UF Health patient billing system (e.g. Epic)
- research-only standalone visits in a **Shands facility or UF clinic**
- research-only activity that **prolongs patient encounters that are billed according to time** (e.g. surgical procedures, anesthesiology services etc.)
- research services that will be performed by Shands personnel, including hospital nurses and other professional/technical staff
- an outside sponsor who is willing to **pay for subject injury**

○ **Yes** ○ **No**

2.0

* Does this study involve a UF Principal Investigator and activities conducted in a **Jacksonville Health Science Center (HSC) facility**?

Examples of **Jacksonville** HSC facilities include, but are not limited to:

- Shands Hospital
- Shands Hospital North
- Shands Ancillary Departments (e.g. lab, radiology, etc.)
- Shands/UF Clinic Space
- Pavilion
- Total Care Clinic

● **Yes** ○ **No**

NOTE:

Note: If you answered "Yes" to question 1.1 above, the UF Office of Clinical Research (OCR) will need to assess your study for research billing compliance risk. For most OCR reviews, you will need to prepare and submit a packet of documents, which includes a billing grid that indicates the location and funding plan for each protocol-required item/activity/service. Depending on the study details, the billing grids can be quite complex, and

may require some time to prepare.

Date Page Modified:

ID: IRB201901192 View: Banking of Tissue/Data/Contact Registry

Banking of Tissue/Data/Contact Registry

1.0 * Indicate the type of bank being submitted:

- [x] **Tissue Bank**
- [x] **Data Bank**
- [x] **Contact Registry Bank**

2.0 Where will the tissue/data/contact registry bank be located?

	Locale	Facility Name	Facility Location	Room Number	Non-Local IRB Appr	No Non-Local IRB Appr
View	Local	University of Florida COM-Jacksonville	Biomedical Laboratory	213		

3.0 Indicate how information about tissue/data/contact registry will be stored:

- [x] **with identifiers or direct links/codes** — **For example: name, medical record number, address, insurance information, diagnosis, pathology results or other medical information, survey results, or any other specific kinds of data points**
- [ ] **data/samples will be completely anonymous** — **Answering this question no means that there are no codes or links between the subject and their banked data/tissue, including the HIPAA identifiers as listed on http://irb.ufl.edu/irb01/hipaa/hipaa-identifiers.html**

3.1 If "with identifiers or direct links/codes", are there mechanisms in place to fulfill any subject requests to have their tissue/data removed & destroyed?

(●) **Yes** ( ) **No**

3.1.1 Describe:

If a patient decides to withdraw from the study at any time or decides they do not want to share their tissue/data/DNA/saliva sample we will destroy any samples that are stored and all data that has been saved.

Date Page Modified:

ID: IRB201901192 View: Banking of Tissue

Banking of Tissue

1.0 * If Tissue Bank, Indicate the **type of tissue** being collected:

- [ ] Left over Tissue collected and stored for clinical purpose
- [ ] Left over Tissue collected for clinical purpose and usually discarded
- [ ] Tissue collected as part of other IRB approved research protocols
- [x] **Tissue collected only to bank for future research**

1.1 Explain/Describe:
Tissue/DNA/Saliva Samples
Research coordinators will collect DNA using buccal swabs (2 total, 1 from each buccal mucosa) using a Qiagen Buccal Cell Kit. Genomic DNA will be extracted and quantified using a Qiagen extraction kit and the Qubit Fluorometer. DNA will be stored in -80 freezers.

Date Page Modified:

ID: IRB201901192 View: Banking of Data

Banking of Data

1.0 * If Data Bank, Indicate the **type of data** being collected:

- [x] **Data collected and stored as part of the normal hospital or clinic operations or normal clinical care of patients**
- [ ] Data collected as part of other IRB approved research protocols
- [x] **Data collected only to bank for future research**

1.1 Explain/Describe:
MRN, name, telephone number, mailing address, and email address.

Date Page Modified:

ID: IRB201901192 View: Banking of Contact Registry Data

Banking of Contact Registry Data

1.0 * If Contact Registry Bank, Indicate the **type of contact registry** being collected:

- [ ] Contact information collected as part of other IRB approved research protocols aimed at re-contacting study subjects for potential enrollment in future research
- [x] **Contact information collected as part of this protocol (Bank) aimed at re-contacting study subjects for potential enrollment in future research**

1.1 Explain/Describe:
name, telephone number, mailing address, and email address

Date Page Modified:

ID: IRB201901192 View: Banking of Tissue/Data/Contact Registry - Local

Banking of Tissue/Data/Contact Registry - Local

1.0 * Who will the gatekeeper(s) be for this tissue/data/contact registry bank?

