UF | myIRB

Date: Friday, April 10, 2020 12:22:46 PM

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ID: IRB201903257 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.

* 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)

O Yes No

* Project Title:

T1D Exchange Quality Improvement Initiative

3.0 Short Title:

T1D Quality Improvement Initiative

4.0 Provide a summary description or abstract for this study:

The University of Florida will join the T1D Exchange Quality Improvement Initiative to facilitate the improvement in the quality of care delivered to those with type 1 diabetes (T1D). Data will be extracted from EPIC and shared with the T1D Exchange data bank via web portal to collect and report on standardized clinical diabetes data in connection with different diabetes related procedures and conditions.

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

O Yes No

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

Yes No

* Principal Investigator:

	Interacts or intervenes directly (including remoter interactions by phone, internet, etc.) with study subjects
~	Performs study related activities but does not interact directly with the study subjects
	Obtains informed consent
~	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
~	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
Janey Adams	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
Jennifer Hosford	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
Eleni Sheehan	Co- Investigato	 Performs study related activities but does not interact directly with the study subjects 	Shands
Angelina Bernier	Co- Investigato	 Performs study related activities but does not interact directly with the study subjects 	UF
Kristin Dayton	Co- Investigato	 Performs study related activities but does not interact directly with the study subjects 	UF
Elizabeth Fudge	Co- Investigato	 Performs study related activities but does not interact directly with the study subjects 	UF
Michael Haller	Co- Investigato	 Performs study related activities but does not interact directly with the study subjects 	UF
Laura	Co-	 Performs study related activities but 	UF

Jennifer Miller Co-Investigator Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Paul Hiers Co-Investigator Performs study related activities but does not interact directly with the study subjects Paul Hiers Co-Investigator Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects	Jacobsen	Investigator	does not interact directly with the study subjects	
Patrick Investigator does not interact directly with the study subjects Henry Co- Investigator Performs study related activities but does not interact directly with the study subjects Desmond Co- Investigator Performs study related activities but does not interact directly with the study subjects Janet Co- Investigator Performs study related activities but does not interact directly with the study subjects Brittany Co- Bruggeman Investigator Performs study related activities but does not interact directly with the study subjects Paul Hiers Co- Investigator Performs study related activities but does not interact directly with the study subjects Chelsea Co- Zimmerman Investigator Performs study related activities but does not interact directly with the study subjects * Is this study a NIH funded clinical trial? Yes No			does not interact directly with the study	UF
Desmond Co-Schatz Investigator Desmond Co-Investigator Janet Co-Silverstein Investigator Brittany Co-Bruggeman Investigator Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Brittany Co-Bruggeman Investigator Performs study related activities but does not interact directly with the study subjects Paul Hiers Co-Investigator Performs study related activities but does not interact directly with the study subjects Chelsea Co-Zimmerman Investigator Performs study related activities but does not interact directly with the study subjects Shands UF * Is this study a NIH funded clinical trial? Yes No			does not interact directly with the study	UF
Janet Co- Silverstein Co- Investigator	•		does not interact directly with the study	UF
Brittany Co-Bruggeman Investigator Performs study related activities but does not interact directly with the study subjects Paul Hiers Co-Investigator Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Chelsea Co-Zimmerman Investigator Performs study related activities but does not interact directly with the study subjects Shands UF * Is this study a NIH funded clinical trial? Yes No			does not interact directly with the study	UF
Bruggeman Investigator does not interact directly with the study subjects Paul Hiers Co-Investigator Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects Performs study related activities but does not interact directly with the study subjects * Is this study a NIH funded clinical trial? Yes No			does not interact directly with the study	UF
Investigator does not interact directly with the study subjects Chelsea Co- Zimmerman Investigator Performs study related activities but does not interact directly with the study subjects * Is this study a NIH funded clinical trial? Yes No	•		does not interact directly with the study	UF
* Is this study a NIH funded clinical trial? Yes No	Paul Hiers		does not interact directly with the study	UF
O Yes ● No			does not interact directly with the study	
* Is this study related to COVID-19/Coronavirus?			d clinical trial?	
O Yes No	_		OVID-19/Coronavirus?	

Date Page Modified:1/22/2020

Researcher Training Summary

7.0

8.0

ID: IRB201903257 View: Researcher Training Summary

1.0 Researcher Training Summary 1.1 PI Training: Anastasia Albanese-O'Neill: Course Name Completed Course

ID			Due	
H70	CITI Mandatory IRB Trng- Biomed	8/20/2018	8/12/2048	
H70	CITI Mandatory IRB Trng- Biomed	10/27/2015	10/19/2045	
H70	CITI Mandatory IRB Trng- Biomed	1/4/2013	12/28/2042	
NIH	NIH Extramural Education	9/14/2010	9/6/2040	
IRB802	IRB01 Local Training Refresher	11/13/2018	11/12/2021	
Study Staf	•			
Course ID	Name	Complet	ed Course Due	
H70	CITI Mandatory IRB Trng-Biomed	7/20/2018	7/12/2048	
H70	CITI Mandatory IRB Trng-Biomed	6/3/2015	5/26/2045	
GCP200	Good Clinical Practice: Biomedica Research	al 2/21/2020	2/20/2023	
IRB802	IRB01 Local Training Refresher	8/24/2018	8/23/2021	
Jennifer H	Hosford			
Course ID	Name	Complete	d Course Due	
H70	CITI Mandatory IRB Trng-Biomed	3/29/2019	3/21/2049	
H70	CITI Mandatory IRB Trng-Biomed	6/27/2016	6/20/2046	
H70	CITI Mandatory IRB Trng-Biomed		6/25/2043	
CITI	CITI Mandatory IRB Trng-Spec Mods	11/2/2012	10/26/2042	
IRB803 GCP200	IRB Training Good Clinical Practice: Biomedica	10/28/2019 al 2/22/2019	10/27/2022 2/21/2022	
IRB802	Research IRB01 Local Training Refresher	8/30/2017	8/29/2020	
Eleni She	· ·	0,00,00	000-0	
Course ID	Name	Completed	Course Due	
H70	CITI Mandatory IRB Trng- Biomed	2/13/2018	2/6/2048	
H70	CITI Mandatory IRB Trng- Biomed	3/6/2013	2/27/2043	
IRB802	IRB01 Local Training Refresher	2/14/2018	2/13/2021	
Angelina	Bernier			
Course ID	Name	Completed	Course Due	
H70	CITI Mandatory IRB Trng- Biomed	1/5/2016	12/28/2045	
IRB802	IRB01 Local Training Refresher	2/13/2019	2/12/2022	
Kristin Alexandra Dayton				
Course ID	Name	Completed	Course Due	
H70	CITI Mandatory IRB Trng- Biomed	11/9/2013	11/2/2043	
IDD000	IDD Training	2/5/2020	2/4/2022	

