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:

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?

○ Yes ● No

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

○ Yes ● No

5.0

* Principal Investigator:

Anastasia Albanese-O'Neill	**MD-PEDS-ENDOCRINOLOGY**	UF

- [ ] Interacts or intervenes directly (including remote interactions by phone, internet, etc.) with study subjects
- [x] **Performs study related activities but does not interact directly with the study subjects**
- [ ] 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
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-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**Shands**
Angelina Bernier	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Kristin Dayton	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Elizabeth Fudge	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Michael Haller	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Laura	Co-	▪ **Performs study related activities but**	**UF**

Jacobsen	Investigator	**does not interact directly with the study subjects**	
Jennifer Miller	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Shannon Patrick	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Henry Rohrs	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Desmond Schatz	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Janet Silverstein	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Brittany Bruggeman	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Paul Hiers	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**UF**
Chelsea Zimmerman	Co-Investigator	▪ **Performs study related activities but does not interact directly with the study subjects**	**Shands UF**

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:1/22/2020

ID: IRB201903257 View: Researcher Training Summary

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**

1.2 Study Staff Training:

Janey Adams

Course ID	Name	Completed	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: Biomedical Research	2/21/2020	2/20/2023
IRB802	IRB01 Local Training Refresher	8/24/2018	8/23/2021

Jennifer Hosford

Course ID	Name	Completed	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	7/2/2013	6/25/2043
CITI	CITI Mandatory IRB Trng-Spec Mods	11/2/2012	10/26/2042
IRB803	IRB Training	10/28/2019	10/27/2022
GCP200	Good Clinical Practice: Biomedical Research	2/22/2019	2/21/2022
IRB802	IRB01 Local Training Refresher	8/30/2017	8/29/2020

Eleni Sheehan

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
IRB803	IRB Training	2/5/2020	2/4/2023

Elizabeth B. Fudge

Course ID	Name	Completed	Course Due
IRB803	IRB Training	2/7/2020	2/6/2023

Michael J Haller

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	1/9/2018	1/2/2048
NIH	NIH Extramural Education	12/20/2012	12/13/2042
IRB803	IRB Training	1/14/2020	1/13/2023
IRB802	IRB01 Local Training Refresher	1/11/2019	1/10/2022
GCP200	Good Clinical Practice: Biomedical Research	5/15/2018	5/14/2021

Laura Jacobsen

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	12/20/2018	12/12/2048
H70	CITI Mandatory IRB Trng-Biomed	7/28/2015	7/20/2045
GCP200	Good Clinical Practice: Biomedical Research	4/30/2019	4/29/2022
IRB802	IRB01 Local Training Refresher	7/1/2018	6/30/2021

Jennifer Lynne Miller

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	1/29/2014	1/22/2044
IRB802	IRB01 Local Training Refresher	5/3/2017	5/2/2020

Shannon Fennell Patrick

Course ID	Name	Completed	Course Due
IRB803	IRB Training	2/11/2020	2/10/2023

Henry Rohrs

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	2/21/2014	2/14/2044
IRB802	IRB01 Local Training Refresher	8/7/2017	8/6/2020
IRB800	IRB01 Local Training	8/7/2017	8/6/2020

Desmond A Schatz

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	3/19/2019	3/11/2049
H70	CITI Mandatory IRB Trng-Biomed	6/17/2016	6/10/2046
NIH	NIH Extramural Education	12/13/2012	12/6/2042
GCP200	Good Clinical Practice: Biomedical Research	3/19/2019	3/18/2022
IRB802	IRB01 Local Training Refresher	10/30/2018	10/29/2021

Janet Hope Silverstein

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	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 Bruggeman

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	1/23/2019	1/15/2049
H70	CITI Mandatory IRB Trng-Biomed	12/13/2015	12/5/2045
IRB803	IRB Training	3/21/2019	3/20/2022
GCP200	Good Clinical Practice: Biomedical Research	1/23/2019	1/22/2022
IRB802	IRB01 Local Training Refresher	11/8/2018	11/7/2021

Paul Hiers

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	4/20/2017	4/13/2047
H70	CITI Mandatory IRB Trng-Biomed	7/5/2013	6/28/2043
IRB802	IRB01 Local Training Refresher	3/5/2018	3/4/2021
GCP200	Good Clinical Practice: Biomedical Research	9/23/2017	9/22/2020