Jennifer Fishe, MD

2.0 * Describe the operational processes and security measures to prevent release of tissue/data/contact registry being stored in this bank:

Potential subjects will be identified by trained Research Coordinators in the Department of Emergency Medicine. We will only recruit subjects presenting to the Emergency Department with an acute asthma exacerabation. We will not recruit inpatients.
The saliva samples will be stored at room temperature until processing and storage by Dr. Brett Baskovich. The purified DNA will then be stored in a 24/7 monitored -80^{0}C freezer in the UF College of Medicine Biomedical laboratory, a secure, badge-only access lab on UFHealth Jacksonville's campus.
Only IRB-approved research members have access to logs, the lab, and freezer. Each research member is up to date on IRB required trainings, as well laboratory training- biomedical waste, hazardous waste management, and lab safety actions and reactions. Samples and data will only be released to researches with appropriate IRB approval.
Confidentiality is maintained through use of the Department of Emergency Medicine offices and computers. PHI data collected as part of the study are stored in locked, badge-access filing cabinets and stored electronically on the dedicated research drive on locked computers in the Department of Emergency Medicine Division of Research. Electronic data will also be stored in REDCap.
UF Health firewall functions maintained by UF Health Information Technology are constantly in effect as basic electronic data protection. Research-related samples are patient-number identified and stored samples are barcode-labeled. No PHI is on the barcode-label.
Dr. Fishe and/or Dr.Baskovich is receiving in-kind support from Emergency Medicine and Pathology for the saliva sample kits.

3.0 * What will happen to the tissue/data if the Principal Investigator leaves the institution (UF/Shands/VA)?

- ○ Tissue/Data/Contact Registry will be destroyed
- ● **A new, local PI will be assigned**
- ○ Written permission will be obtained from the Dean or appropriate University authority to move the bank

4.0 Do you have any provisions to maintain item integrity during a disaster?

● **Yes** ○ **No**

4.1 If "Yes", Describe:
Freezers are connected to a 24/7 monitoring system. If the temperature goes below the desired temperature, the Director of Research and Research Coordinators and Assistants receive notification by email and text. The samples could then be moved if necessary. The Biomedical Laboratory also has a generator for backup power if the power goes out in the building that is maintained by the hospital.

Date Page Modified:5/17/2019

ID: IRB201901192 View: Study Population, Overview

Study Population, Overview

1.0 * Will subjects of a specific race or ethnicity (as defined by NIH) be studied?

○ **Yes** ● **No**

1.1 Indicate if you will target any of the following ethnic groups:

- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Will not target a specific ethnic group

1.2 Indicate if you will target any of the following racial groups?

- ☐ Native American/Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Black or African American
- ☐ White
- ☐ Will not target any specific racial groups

1.3 If any racial or ethnic group has been selected, the justification is:

- ☐ The condition being studied only occurs in the selected group(s)
- ☐ Other

1.3.1 If "Other", Provide rationale for selection of specific groups

2.0 * Gender:

- ○ Male
- ○ Female
- ● **Both**

2.1 Provide the rationale for studying a single gender:

Date Page Modified:

ID: IRB201901192 View: Subject Description (Expedited/Full Board/Banking)

Subject Description (Expedited/Full Board/Banking)

1.0 * Describe the type(s) of subjects to be studied in this project.