IRB Training

2/5/2020

2/4/2023

IRB803

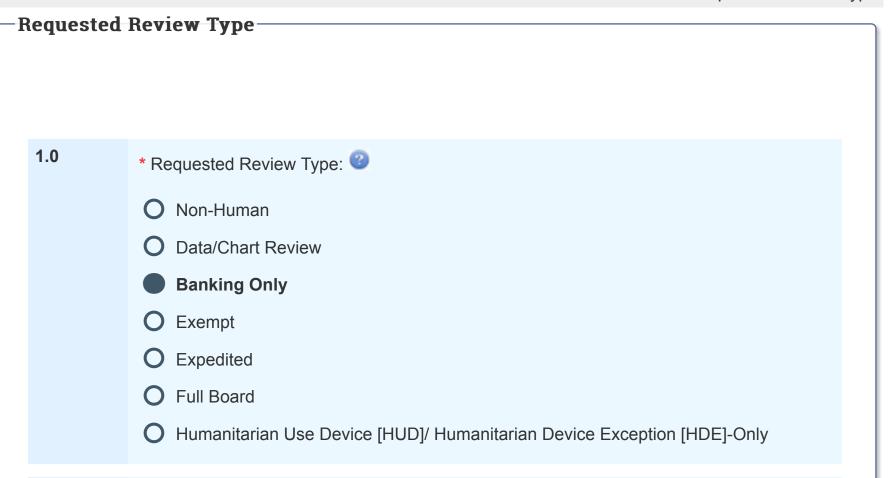
1.2

Elizabeth	B. Fudge			
Course	ID Name	Complet	ed Cour	se Due
IRB803	IRB Training	2/7/2020	2/6/20)23
Michael J	Haller			
Course ID	Name		Complete	d Course Due
H70 NIH IRB803 IRB802 GCP200	CITI Mandatory IRB T NIH Extramural Educa IRB Training IRB01 Local Training Good Clinical Practice Research	ation Refresher	12/20/2012 1/14/2020 1/11/2019	1/13/2023
Laura Jac	obsen			
Course ID	Name		Complete	d Course Due
H70 H70 GCP200	CITI Mandatory IRB T CITI Mandatory IRB T Good Clinical Practice Research	rng-Biomed	7/28/2015	12/12/2048 7/20/2045 4/29/2022
IRB802	IRB01 Local Training	Refresher	7/1/2018	6/30/2021
Jennifer L	ynne Miller			
Course ID	Name		Completed	Course Due
H70	CITI Mandatory IRB Biomed	Trng-	1/29/2014	1/22/2044
IRB802	IRB01 Local Training Refresher	g	5/3/2017	5/2/2020
Shannon	Fennell Patrick			
Course	ID Name	Complet	ed Cour	se Due
IRB803	IRB Training	2/11/2020	2/10/2	2023
Henry Ro	hrs			
Course ID	Name		Completed	Course Due
H70	CITI Mandatory IRB Biomed	Trng-	2/21/2014	2/14/2044
IRB802	IRB01 Local Training Refresher	g	8/7/2017	8/6/2020
IRB800	IRB01 Local Trainin	g	8/7/2017	8/6/2020
Desmond	A Schatz			
Course ID	Name		Complete	d Course Due
H70 H70 NIH GCP200	CITI Mandatory IRB TO CITI Mandatory IRB TO NIH Extramural Education Good Clinical Practice Research	rng-Biomed ation	6/17/2016 12/13/2012	6/10/2046 12/6/2042
IRB802	IRB01 Local Training	Refresher	10/30/2018	10/29/2021
Janet Hop	oe Silverstein			
Course ID	Name		Completed	Course Due
H70	CITI Mandatory IRB Biomed	Trng-	2/24/2017	2/17/2047
H70	CITI Mandatory IRB	Trng-	2/4/2014	1/28/2044

	Biomed		
IRB802	IRB01 Local Training Refresher	4/26/2018	4/25/2021
IRB800	IRB01 Local Training	8/16/2017	8/15/2020
Brittany B	ruggeman		
Course ID	Name	Comple	ted Course Due
H70 H70 IRB803 GCP200	CITI Mandatory IRB Trng-Biomed CITI Mandatory IRB Trng-Biomed IRB Training Good Clinical Practice: Biomedica Research IRB01 Local Training Refresher	12/13/201 3/21/2019	15 12/5/2045 3/20/2022 1/22/2022
Paul Hiers	· ·		-
Course ID		Comple	ted Course Due
H70 H70 IRB802 GCP200	CITI Mandatory IRB Trng-Biomed CITI Mandatory IRB Trng-Biomed IRB01 Local Training Refresher Good Clinical Practice: Biomedica Research	7/5/2013 3/5/2018	6/28/2043 3/4/2021
Chelsea Z	immerman		
Course ID	Name	Complete	ed Course Due
H70 H70 IRB803 IRB803 GCP200	CITI Mandatory IRB Trng-Biomed CITI Mandatory IRB Trng-Biomed IRB Training IRB Training Good Clinical Practice: Biomedica Research IRB01 Local Training Refresher	10/10/2015 11/14/2019 3/22/2019	5 10/2/2045 0 11/13/2022

Date Page Modified:

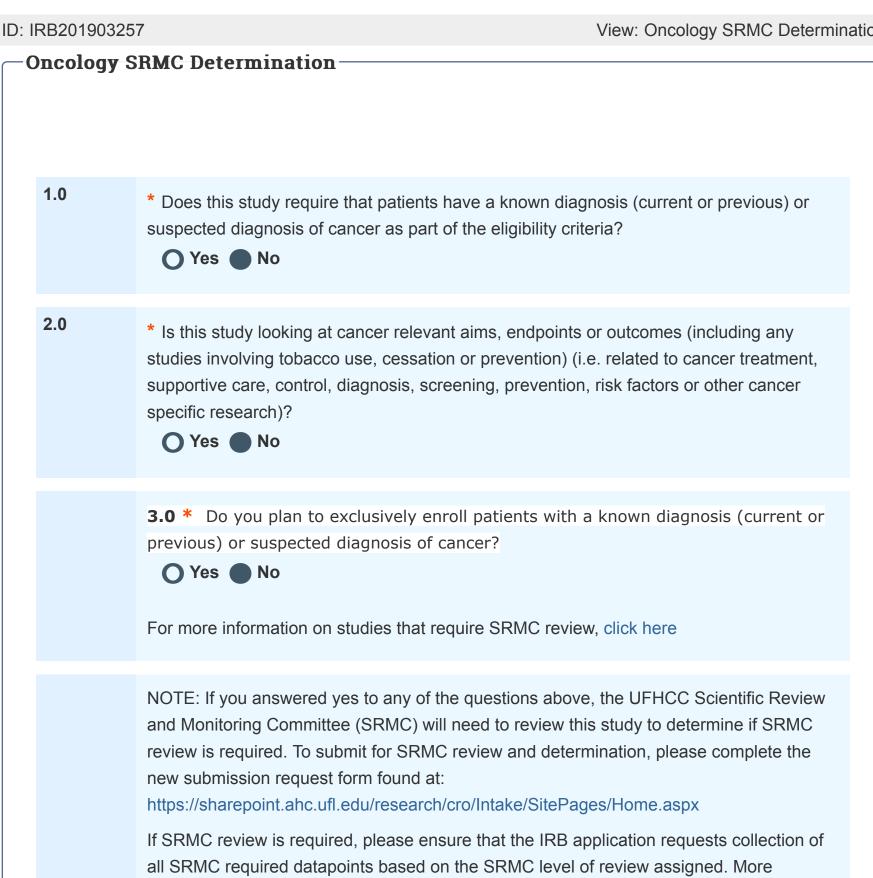
ID: IRB201903257 View: Requested Review Type



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. O 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 O No
5.0	* Is this research considered "classified"? O Yes No

Date Page Modified:

View: Oncology SRMC Determination



information can be found at: https://cancer.ufl.edu/wordpress/files/2019/05/ADM-004-V3-

2019-02-20.pdf

ID: IRB201903257

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 <u>email</u> 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	I COI Compliance	Affiliation UIA
Janey Adams	Other	yes	no	UF
Eleni Sheehan	Co-Investigator	yes	no	Shands
Jennifer Hosford	Other	yes	no	UF
Angelina Bernier	Co-Investigator	yes	no	UF
Kristin Dayton	Co-Investigator	yes	no	UF
Elizabeth Fudge	Co-Investigator	yes	no	UF
Michael Haller	Co-Investigator	yes	no	UF
Laura Jacobsen	Co-Investigator	yes	no	UF
Jennifer Miller	Co-Investigator	yes	no	UF
Shannon Patrick	Co-Investigator	yes	no	UF
Henry Rohrs	Co-Investigator	yes	no	UF
Desmond Schatz	Co-Investigator	yes	no	UF
Janet Silverstein	Co-Investigator	yes	no	UF
Brittany Bruggeman	Co-Investigator	yes	no	UF
Paul Hiers	Co-Investigator	yes	no	UF
Chelsea Zimmerman	Co-Investigator	yes	no	Shands UF

2.0 PI Conflict of Interest and Affiliation Summary

PI Name	Agreed	COI Compliance COI Doc Doc	UIA Affiliation Doc
View Anastasia Albanese-O'Neill	yes	no	UF

IRB20190	3257 View: EHS Determin	natio
	ermination————————————————————————————————————	
1.0	Will you send shipments of tissues/specimens/samples known or suspected to contain a human disease agent	
	* 1.1 To others inside UF: O Yes No	
	* 1.2 To others outside UF but within the US: O Yes No	
	* 1.3 To others outside the US: O Yes No	
2.0	Will you receive shipments of tissues/specimens/samples known or suspected to contain a human disease agent	
	* 2.1 From inside UF: O Yes No	
	* 2.2 From outside UF but within the US: O Yes No	
	* 2.3 From outside the US: Yes No	
3.0	Will you hand carry shipments of ANY tissues/specimens/samples	
	* 3.1 To or from others outside UF but within the US: O Yes No	
	* 3.2 To or from others outside the US: O Yes No	
te Page Mo	dified:	
IRB20190	3257 View: Risk Benefit Assessment - Banking	Onl
Risk & B	enefit 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:1/29/2020

D: IF	RB20190325	7	View: Study Locations
-s	tud y Loca	tions	
	1.0	* Where are you going to conduct this project? (choose all that apply) ✓ UF and/or UF Health ☐ UF and/or UF Health Jacksonville ☐ VA ☐ Other sites in the USA ☐ Other sites outside the USA	
	2.0	Are you getting any data or tissue from international locations? Yes No	
	2.0	Are you getting any data or tissue from international locations?	

Date Page Modified:

ID: IRB201903257 View: Study Funding Study Funding 1.0 * Indicate appropriate **funding types** for this project: ☐ DHHS, including NIH and NCI or NSF Federal Grant (other than DHHS or VA) Veteran Affairs (VA) State or Local Government **Non-Profit Organization** Industry Internally Funded, CTSI Internally Funded, Other No Funding required to initiate or complete this study 2.0 Provide the **UFIRST Number** for this project, if available:

<u>NOTE:</u> Industry Sponsored research in the <u>College of Medicine</u> is required to be submitted to WIRB.