Chelsea Zimmerman

Course ID	Name	Completed	Course Due
H70	CITI Mandatory IRB Trng-Biomed	7/17/2018	7/9/2048
H70	CITI Mandatory IRB Trng-Biomed	10/10/2015	10/2/2045
IRB803	IRB Training	11/14/2019	11/13/2022
IRB803	IRB Training	3/22/2019	3/21/2022
GCP200	Good Clinical Practice: Biomedical Research	1/7/2019	1/6/2022
IRB802	IRB01 Local Training Refresher	9/25/2018	9/24/2021

Date Page Modified:

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: IRB201903257 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: 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 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 Doc	Compliance Doc	Affiliation	UIA Doc
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	COI Doc	Compliance Doc	Affiliation	UIA Doc
View **Anastasia Albanese-O'Neill**	**yes**	**no**			**UF**	

Date Page Modified:

ID: IRB201903257 View: EHS Determination

EHS Determination

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:
○ **Yes** ● **No**

* **1.2** To others outside UF but within the US:
○ **Yes** ● **No**

* **1.3** To others outside the US:
○ **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:
○ **Yes** ● **No**

* **2.2** From outside UF but within the US:
○ **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:
○ **Yes** ● **No**

* **3.2** To or from others outside the US:
○ **Yes** ● **No**

Date Page Modified:

ID: IRB201903257 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:1/29/2020

ID: IRB201903257 View: Study Locations

Study Locations

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

- [x] **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**

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
- [x] **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:

NOTE: **Industry Sponsored research in the College of Medicine 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? ○ **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: 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)

○ **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:1/29/2020

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

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?

	Locale	Facility Name	Facility Location	Room Number	Non-Local IRB Appr	No Non-Local IRB Appr
View	Non-Local				NHS Exemption Determination Letter.doc(0.01)	
View	Local	University of Florida Pediatrics	Gainesville, Florida	Encrypted server managed by EPIC staff		

3.0

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

☑	**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:

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

Banking of Tissue/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.

Date Page Modified:1/29/2020

ID: IRB201903257 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?

- ☐ 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:

Date Page Modified:

ID: IRB201903257 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	**People with Type 1 Diabetes**		**1**	**Days**	**100**	**Years**	**A minimum of five years and up to 20 years.**	**no**	

Date Page Modified:1/29/2020

ID: IRB201903257 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:1/29/2020

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 Ill 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

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

Child participants are directly involved in their own diabetes care and would thereby benefit from any improvements to the clinical paradigm.

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:
This is a data banking study only.

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:

- ☐ 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.

☑ **Assent should not be required**

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.

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

☑ **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.

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:1/29/2020

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
- [ ] 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:
Data will be extracted directly from the electronic health record by EPIC staff. The study team will not be involved in data extraction.

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:1/29/2020

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:
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

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: IRB201903257 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:1/29/2020

ID: IRB201903257 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: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 ○ No

Date Page Modified:1/29/2020

ID: IRB201903257 View: Types of Waivers or Modifications

Types of Waivers or Modifications

1.0

* What type of Waiver or Modification of Informed Consent are you requesting for ENROLLING subjects

☐	**Waiver of Documentation of Informed Consent**	**The researcher will still inform the potential subject about the research and seek to obtain consent, sometimes by including an IRB approved written statement that includes the mandatory elements of consent. However, consent of the subject is not documented by having the subject sign an Informed Consent form.**
☐	**Modification of Informed Consent**	**Written Informed Consent is obtained in a non-standard way, e.g. delaying written informed consent**
☑	**Full Waiver of Informed Consent**	**Subjects will not be informed nor will consent be sought or obtained prior to their involvement in the research (including collection of data from identifiable records or tissue)**

2.0

* Does this study involve the development, collection, use, or sharing of protected health information (PHI)?

○ **No**

● **Yes**

Date Page Modified:1/29/2020

ID: IRB201903257 View: Full Waiver of Informed Consent

Full Waiver of Informed Consent

1.0

* Is this research project subject to FDA regulations?

○ **Yes** ● **No**

2.0

* Describe and Justify why the research could not practicably be carried out without the waiver.

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. Complete data collection for the entire clinic population is essential to adequately and accurately describe type 1 diabetes outcomes and ultimately guide quality improvement. Approximately 1500 unique patient records will be included retrospectively and 700

unique patient records prospectively.

3.0 * Is this project:

1. conducted by or subject to the approval of state or local government officials, and
2. designed to study, evaluate, or otherwise examine:
   (i) public benefit or service programs;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs?

○ **Yes** ● **No**

3.1 If "No", Does this research involve medical treatment?

○ **Yes** ● **No**

3.2 If "No", Describe why the waiver will not adversely affect the rights and welfare of the subjects:
These data from past, present, and future patients seen at UF Health for diabetes care will inform quality improvement initiatives to improve outcomes for people with diabetes at the population level.