	Type Description	Min Age	Max Age	Participation Time	Screening Required	Screening Description
View	We are looking at all patients aged 2-18 diagnosed with asthma that come through the Emergency Department.	2 Years	18 Years	Active participation will be approximately 10 minutes. Samples will be stored until the biobank has been closed with the IRB.	no	

Date Page Modified:

ID: IRB201901192 View: Compensation Determination

Compensation Determination

1.0 * Are research subjects compensated? ○ **Yes** ● **No**

1.1 If "Yes", provide details on each type of compensation:

Type	Amount	Undue Influence	Influence Description	Compensation Schedule

There are no items to display

Date Page Modified:

ID: IRB201901192 View: Vulnerable Subjects (Expedited/Full Board/Banking Only Studies)

Vulnerable Subjects (Expedited/Full Board/Banking Only Studies)

1.0 * Will vulnerable subjects be considered for participation in this project?

(●) **Yes** ( ) **No**

1.1 If "YES", indicate which of the following vulnerable populations will be considered for this project:

- [ ] Pregnant Women
- [ ] Human Fetus
- [ ] Neonates
- [x] **Children**
- [ ] Prisoners
- [ ] Decisionally Impaired/Comatose Individuals
- [ ] Institutional Residents
- [ ] Terminally Ill Patients
- [ ] Staff at the Institution
- [ ] Students at the Institution

Date Page Modified:

ID: IRB201901192 View: Vulnerable Subject Inclusion - Banking Only

Vulnerable Subject Inclusion - Banking Only

1.0 You have indicated that the following vulnerable populations will be considered for this project:

Children

1.1 * Explain why these vulnerable subjects are to be enrolled in this project:
We are specifically looking at children presenting to the Emergency Department with an acute asthma exacerbation.

Date Page Modified:5/17/2019

ID: IRB201901192 View: Minor Subjects: Risk Assessment

Minor Subjects: Risk Assessment

1.0 * Describe the RISKS associated with involving children in this research:

The child may experience minor discomfort when the saliva sample is collected. There is less than minimal risk of bleeding or infection during the saliva sample collection.

Although every effort will be made to keep the child's information confidential, there is a small risk that an unauthorized person may obtain the child's information. Therefore, there is a very slight risk that a test result could be linked to the child's identity and inadvertently disclosed to a third party.

If the child or parent were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological distress. In addition, the child or parent might have to decide whether or not to discuss the findings with members of their family. If a third party learned the results, there is a risk of social stigma and of the unpredicted disclosure of this information to others.

2.0 * Describe the BENEFITS associated with involving children in this research:

Children are frequently diagnosed with asthma and comprise the majority of exacerbation visits to the emergency department.

3.0 * Indicate the Risk-Benefit level for the minors involved in this research project.

- (●) **a. Research poses no greater than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Explain below 3.1.;**
- ( ) b. Research poses greater than minimal risk but presents the prospect of direct benefit to the individual subjects. In order to qualify for this category all of following must be true: i. The risk is justified by the anticipated benefit to the subjects. Explain below 3.2.; ii. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. Explain below 3.3.;
- ( ) c. Research is greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition. In order to qualify for this category the all of the following must be true: i. The risk represents a minor increase over minimal risk. Explain below 3.4.; ii. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations. Explain below 3.5.; iii. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. Explain below 3.6.;
- ( ) d. Research is not otherwise approvable under one of the conditions above but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Explain below 3.8; This requires approval from the Secretary of the federal office of the Department of Health and Human Services. Please contact the IRB office for assistance. Upload approvel letter below 3.7.

3.1 If "a." above, Provide protocol specific information to justify that the study is minimal risk to children:

The child may experience minor discomfort when the saliva sample is collected. There is less than minimal risk of bleeding or infection during the saliva sample collection.

Although every effort will be made to keep the child's information confidential, there is a small risk that an unauthorized person may obtain the child's information. Therefore, there is a very slight risk that a test result could be linked to the child's identity and inadvertently disclosed to a third party.

If the child or parent were to receive the result of a genetic test that indicated a problem, it could cause anxiety or other psychological distress. In addition, the child or parent might have to decide whether or not to discuss the findings with members of their family. If a third party learned the results, there is a risk of social stigma and of the unpredicted disclosure of this information to others.