If you wish to submit to IRB-01 with industry funding, 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: IRB201903257 View: External Funding Sources

External Funding Sources

1.0

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

ID	Status	Source Name	Other	Deadline
ID00030310	Obtained	T1D EXCHANGE		

Date Page Modified:

ID: IRB201903257 View: Funding Summary

Funding Summary

1.0

Funding Sources:

Government Funding Sources:

ID Status Source Name Other Deadline Grant Number Grant

There are no items to display

External Funding Sources:

ID Status Source Name Other Deadline

ID00030310 Obtained T1D EXCHANGE

Internal Funding Sources:

ID Status College Dept Unit

There are no items to display

1.1 Upload Additional Funding documentation/attachments here:

Document Description

There are no items to display

Date Page Modified:

ID: IRB201903257 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? O Yes No
3.0	* Does the institution (University of Florida, Shands, NF/SG VHS) own stock in the company sponsoring the project? O 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: IRB201903257

View: Study Billing: RAC Review Determination

Study Billing: Research Billing Compliance Review Determination

1.0

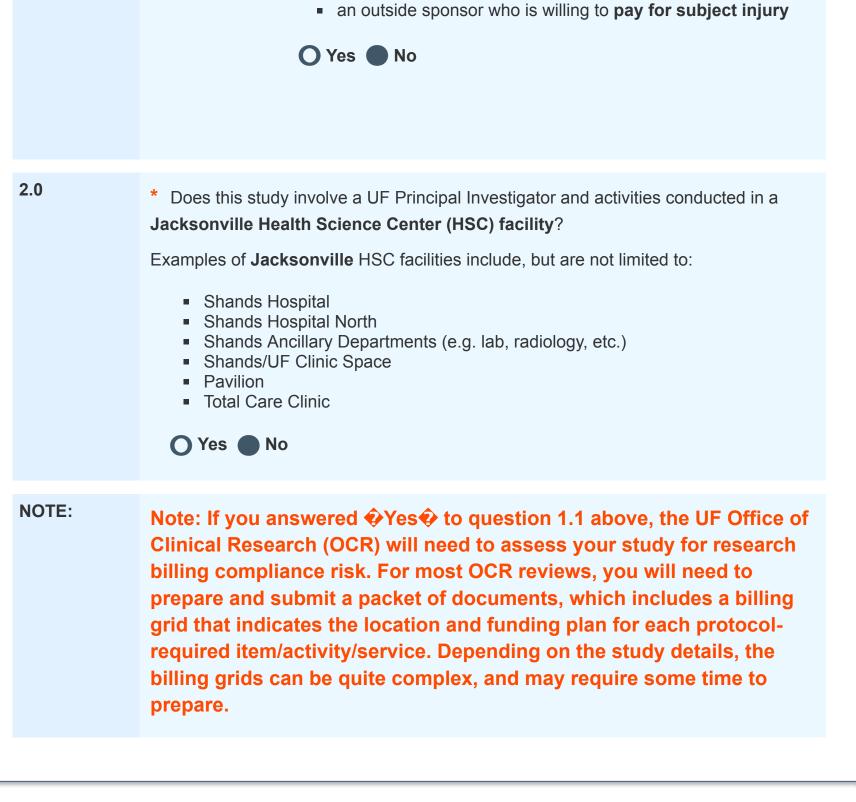
* Does this study involve a **UF Principal Investigator** and activities conducted in a **Gainesville Health Science Center (HSC) facility**?

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)



- **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



Date Page Modified:1/29/2020

ID: IRB201903257

Banking of Tissue/Data/Contact Registry 1.0 * Indicate the type of bank being submitted: Tissue Bank **Data Bank** Contact Registry Bank 2.0 Where will the tissue/data/contact registry bank be located? No Non-Locale Facility Name **Non-Local IRB** Facility Room Local IRB **Location Number** Appr Appr View Non-**NHS Exemption** Local Determination Letter.doc(0.01) View Local University of Gainesville, Encrypted server Florida Florida managed by **Pediatrics EPIC** staff 3.0 Indicate how information about tissue/data/contact registry will be stored:

View: Banking of Tissue/Data/Contact Registry

wi co an	rill be ompletely nonymous 3.1 If " to f	links between the including the HIF http://irb.ufl.edu/	question no means that there are no codes or e subject and their banked data/tissue, PAA identifiers as listed on irb01/hipaa/hipaa-identifiers.html direct links/codes", are there mechanisms in place equests to have their tissue/data removed &
3	to f	fulfill any subject restroyed?	·
		3.1.1	Describe: Data stored at UF will include zip codes and dates. The MRN for each subject will be replaced with a unique identifier. Study personnel will not have access to the MRN. The code linking the unique identifier to the MRN will be held by EPIC. Data that has only the unique identifier but does include dates and zip codes will be uploaded via portal to the T1D Exchange data bank.

Date Page Modified: 1/29/2020

ID: IRB201903257 View: Banking of Data

Banking of Data 1.0 * If Data Bank, Indicate the **type of data** being collected: 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 Data collected only to bank for future research 1.1 Explain/Describe: The T1D Exchange Quality Improvement Initiative aims to improve care of people with type 1 diabetes in the United States. A web portal has been created to upload data from participating clinics. These clinical data will be summarized at the national/regional level in order to advance medical practice quality improvement initiatives. We will collect clinical outcomes data, PRO, and summary device (glucose and insulin delivery) data. Data from individuals will be collected for the duration of their care provided at UF Health starting in 2015 and continuing through the end of the study.

Date Page Modified: 1/29/2020

ID: IRB201903257 View: Banking of Tissue/Data/Contact Registry - Local

anking of	1 1188ue/Data/Contact Registry - Local
1.0	* Who will the gatekeeper(s) be for this tissue/data/contact registry bank? EPIC staff at the University of Florida under the leadership of Bonnie Poprock. This project has been approved by the UF Department of Pediatrics.
2.0	* Describe the operational processes and security measures to prevent release of tissue/data/contact registry being stored in this bank: Data will be managed by the EPIC staff. Only EPIC staff will hold the code to link data to a subject's MRN. Data will be stored on secure, encrypted servers. Data
	uploaded to the portal will only include the unique identifier and zip codes and dates. The local bank will only distribute data when it shares it via portal with the T1D Exchange. When data are shared with the T1D Exchange via portal, it will not include direct identifiers, only dates and zip codes.
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: Data will be backed up per university protocol.
Page Modifi	ed:1/29/2020
RB20190325	View: Study Population, Over
tudy Popi	ulation, Overview
1.0	* Will subjects of a specific race or ethnicity (as defined by NIH) be studied? O Yes No

* 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?