3.3 If "No", Is it appropriate to give subjects additional pertinent information after participation?

○ **Yes** ● **No**

3.3.1 If "Yes", Describe:

3.3.2 If "No", explain why subjects should not receive additional pertinent information after participation in the study.
Data will be utilized to conduct quality improvement initiatives at the population and clinic level. It will not be linked a specific individual and will not be used to inform the care of that individual.

Date Page Modified:1/29/2020

ID: IRB201903257 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:1/29/2020

ID: IRB201903257 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:

- [x] **HIPAA Waiver of authorization**
- [ ] 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:1/29/2020

ID: IRB201903257 View: HIPAA Waiver Determination

HIPAA Waiver Determination

1.0

* This is a request to waive a patients' HIPAA authorization:

- [x] **to enroll subjects in the study**
- [ ] to identify, for the purpose of recruiting, potential subjects for the study
- [ ] Not Applicable

NOTE: In chart review studies, collecting the data for your study from a medical record is considered enrolling a study subject.

1.1 If UF/Shands/OneFlorida institution, and if this request is to **identify and/or contact potential subjects**,
Will you disclose identifiable information to anyone **outside** your covered entity? *(e.g. release initials, names, birthdates, etc. of people who do not meet eligibility criteria to the study sponsor)*

○ **Yes** ● **No**

If VA is involved, a HIPAA Waiver of Authorization must be completed. If VA is not involved, a HIPAA Waiver of Authorization to Identify or Recruit only needs to be completed if you are disclosing identifiable information outside of the covered entity.

Date Page Modified:

ID: IRB201903257 View: HIPAA Waiver of Authorization

HIPAA Waiver of Authorization

1.0

* What protected health information will you collect, create, use, or disclose *(disclose = outside the covered entity)*, **under this waiver**?

5 digit zip code and dates of service.

NOTE 1: Do not list the information that you are collecting, using, disclosing under an authorization signed by the subject. This section is just for information collected/used/disclosed under this waiver.

NOTE 2: *(click*  *for suggested language)*

2.0

* **I certify** that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals based on, at least the following elements:

a. An adequate plan is in place to protect the identifiers from improper use and disclosure.
Add each type of storage used and describe how identifiers will be protected for each type:

Storage type	Protection Plan Description
Data is stored on an institutional server that is encrypted, password protected, and backed up	

b. Approval of a HIPAA waiver requires that an adequate plan is in place to de-identify (destroy the identifiers) at the earliest opportunity consistent with conduct of the research *(no later than the completion of data analysis, sooner if appropriate)*, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
Indicate which methods you will use to de-identify the data that you have collected/used under this waiver. *(check all that apply)*

- ☐ **Hardcopy of identifiers/key code shredded**
- ☐ **Electronic copies de-identified and are now anonymous**
- ☐ **Redacting identifiers as you record information**
- ☐ **Research conducted at the VA, therefore all research records including identifiers must be retained in accordance with the VHA Record Control Schedule or a minimum of 6 years, whichever is longer.**
- ☑ **Other**

b.1 If "Other", Specify:
Data will be extracted from patient charts by EPIC staff. It will include clinical data (see list of variables), MRN, zip codes, and dates. The data staff will replace the MRN with a unique identifier before it is uploaded to the T1D Exchange Portal. Study personnel will not view data that includes the participants' MRN.

c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of protected health information would be permitted by HIPAA regulations.

3.0

* **I certify** that this research could not practicably be conducted without access to and use of the protected health information.

a. Explain why it is impractical to conduct the research without the waiver of authorization:
(check all that apply)

- ☐ **It would be inappropriate to contact people who do not qualify for the study**
- ☐ **No direct subject 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.

Date Page Modified:1/29/2020

ID: IRB201903257 View: Privacy Confidentiality Complete

Privacy & Confidentiality Complete

You have completed the Privacy & Confidentiality section.

Please continue to the next section.

Date Page Modified:

ID: IRB201903257 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
IRB Determination Letter	1/22/2020 1:33 PM	0.01
QI Collaborative Participation Agreement	4/3/2020 7:50 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:4/3/2020

ID: IRB201903257 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: IRB201903257 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: 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**
- ( ) 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

ID: IRB201903257 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)
- **2.2** What is the **location** of the facility where the tissue/data is being stored? (required for local)
- **2.3** What is the **room number** where the tissue/data is being stored?

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)
  NHS Exemption Determination Letter.doc(0.01)
- **3.2** If you do not have a copy of other IRB approval letter for this bank, explain why:

ID: IRB201903257 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 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 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: 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:

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

you selected.