3.2

If "b." above, Explain how the risk is justified by the anticipated benefit to the subjects:

3.3 If "b." above, Explain how the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches

3.4 If "c." above, Explain how the risk represents a minor increase over minimal risk:

3.5 If "c." above, Explain how the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

3.6 If "c." above, Explain how the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition:

3.7 If "d." above, Upload letter of approval:

3.8 If "d." above, Provide protocol specific information to justify how the study presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:

4.0 Please indicate whether or not you need to solicit assent from the subject who is under 18 years of age:

4.0 * Please indicate whether or not you need to solicit assent from the subject who is under 18 years of age:

- [x] **Written assent is required in order to enroll the subject**
- [ ] Assent is required in order to enroll the subject and will be documented.
- [ ] Written assent will be sought but not required because research holds out prospect of direct benefit that is important to the health or well being of the child subject and is only available in the context of the research.
- [x] **Assent should not be required**

4.1 * Explain your response above:
We will seek written assent from children 12-17 years of age. Assent is not required for children under 12. Consent will be obtained from the parent/guardian of all children under 18.

4.2 If "Assent should not be required" indicate reason:

- [ ] capability of some or all of the children is so limited they cannot be reasonably consulted
- [ ] research holds out prospect of direct benefit that is important to health or well-being of child subject and is only available in the context of the research, described above
- [x] **Otherwise meets requirements to waive consent as previously described in the myIRB SmartForms**

4.2.1 Explain your response above:
Assent is not required for children under 12. Consent will be obtained from the parent/guardian of all children under 18.

5.0 * How will you seek consent from the subject's parent(s) or guardian(s)?

- (●) **Consent of one parent/guardian is sufficient. NOTE: May only be selected for minimal risk research OR research that offers potential for direct benefit to child subject.**
- ( ) Consent of both parents/guardians is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- ( ) Otherwise meets requirements to waive consent . Please refer to the Informed Consent section for additional information.

6.0 * Do you wish to enroll children who are the wards of the state or any other agency, institution, or entity?

○ **Yes** ● **No**

6.1 If "Yes", one of the following must be applicable:

- ○ The research is related to the subject's status as a ward.
- ○ The research will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

6.2 Explain:

6.3 Describe who will be the advocate for the ward subjects:
If the research is approved to include wards you will be required to obtain an advocate for each child who is a ward. This advocate is in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Date Page Modified:

ID: IRB201901192 View: Recruitment Methods (Banking Only Studies)

Recruitment Methods (Banking Only Studies)

1.0 How are you planning to recruit subjects? (check all that apply)

- [ ] Inpatient Population
- [ ] Outpatient Population
- [ ] Advertisement
- [ ] Undergraduate Student Pool (e.g. SONA)
- [ ] Research Database/other IRB approved protocol
- [ ] Healthstreet
- [ ] StudyConnect
- [ ] Consent2Share
- [ ] Research Match
- [ ] Social Media Recruitment
- [ ] No recruitment is necessary
- [x] **Other**

1.1 If "Research Database", specify:

Name	IRB Number	Description

There are no items to display

1.2 If "Other", specify:
Patients presenting to the Emergency Department. Study team members will watch the ED tracking board for any Pediatric asthma patients during the study hours. ED staff will also be made aware of the study and can contact the study team when eligible patients arrive.

2.0 How do you have access to the subject population?

- [ ] Advertisement
- [x] **As a part of normal clinical care**
- [ ] Instructor / Faculty
- [ ] Primary physician
- [ ] Other

2.1 If "Other", specify:

3.0 If **advertising** is used, attach copies of the advertisements, including phone and/or email scripts:

Name	Description

There are no items to display

Date Page Modified:5/22/2019

ID: IRB201901192 View: Data Collection (Banking Only Studies)

Data Collection (Banking Only Studies)

1.0 * Are you collecting any information that could
(a) be sensitive and possibly affect the reputation, status, or insurability of the research subjects,
(b) place the subject at risk of criminal or civil liability, or
(c) be damaging to the subject's financial standing or employability?