American Indian/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:	
ID:	-		nking)
	1.0	* Describe the type(s) of subjects to be studied in this project. Type Min Max Participation Screening Screening Page 1 in the	
		View People with 1 Days 100 Years A minimum of no Type 1 five years and up Diabetes to 20 years.	
	Page Modific	ied:1/29/2020 57 View: Compensation Determi	nation
		tion Determination	
	1.0	* Are research subjects compensated?	
		1.1 If "Yes", provide details on each type of compensation: Type Amount Undue Influence Influence Description There are no items to display	ompensation Schedule

ID: IRB201903257

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 Children Prisoners Decisionally Impaired/Comatose Individuals Institutional Residents Terminally III Patients UF/Shands/VA/OneFlorida Institution Staff UF/OneFlorida Institution Students

Date Page Modified:1/29/2020

ID: IRB201903257

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: Children with type 1 diabetes should be eligible to participate in this study because their lives and health are affected by the disease.

Date Page Modified: 1/29/2020

ID: IRB201903257

View: Minor Subjects: Risk Assessment

Minor Subjects: Risk Assessment

1.0

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

The risks involving children in this research study are minimal. The primary risk is a privacy

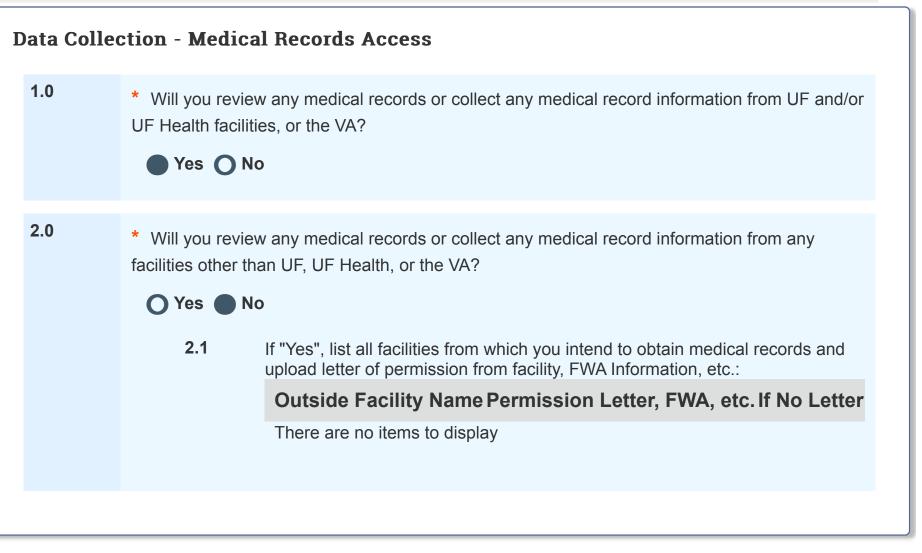
	breach.	
2.0	Child participa	BENEFITS associated with involving children in this research: Ints are directly involved in their own diabetes care and would thereby benefit from ents to the clinical paradigm.
3.0	a. Research magnitude themselve routine phomosome because individual signification alternative. b. Research individual signification and intervention condition with the second condition with the seco	isk-Benefit level for the minors involved in this research project. The poses no greater than minimal risk. Minimal risk means that the probability and to for harm or discomfort anticipated in the research are not greater in and of its than those ordinarily encountered in daily life or during the performance of the sysical or psychological examinations or tests. Explain below 3.1.; the poses greater than minimal risk but presents the prospect of direct benefit to the subjects. In order to qualify for this category all of following must be true: i. The risk is the anticipated benefit to the subjects. Explain below 3.2.; ii. The relation of the benefit to the risk is at least as favorable to the subjects as that presented by available approaches. Explain below 3.3.; this greater than minimal risk with no prospect of direct benefit to individual subjects, by yield generalizable knowledge about the subjects' disorder or condition. In order to this category the all of the following must be true: i. The risk represents a minor increase lal risk. Explain below 3.4; ii. The intervention or procedure presents experiences to at are reasonably commensurate with those inherent in their actual or expected ental, psychological, social, or educational situations. Explain below 3.5; iii. The nor procedure is likely to yield generalizable knowledge about the subjects' disorder or which is of vital importance for the understanding or amelioration of the subjects' condition. Explain below 3.6.: It is not otherwise approvable under one of the conditions above but presents an young to otherwise approvable under one of the conditions above but presents an young to otherwise approvable under one of the conditions above but presents an young test of the produce of the conditions are provided protocol specific information to justify that the study is minimal risk to children: If "a." above, Provide protocol specific information to justify that the study is minimal risk to the subjects as that presented by available alternative appro
4.0	Please indicate 4.0	 * Please indicate whether or not you need to solicit assent from the subject who is under 18 years of age: Written assent is required in order to enroll the subject and will be documented.

4.1	* Explain your response above: This study will collect data retrospectively beginning in January 2015 and prospectively until the termination of the study. Data may be collected on a significant number of subjects who are no longer seen in clinic. 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 Otherwise meets requirements to waive consent as previously described in the myIRB SmartForms 4.2.1 Explain your response above: This study will collect data retrospectively beginning in January 2015 and prospectively until the termination of the study. Data may be collected on a significant number of subjects who are no longer seen in clinic.
Consent of research O Consent of incompeter care and cu Otherwise	eek consent from the subject's parent(s) or guardian(s)? one parent/guardian is sufficient. NOTE: May only be selected for minimal risk R research that offers potential for direct benefit to child subject. both parents/guardians is required unless one parent is deceased, unknown, at, or not reasonably available, or when only one parent has legal responsibility for the sustody of the child. meets requirements to waive consent. Please refer to the Informed Consent radditional information.
* Do you wish to Yes No. 6.1 6.2 6.3	If "Yes", one of the following must be applicable: The research is related to the subject 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. Explain: 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 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.
	* How will you so Consent of research O Consent of incompeter care and co Otherwise section for * Do you wish to Yes No. 6.1