○ **Yes** ● **No**

1.1 If "Yes", Describe:

1.2 If "Yes", Describe how you will insure the confidentiality of this information:

2.0 Check all of the HIPAA identifiers that are part of your data set:

- ☐ Social Security Number
- ☑ **Telephone Numbers**
- ☐ Full Face Photographic Image
- ☑ **Email Address**
- ☑ **Medical Record Identifiers**
- ☑ **Name**
- ☑ **Dates**
- ☑ **Geographic subdivision smaller than a state or the first three digits of a zip code**
- ☐ Facsimile numbers
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☐ Certificate/License Numbers
- ☐ Vehicle Identifiers
- ☐ Device Identifiers
- ☐ Web URLs
- ☐ IP Address Numbers
- ☐ Biometric Identifiers
- ☑ **Any other unique identifying number, characteristic, or code.**

2.1 If "Other", Specify:
date and time of arrival

3.0 Only attach a copy of all the data fields in the database being used to track all the data elements for the items in your bank if you did not select any HIPAA identifiers.

Name	Description
There are no items to display	

Date Page Modified:

ID: IRB201901192 View: UF VA UF Health Data Collection - Medical Records Access

Data Collection - Medical Records Access

1.0 * Will you review any medical records or collect any medical record information from UF and/or UF Health facilities, or the VA?

● **Yes** ○ **No**

2.0 * Will you review any medical records or collect any medical record information from any facilities other than UF, UF Health, or the VA?

○ **Yes** ● **No**

2.1 If "Yes", list all facilities from which you intend to obtain medical records and upload letter of permission from facility, FWA Information, etc.:

Outside Facility Name	Permission Letter, FWA, etc.	If No Letter

There are no items to display

Date Page Modified:

ID: IRB201901192 View: Safety Monitoring (Banking Only Studies)

Safety & Monitoring (Banking Only Studies)

1.0 * Is there a person or group (e.g. DSMB, sponsor) other than the Principal Investigator that is responsible for oversight of the storage or use of the tissue/data being stored in this bank?

○ **Yes** ● **No**

Date Page Modified:

ID: IRB201901192 View: Written Informed Consent Determination

Written Informed Consent Determination

1.0 * Are you going to seek **written Informed Consent** from any subjects in order to enroll them?

- ○ No written informed consent will not be obtained
- ● **Yes**

Date Page Modified:

ID: IRB201901192 View: Upload Informed Consent Documents

Upload Informed Consent Documents

1.0 * Upload consent forms, assent forms, information sheets, and UF addendum here:

*Click on the link to a document (listed under Attachment ICF) to revise or update an existing consent form so that changes can be tracked. Use the **Add** button to add an additional type of consent form. **Attach MS Word docs only.***

Target Population	Attachment ICF	Date Modified
Patients who are 18 years of age and qualify for inclusion in the study.	No longer in use.docx(0.10)	10/10/2019
Assent from children 12-17 years of age who qualify for inclusion in the study.	No longer in use.docx(0.11)	10/10/2019
Parents/LARs of children 12-17 years of age who qualify for inclusion in the study, as well as 18 year olds who qualify for inclusion and can consent for themselves.	201901192 -Fishe Biobanking Consent for ALL_clean 021220.docx(0.17)	2/18/2020

NOTE: YOU MUST SAVE THIS PAGE TO SAVE ATTACHMENTS

Date Page Modified:5/22/2019

ID: IRB201901192 View: Informed Consent Process (Banking Only Studies)

Informed Consent Process (Banking Only Studies)

Staff Obtaining Consent

The following staff have been designated to obtain informed consent on this project:

Name		Role
Viviana	Bartlett	Study Coordinator
Andrew	Bertrand	Study Coordinator
Kathryn	Blake	Co-Investigator
Margaret	Carmona	Study Coordinator
Megan	Curtis Gonzalez	Study Coordinator
Kimberly	Daly-Crews	Study Coordinator
Courtlin	Gentry	Study Coordinator
Phyllis	Hendry	Co-Investigator
Morgan	Henson	Study Coordinator
Rebecca	Higley	Co-Investigator
Dusan	Lazic	Other
Michelle	Lott	Study Coordinator
Reginald	Mason	Other
Nolan	Menze	Study Coordinator
Taylor	Munson	Study Coordinator
Edward	Swaray	Study Coordinator
Jennifer	Fishe	PI

1.0

* Indicate who will provide informed consent :

- [x] **Subject**
- [x] **Parent(s) of a child subject**
- [x] **Legally Authorized Representative (LAR) for the subject**
- [ ] Other

2.0

What is the general setting where subjects will be asked to consent?

Subjects and/or their LAR will be asked to sign informed consent in the UF Health Jacksonville Emergency Department.

3.0

When will subjects be asked to consent?

Generally, 7am - 12am, 7 days per week. No study activities will be performed until consent has been obtained.

Date Page Modified:

ID: IRB201901192 View: Waivers or Alterations of Informed Consent Determination

Waivers or Alterations of Informed Consent Determination

1.0 * Are you seeking a Full Waiver of Informed Consent, Partial Waiver, Waiver of Documentation, or Alteration of Informed Consent?

○ **Yes** ● **No**

Date Page Modified:

ID: IRB201901192 View: Consent Obtained From Other Protocol - Banking Only

Consent Obtained From Other Protocol - Banking Only

1.0 * Are you obtaining tissue/data/contact registry for a local bank from any of the following:

- Other Protocols
- Outside UF
- Outside USA

○ **Yes** ● **No**

1.1 If "Yes", provide details about outside tissue/data/contact registry obtained:

Description	Consent/Agreement Attachment
There are no items to display	

Date Page Modified:

ID: IRB201901192 View: HIPAA Authorization Determination

HIPAA Authorization Determination

1.0 You have indicated that **IDENTIFIERS** will be used or collected on this project.

Indicate how authorization will be obtained:

- [ ] HIPAA Waiver of authorization
- [x] **Direct authorization through consent form**
- [ ] Direct authorization through separate written document
- [ ] No HIPAA Authorization or HIPAA Waiver needed because we are not collecting/using any health information

Date Page Modified:

ID: IRB201901192 View: Privacy Confidentiality Complete

Privacy & Confidentiality Complete

You have completed the Privacy & Confidentiality section.

Please continue to the next section.

Date Page Modified:

ID: IRB201901192 View: Ancillary Reviews

Ancillary Reviews

1.0 Ancillary Reviews Required:

RAC
CTSI

Date Page Modified:

ID: IRB201901192 View: CTSI Ancillary

CTSI Ancillary

CTSI Protocol Number: **IRB201901192**

Protocol Category:

UFIRST Number:

Project Title: **RePEAT Tissue/DNA/Saliva Sample/Data Bank**

Funding Sources:

DHHS, including NIH and NCI or NSF
Non-Profit Organization

1.0 eRA Commons ID:

2.0 You have indicated that you are using CTSI resources (tools, funding, space) throughout the submission. Please check all that apply to this study proposal:

- ☐ UF Clinical Research Center
- ☐ BERD (Biostatistics, Epidemiology, and Research Design)

- [x] **Research Electronic Data Capture (REDCap)**
- [ ] Research IT
- [ ] Regulatory Assistance includes assistance with IRB, RAC, and/or ClinicalTrials.gov
- [ ] IDE, IND submission assistance
- [ ] Research Subject Advocate, Ethics consultation
- [ ] Quality Assurance
- [ ] Biorepository
- [ ] South East Center for Integrated Metabolomics (SECIM)
- [ ] CTSI Human Imaging Core
- [ ] Integrated Data Repository (IDR)
- [ ] Genotyping Core
- [ ] HealthStreet
- [ ] Biobehavioral Core
- [ ] Recruitment Assistance

Date Page Modified:

ID: IRB201901192 View: RAC Ancillary

RAC Ancillary

NOTE:

The Office of Clinical Research (OCR) will need to review your study.

To submit your study to OCR, please use the web-based OCR electronic intake form located at https://sharepoint.ahc.ufl.edu/ocr/intake.

Questions? Please email OCR-Intake@ahc.ufl.edu.