: IRB20190325	57		View: Recruitmen	t Methods (Banking Only St	udie		
Recruitme	nt Methods ((Banking Only Studies	;)				
How are you planning to recruit subjects? (check all that apply)							
		Inpatient Population					
		ent Population					
	<u> </u>	Advertisement					
		Undergraduate Student Pool (e.g. SONA) Research Database/other IRB approved protocol					
	☐ Healthst		ved protocor				
	StudyCo						
	Consent						
		uitment is necessary					
	— 241	nument is necessary					
	Otner						
	1.1	If "Research Database",	specify:				
		Name IRB Nui	· ·	Description			
		There are no items to d		2000			
	1.2		,				
	1.2		_	ctronic health record by			
		EPIC staff. The study to	am will not be invo	olved in data extraction.			
2.0	How do you h	ave access to the subject po	pulation?				
	☐ Advertis	sement					
	As a pa	rt of normal clinical care					
		or / Faculty					
	Primary	physician					
	Other						
	2.1	If "Other", specify:					
		. , .					
3.0	16 1 41 1						
0.0	scripts:	is used, attach copies of the	advertisements, inc	luding phone and/or email			
	Name	Description	on				
	There are no	items to display					
e Page Modifi	ed:1/29/2020						
IRB20190325			View: Data	Collection (Banking Only St	udie		
Data Collec	ction (Banki	ng Only Studies)					

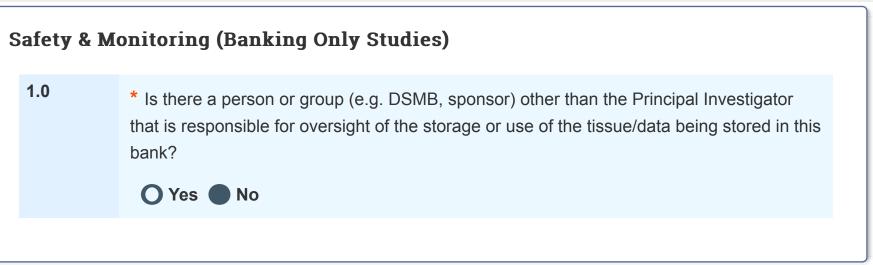
1.0	* Are you collecting any information that could (a) be sensitive and possibly affect the reputation, status, or insurability of the research subjects, (b) place the subject at risk of criminal or civil liability, or (c) be damaging to the subject s financial standing or employability?
	O Yes ● No
	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: NPI number of providers in UF Health clinics. It is an accepted norm of clinical practice to analyze outcomes at the provider level. All providers will be members of the study team.
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
	Data Points Extracted from EPIC

Date Page Modified:2/18/2020



Date Page Modified:

ID: IRB201903257 View: Safety Monitoring (Banking Only Studies)



Date Page Modified: 1/29/2020

Written Informed Consent Determination

* 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: 1/29/2020

ID: IRB201903257 View: Waivers or Modification of Consent Determination

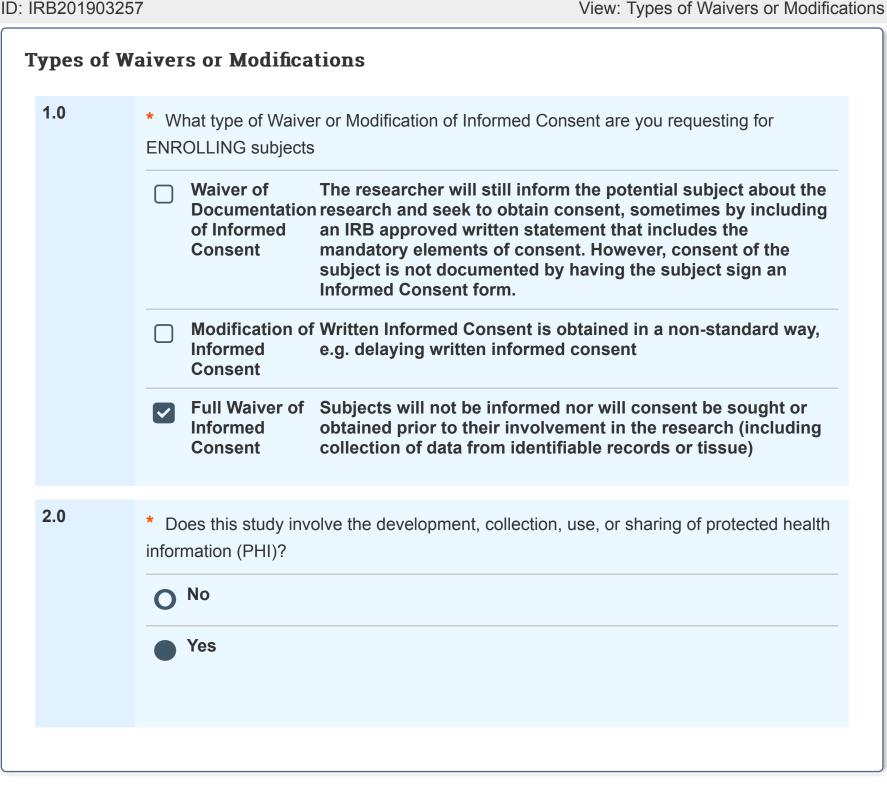
Waivers or Modification of Informed Consent Determination

1.0

* Are you seeking a Waiver of Informed Consent, Modification of Informed Consent, or

Waiver of Documentation of Informed Consent for Enrolling any subjects?	
Yes O No	