To submit your study to Jax ORA please e-mail: Jax-OCR-Intake@jax.ufl.edu

Date Page Modified:6/12/2019

ID: IRB201901192 View: Miscellaneous Attachments

Miscellaneous

1.0 Certificate of Decedent Information Form:

2.0 Approved Social Security Exception Form:

3.0 Upload miscellaneous study attachments below:

Name	Modified	Version
Blourne HIPAA 121019.pdf	3/2/2020 4:12 PM	0.01
Carmona HIPAA.pdf	2/18/2021 3:47 PM	0.01
DeCuir- HIPAA -14AUG20.pdf	8/25/2020 12:32 AM	0.01
Gentry HIPAA and Privacy.pdf	5/26/2022 10:16 AM	0.01
Godwin Thomas HIPAA 2019.pdf	6/5/2019 11:33 AM	0.01
Gomer UF Training Cert HIPPA.pdf	9/8/2021 3:44 PM	0.01
Herren HIPAA Training.pdf	1/12/2022 3:36 PM	0.01
Hester HIPAA Gen Awareness 032119.pdf	6/12/2019 10:02 AM	0.01
Hill Karli HIPAA Gen Awareness 121319.pdf	3/2/2020 4:12 PM	0.01
HIPAAPrivacy_General Awareness_Casey Jenkins.pdf	5/18/2021 12:17 PM	0.01
Lazic HIPAA Training.pdf	5/18/2021 12:17 PM	0.01
Lee HIPAA Gen Awareness 050719.pdf	6/12/2019 10:02 AM	0.01
Mason HIPPA certificate.pdf	9/1/2022 12:00 PM	0.01
Metcalf-Parker HIPPA Training Certification.pdf	5/26/2022 10:16 AM	0.01
Thompson HIPAA Certificate.pdf	9/8/2021 3:44 PM	0.01
Velasquez HIPAA Gen Awareness 032719.pdf	6/12/2019 10:03 AM	0.01

4.0 List any specific information that needs to be included in the IRB approval letter:

NOTE: **YOU MUST SAVE THIS PAGE TO SAVE ATTACHMENTS**

Date Page Modified:

ID: IRB201901192 View: Legacy Paper Determination

Legacy Paper Determination

1.0 * **Is this a conversion from a paper study**?

○ **Yes** ● **No**

2.0 * Is this paper study in the state of Expired Non-renew?

○ **Yes** ● **No**

2.1 If Yes, please state why you want to regenerate this study and your plan for the previously collected data:

Date Page Modified:

ID: IRB201901192 View: Study: Final Page

Study: Final Page

Completion Instructions:

1. Select "Finish", to access the Study Workspace.
2. From the Study Workspace, execute the "Submit Study" activity to initiate the approval process.
   This activity is only available to the Principal Investigator.

NOTE: Prior to submitting the study, the PI and all Study Staff must perform the **"Agree To Participate"** activity, located in the My Activities area for this Study.

NOTE: *Please click on the **"Hide/Show Errors"** option. This will open a split screen which will show you any errors that may have occurred during the process of completing the forms. Once you have fixed all of the errors identified by myIRB, you will need to click on the **"Hide/Show Errors"** link again to return the screen to normal size.*

Important Note! If you plan to publish in an ICMJE member journal, you may be required to register your study in ClinicalTrials.gov PRIOR to enrolling the first subject into the study. For assistance with ClinicalTrials.gov questions, please contact 352-273-5946 or email UFCT-gov@ufl.edu .

Date Page Modified:

ID: IRB201901192 View: Government Funding Source Detail

Government Funding Source - Detail

1.0 * Which **government agency** is funding this project?

NATL INST OF HLTH NCATS

1.1 If "Other", specify government sponsor name.

1.2 * Please select the UFIRST proposal or CTA associated with this funding:

2.0 ***NOTE:*** *Since October 2020 this entry is only kept for historical record.*

* Funding Status:

Obtained

4.0 What is the **Sponsors Identifying/Grant Number** ? **2UL1TR001427-05**

5.0 * Did the Grant originate locally at UF/Shands/VA?

● **Yes** ○ **No**

NOTE: *Prior to 03/26/2020 the following attachment was required. The response has been preserved for historical record.*

5.1 If "Yes", Attach Grant if DHHS/NIH/NSF
CTSI Pilot Asthma Fishe Revision 062419.pdf(0.01)

6.0 ***NOTE:*** *Since October 2020 this entry is only kept for historical record.*

* Who is the **PI** for this funding source?

Jennifer Fishe, MD

7.0 ***NOTE:*** *Since October 2020 this entry is only kept for historical record.*

Please provide the title of the award that was submitted to the Division of Sponsored Programs (DSP):
Researching Precision Emergency Asthma Treatment (RePEAT): Pharmacogenomics of Bronchodilator Response

ID: IRB201901192 View: External Funding Source Detail

External Funding Source - Detail

1.0 * Sponsor Name:

SCOTT R MACKENZIE FOUNDATION

1.1 If "Other", specify Sponsor name.

1.2 * Please select the UFIRST proposal or CTA associated with this funding:

2.0 ***NOTE:*** *Since October 2020 this entry is only kept for historical record.*

Funding Status:

Obtained

3.0

NOTE: *Since October 2020 this entry is only kept for historical record.*

Please provide the title of the award that was submitted to the Division of Sponsored Programs (DSP):

Researching Precision Emergency Asthma Treatment (RePEAT): Pharmacogenomics of Bronchodilator Response

ID: IRB201901192 View: Tissue Data Bank Location Detail

Tissue/Data Bank Location - Detail

1.0 * Is the location of this bank Local or Non-Local?

- ○ Non-Local
- ● **Local**

2.0 If "Local":

2.1 What is the **name** of the facility where the tissue/data is being stored? (required for local)
University of Florida COM-Jacksonville

2.2 What is the **location** of the facility where the tissue/data is being stored? (required for local)
Biomedical Laboratory

2.3 What is the **room number** where the tissue/data is being stored?
213

3.0 If "Non-Local":

3.1 Attach a copy of other IRB approval letter for this bank: (required for non-local, single document only)

3.2 If you do not have a copy of other IRB approval letter for this bank, explain why:

ID: IRB201901192 View: Type of Subjects - Detail

Type of Subjects - Expedited/Full Board/Banking: Detail

1.0 * Description:

We are looking at all patients aged 2-18 diagnosed with asthma that come through the Emergency Department.

2.0 * Indicate the age range of subjects (for each group, if applicable) to be studied :

2.1 Minimum Age: **2 Years** Units

2.2 Maximum Age: **18 Years** Units

3.0 Will this group of potential subjects need to undergo screening that is not part of their routine care in order to determine if they are eligible for this project?

○ **Yes** ● **No**

3.1 If "Yes", Describe what screening procedures are needed for this group:

4.0 What is the expected length of time that each individual subject in this group will participate in this project?

Active participation will be approximately 10 minutes. Samples will be stored until the biobank has been closed with the IRB.

ID: IRB201901192 View: Consent Document - Detail

Consent Document - Detail

1.0 * *Upload Document*

Please enter your IRB number in the footer of your informed consent forms before submitting

No longer in use.docx(0.10)

2.0 *Describe/Indicate the target population for this consent*

Patients who are 18 years of age and qualify for inclusion in the study.

ID: IRB201901192 View: Consent Document - Detail

Consent Document - Detail

1.0 * *Upload Document*

Please enter your IRB number in the footer of your informed consent forms before submitting

No longer in use.docx(0.11)

2.0 *Describe/Indicate the target population for this consent*

Assent from children 12-17 years of age who qualify for inclusion in the study.

ID: IRB201901192 View: Consent Document - Detail

Consent Document - Detail

1.0 * *Upload Document*

Please enter your IRB number in the footer of your informed consent forms before submitting

201901192 -Fishe Biobanking Consent for ALL_clean 021220.docx(0.17)

2.0 *Describe/Indicate the target population for this consent*

Parents/LARs of children 12-17 years of age who qualify for inclusion in the study, as well as 18 year olds who qualify for inclusion and can consent for themselves.