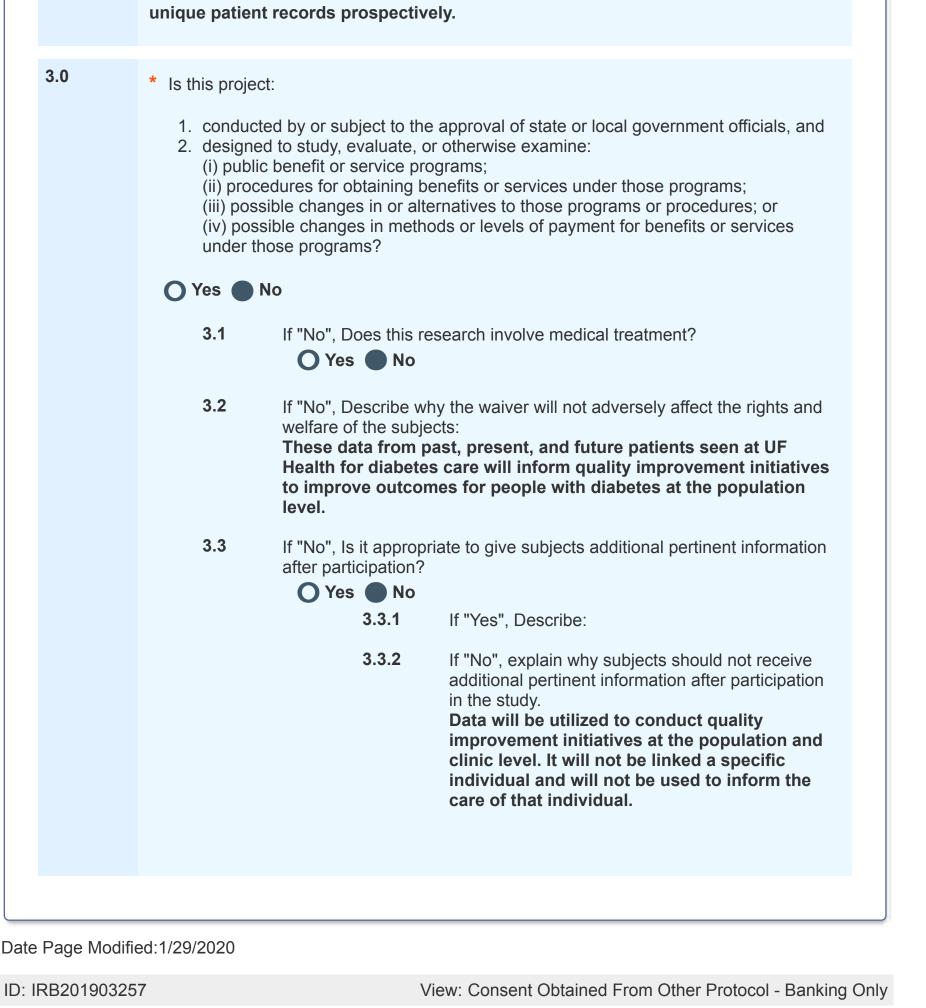
Date Page Modified: 1/29/2020

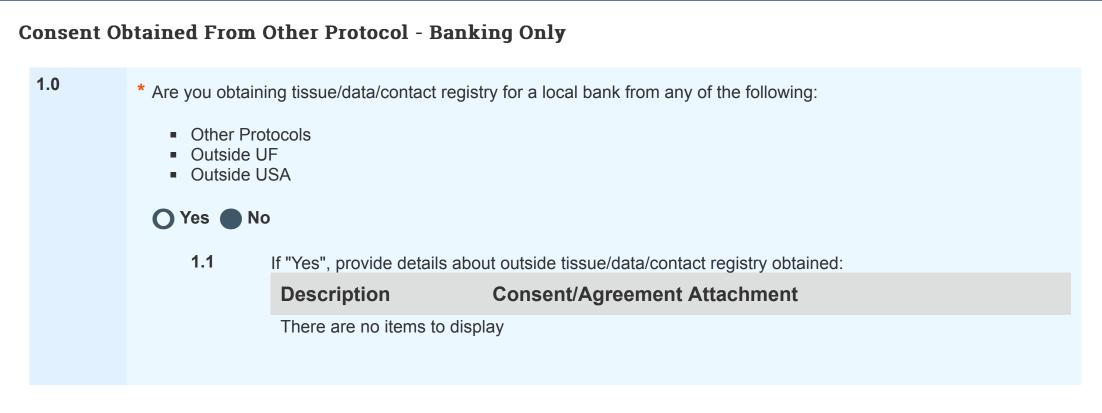


Date Page Modified: 1/29/2020

describe type 1 diabetes outcomes and ultimately guide quality improvement.

Approximately 1500 unique patient records will be included retrospectively and 700





View: HIPAA Authorization Determination

Date Page Modified:

ID: IRB201903257

ID: IRB201903257 View: HIPAA Waiver of Authorization

	* What protected under this waive		will you collect, create, use, or disclose (disclose = outsi	de the covered entity),
	5 digit zip code	and dates of servic	e.	
			hat you are collecting, using, disclosing under an author nation collected/used/disclosed under this waiver.	ization signed by the
	NOTE 2: (click	for suggested lan	guage)	
2.0	_	d on, at least the follo	of protected health information involves no more than a wing elements: in place to protect the identifiers from improper use and	
		Add each type of sto	prage used and describe how identifiers will be protected	
		Storage type		Description Plan
		Data is stored on a protected, and bac	an institutional server that is encrypted, password ked up	
	b.	identifiers) at the ear completion of data a retaining the identifier	A waiver requires that an adequate plan is in place to derliest opportunity consistent with conduct of the research analysis, sooner if appropriate), unless there is a health ders or such retention is otherwise required by law. ods you will use to de-identify the data that you have conat apply)	n (no later than the or research justification for
		Hardcopy of i	identifiers/key code shredded	
		☐ Electronic co	pies de-identified and are now anonymous	
		Redacting ide	entifiers as you record information	
		identifiers mu	nducted at the VA, therefore all research records incust be retained in accordance with the VHA Record (a minimum of 6 years, whichever is longer.	•
		Other		
		b.1	If "Other", Specify: Data will be extracted from patient charts by EPIC data (see list of variables), MRN, zip codes, and dareplace the MRN with a unique identifier before it is Exchange Portal. Study personnel will not view darparticipants' MRN.	ates. The data staff will is uploaded to the T1D
	C.	required by law, for a	n information will not be reused or disclosed to any othe authorized oversight of the research study, or for other red health information would be permitted by HIPAA regi	esearch for which the use of
.0	* I certify that information.	this research could n	not practicably be conducted without access to and use	of the protected health
	a.	Explain why it is imp	practical to conduct the research without the waiver of au	uthorization:
		lt would be in study	appropriate to contact people who do not qualify fo	r the
		No direct sub	ject contact to obtain authorization	

	Unreliable/inaccurate contact information for subjects
	Subjects may be deceased
	Other
	If "Other", describe: This study will collect data retrospectively beginning in January 2015 and prospectively until the termination of the study. Data may be collected on a significant number of subjects who are no longer seen in clinic.
4.0	* I certify that I will only access PHI under this waiver until the end of the study.
e Page Modifi	ed:1/29/2020

Date

View: Privacy Confidentiality Complete ID: IRB201903257 **Privacy & Confidentiality Complete** You have completed the Privacy & Confidentiality section. Please continue to the next section.

Date Page Modified:

NOTE:

3 - 1				
: IRB201903257		View: Miscella	neous Attachme	
Miscellaneo	us			
1.0	Certificate of Decedent Information Form:			
2.0	Approved Social Security Exception Form:			
3.0	Upload miscellaneous study attachments below:			
	Name	Modified	Version	
	IRB Determination Letter QI Collaborative Participation Agreement	1/22/2020 1:33 PM 4/3/2020 7:50 AM	0.01 0.01	
4.0 List any specific information that needs to be included in the IRB approval letter:				

YOU MUST SAVE THIS PAGE TO SAVE ATTACHMENTS

ID: IRB201903257

View: Legacy Paper Determination

View: Study: Final Page

Legacy Paper Determination

1.0

* Is this a conversion from a paper study?

O Yes No

2.0

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

O 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: IRB201903257

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: IRB201903257 View: External Funding Source Detail

External Funding Source - Detail

1.0

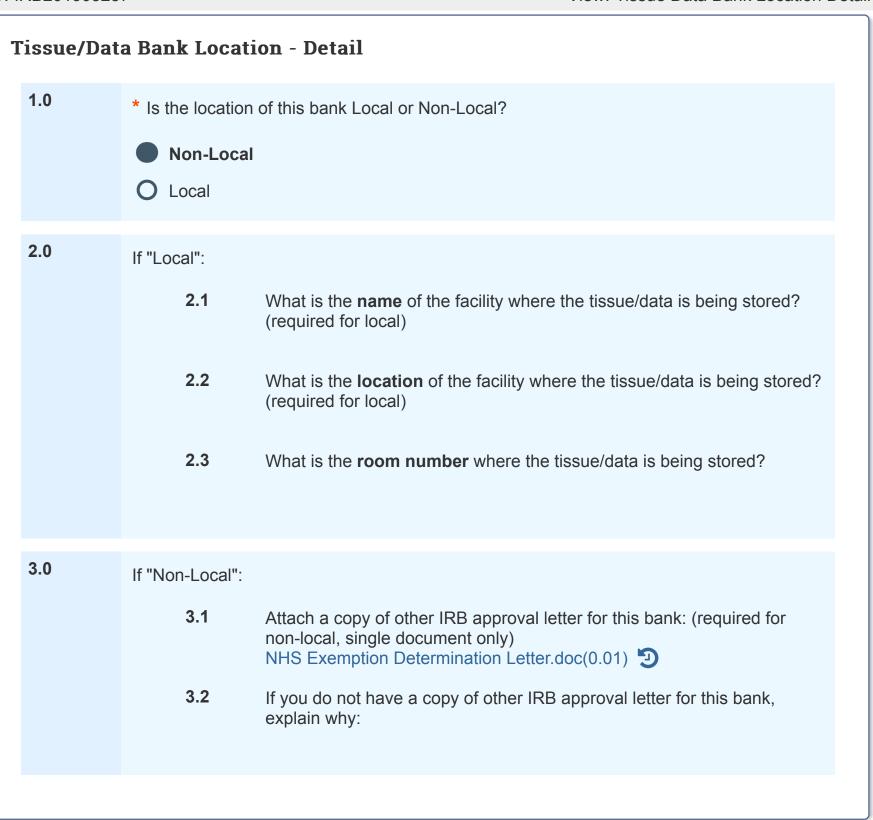
* Sponsor Name:

T1D EXCHANGE

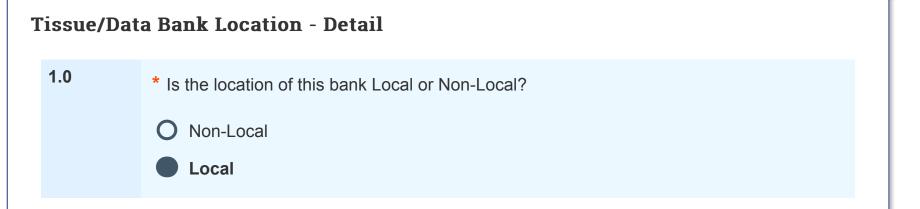
		1.1 If "Other", specify Sponsor name.
	2.0	Funding Status:
		Obtained
		O Pending
	3.0	Please provide the title of the award that was submitted to the Division of Sponsored Programs (DSP): T1D Exchange Quality Improvement Initiative
. I	DD004000F	View Tierr Deta Berlel earlier Deta

ID: IRB201903257

View: Tissue Data Bank Location Detail



ID: IRB201903257 View: Tissue Data Bank Location Detail



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 Pediatrics
	2.2	What is the location of the facility where the tissue/data is being stored? (required for local) Gainesville, Florida
	2.3	What is the room number where the tissue/data is being stored? Encrypted server managed by EPIC staff
3.0		
3.0	If "Non-Local":	
3.0	If "Non-Local":	Attach a copy of other IRB approval letter for this bank: (required for non-local, single document only)
3.0		
3.0	3.1	non-local, single document only) If you do not have a copy of other IRB approval letter for this bank,

ID: IRB201903257 View: Type of Subjects - Detail

Type of Subjects - Expedited/Full Board/Banking: Detail 1.0 * Description: **People with Type 1 Diabetes** 2.0 * Indicate the age range of subjects (for each group, if applicable) to be studied : 2.1 Minimum Age: 1 Days Units 2.2 Maximum Age: 100 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? A minimum of five years and up to 20 years.

ID: IRB201903257 View: Data Entry View

HIPAA Authorization Determination

* Specify the type of storage/data transmission to Describe your protection plan for type of media

be used: you selected.

Data is stored on an institutional server that is encrypted, password protected, and backed up