Collaborative Islet Transplant Registry

Recipient Demographics (DEM)

Version: 1.06; 03-16-05

1. Date of birth: _____ *(mm/dd/yyyy)*

2. Place of primary residence:
   - Alabama
   - Alaska
   - Albania - Europe
   - Alberta - Canada
   - American Samoa
   - *Additional Options Listed Below

3. Gender: ☐ Male ☐ Female ☐ Unknown

4. Ethnicity:
   - Non Hispanic or Latino
   - Hispanic or Latino
   - Unknown

5. Race: Indicate 'No', 'Yes', or 'Unknown' for each race category. At least one race category must be checked 'Yes', or all must be checked 'Unknown'
   - a. American Indian or Alaska Native: ☐ No ☐ Yes ☐ Unknown
   - b. Asian: ☐ No ☐ Yes ☐ Unknown
   - c. Black or African American: ☐ No ☐ Yes ☐ Unknown
   - d. Indian Sub-continent: ☐ No ☐ Yes ☐ Unknown
   - e. Mideast or Arabian: ☐ No ☐ Yes ☐ Unknown
   - f. Native Hawaiian or Other Pacific Islander: ☐ No ☐ Yes ☐ Unknown
   - g. White: ☐ No ☐ Yes ☐ Unknown
   - h. Other: ☐ No ☐ Yes ☐ Unknown
     - If OTHER, specify: _____

Additional Selection Options for DEM

Place of primary residence:
Andorra - Europe
Arizona
Arkansas
Armenia - Europe
Austria - Europe
Azerbaijan - Europe
Belarus - Europe
Belgium - Europe
Bosnia and Herzegovina - Europe
British Columbia - Canada
Bulgaria - Europe
California
Colorado
Connecticut
Croatia - Europe
Cyprus - Europe
Czech Republic - Europe
Delaware
Denmark - Europe
District of Columbia
Estonia - Europe
Faroe Islands - Europe
Finland - Europe
Florida
France - Europe
Georgia
Georgia - Europe
Germany - Europe
Gibraltar - Europe
Greece - Europe
Guam
Guernsey - Europe
Hawaii
Hungary - Europe
Iceland - Europe
Idaho
Illinois
Indiana
Iowa
Isle of Man - Europe
Italy - Europe
Jersey - Europe
Kansas
Kentucky
Latvia - Europe
Liechtenstein - Europe
Lithuania - Europe
Louisiana
Luxembourg - Europe
Maine
Malta - Europe
Manitoba - Canada
Maryland
Massachusetts
Mexico
Michigan
Minnesota
Mississippi
Missouri
Moldova - Europe
Monaco - Europe
Montana
Montenegro - Europe
Nebraska
Netherlands - Europe
Nevada
New Brunswick - Canada
New Hampshire
New Jersey
New Mexico
New York
Newfoundland - Canada
North Dakota
North Carolina
Northwest Territories - Canada

Norway - Europe
Nunavut - Canada
Ohio
Oklahoma
Ontario - Canada
Oregon
Other
Panama Canal Zone
Pennsylvania
Poland - Europe
Portugal - Europe
Prince Edward Island - Canada
Puerto Rico
Quebec - Canada
Republic of Ireland - Europe
Republic of Macedonia - Europe
Rhode Island
Romania - Europe
Russia - Europe
San Marino - Europe
Saskatchewan - Canada
Serbia - Europe
Slovakia - Europe
Slovenia - Europe
South Carolina
South Dakota
Spain - Europe
Svalbard - Europe
Sweden - Europe
Switzerland - Europe
Tennessee
Texas
Turkey - Europe
Ukraine - Europe
United Kingdom - Europe
Unknown
US Virgin Islands
Utah
Vatican City - Europe
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming
Yukon Territory - Canada

Collaborative Islet Transplant Registry

REGISTRATION (ENR)

Version: 1.05; 03-16-05

1. Diabetes type:

Type 1
Pancreatectomy induced
Cystic fibrosis related
Type 2
MODY
*Additional Options Listed Below

Indicate year of onset: *(xxxx)*

2. ABO blood group:

A
B
AB
O
A1
*Additional Options Listed Below

HLA Information

3. HLA typing conducted: ☐ No ☐ Yes ☐ Unknown

If YES:

a. Date typed: *(mm/dd/yyyy)*

b. Class I:

A (1): A (2):

B (1): B (2):

Bw4:

Negative
Positive
Unknown or Not Determined
Confirmed Blank

Bw6:

Negative
Positive
Unknown or Not Determined
Confirmed Blank

c. Class II:

DR (1): DR (2):

DQ (1): DQ (2):

Additional Selection Options for ENR

Diabetes type:
Other

ABO blood group:
A2
A1B
A2B
Unknown

Collaborative Islet Transplant Registry

(1) Deceased Donor (CAD)

Version: 5.01; 03-16-05

Infusion Date:
Panc. # for this infusion:

Donor Information

1. Donor type: (Choose one from each category)

Adult/pediatric
Fetal/embryonic
Other

Islets
Stem/progenitor/precursor cell derived islets
Engineered cell line
Unknown
Other

If FETAL is chosen from above, stop here, save and submit the data.

2. Specify UNOS Donor ID: ☐ Not Available ☐ Not Applicable
3. Specify CORR Donor ID: ☐ Not Available ☐ Not Applicable

If UNOS ID provided, all '*' questions may be skipped.
Make sure that red questions are completed

4. Date of birth:* *(mm/dd/yyyy)*
   If complete date of birth is unknown, enter donor's age at the time of the infusion: *(xxx)* yrs ☐ Unknown
5. Gender:*

Male
Female
Unknown

6. Ethnicity:*

Non Hispanic or Latino
Hispanic or Latino
Unknown

7. Race:* Indicate 'No', 'Yes', or 'Unknown' for each Race category.
   a. American Indian or Alaska Native: ☐ No ☐ Yes ☐ Unknown
   b. Asian: ☐ No ☐ Yes ☐ Unknown
   c. Black or African American: ☐ No ☐ Yes ☐ Unknown
   d. Indian Sub-continent: ☐ No ☐ Yes ☐ Unknown
   e. Mideast or Arabian: ☐ No ☐ Yes ☐ Unknown
   f. Native Hawaiian or Other Pacific Islander: ☐ No ☐ Yes ☐ Unknown
   g. White: ☐ No ☐ Yes ☐ Unknown
   h. Other: ☐ No ☐ Yes ☐ Unknown
      If OTHER, specify race:
8. Weight:* *(xxx.x)* kg **OR** *(xxx.x)* lb ☐ Unknown
9. Height:* *(xxx.x)* cm **OR** *(xxx.x)* in ☐ Unknown
10. ABO blood group:*

A
B
AB
O
A1
*Additional Options Listed Below

11. Cause of death:*

Anoxia/cardiac arrest
Head trauma
Cerebrovascular/stroke
CNS tumor
Other
*Additional Options Listed Below

If OTHER, specify:

12. Mechanism of death:*

Asphyxiation
Blunt injury
Cardiovascular
Death from natural causes
Drowning
*Additional Options Listed Below

13. Circumstances of death:*

Motor vehicle accident
Alleged suicide
Alleged homicide
Alleged child abuse
Non-motor vehicle accident
*Additional Options Listed Below

Donor Medical History

14. History of hypertension:* ☐ No ☐ Yes ☐ Unknown

a. If YES, duration:

0-5 years
6-10 years
>10 years
Unknown

b. If YES, method of control:

Diet: ☐ No ☐ Yes ☐ Unknown

Diuretics: ☐ No ☐ Yes ☐ Unknown

Other hypertensive medication: ☐ No ☐ Yes ☐ Unknown

15. History of alcohol dependency: ☐ No ☐ Yes ☐ Unknown

If YES, continued use in the past six months: ☐ No ☐ Yes ☐ Unknown

16. History of diabetes:* ☐ No ☐ Yes ☐ Unknown

a. If YES, duration:

0-5 years
6-10 years
>10 years
Unknown

b. If YES, is the donor insulin dependent: ☐ No ☐ Yes ☐ Unknown

If YES, indicate number of years donor has been taking insulin:

0-5 years
6-10 years
>10 years
Unknown

Transfusion Information

17. During this hospitalization, total number of transfusion units given prior to surgery:

0 units
0-5 units
6-10 units
>10 units
Unknown

18. Number of transfusion units given intraoperatively:

0 units
0-5 units
6-10 units
>10 units
Unknown

Medications Given to Donor

19. Was Pitressin/DDAVP given:* ☐ No ☐ Yes ☐ Unknown

20. Were vasopressors used: ☐ No ☐ Yes ☐ Unknown

If YES, specify each vasopressor used and dose:

	Medication	Maximum Dose	Units	Dose Unknown
a. Vasopressor 1:	epinephrine hydrochloride (Adrenaline) dobutamine hydrochloride (Dobutrex) dopamine hydrochloride (Intropin) metaraminol bitartrate (Aramine) methoxamine (Vasoxyl) *Additional Options Listed Below	(xxx.x)	µg/kg/min mg/kg µg/min	☐
b. Vasopressor 2:	epinephrine hydrochloride (Adrenaline) dobutamine hydrochloride (Dobutrex) dopamine hydrochloride (Intropin) metaraminol bitartrate (Aramine) methoxamine (Vasoxyl) *Additional Options Listed Below	(xxx.x)	µg/kg/min mg/kg µg/min	☐
c. Vasopressor 3:	epinephrine hydrochloride (Adrenaline) dobutamine hydrochloride (Dobutrex) dopamine hydrochloride (Intropin) metaraminol bitartrate (Aramine) methoxamine (Vasoxyl) *Additional Options Listed Below	(xxx.x)	µg/kg/min mg/kg µg/min	☐
d. Vasopressor 4:	epinephrine hydrochloride (Adrenaline) dobutamine hydrochloride (Dobutrex) dopamine hydrochloride (Intropin) metaraminol bitartrate (Aramine) methoxamine (Vasoxyl) *Additional Options Listed Below	(xxx.x)	µg/kg/min mg/kg µg/min	☐

21. From time of admission, were steroids given: ☐ No ☐ Yes ☐ Unknown

22. From time of admission, was insulin given: ☐ No ☐ Yes ☐ Unknown

HLA Typing

23. HLA typing conducted:* ☐ No ☐ Yes ☐ Unknown

If YES:

a. Date typed: (mm/dd/yyyy)

b. Class I:

A (1): A (2):

B (1): B (2):

Bw4:

Bw6:

Negative
Positive
Unknown or Not Determined
Confirmed Blank

c. Class II:

DR (1): DR (2):

DQ (1): DQ (2):

Crossmatch Information

24. Pre infusion crossmatch date: (mm/dd/yyyy) ☐ Not Done/Unknown

a.

Method	Unseparated	T cell	B cell
Cytotoxicity (NIH, Wash, AHG):	Negative Positive Unknown Not Done	Negative Positive Unknown Not Done	Negative Positive Unknown Not Done
Flourescent antibody (Flow cytometry, ELISA):	Negative Positive Unknown Not Done	Negative Positive Unknown Not Done	Negative Positive Unknown Not Done

b. Was the crossmatch postive: ☐ No ☐ Yes ☐ Unknown

If YES, was the recipient treated to reduce antibody levels: ☐ No ☐ Yes ☐ Unknown

If TREATED, indicate all treatments:

Immunoglobulin: ☐ No ☐ Yes ☐ Unknown

Plasmapheresis: ☐ No ☐ Yes ☐ Unknown

Other treatment: ☐ No ☐ Yes ☐ Unknown

Specify name(s) of other treatment(s):

Donor Blood Glucose and HbA1c Information

		Standard Unit	International Unit	
25.	Minimum pre-insulin blood glucose:	*(xxxx)* mg/dL	*(xx.xx)* mmol/L	☐ Not Done/Unknown
26.	Maximum blood glucose:	*(xxxx)* mg/dL	*(xx.xx)* mmol/L	☐ Not Done/Unknown
27.	HbA1c:	*(xxxx.x)* %		☐ Not Done/Unknown

Terminal Lab Data

		Standard Unit	International Unit	
28.	Serum creatinine:*	*(xx.x)* mg/dL	*(xxxx)* µmol/L	☐ Not Done/Unknown
29.	BUN:*	*(xxx)* mg/dL	*(xx.x)* mmol/L	☐ Not Done/Unknown
30.	Total bilirubin:*	*(xx.x)* mg/dL	*(xxxx)* µmol/L	☐ Not Done/Unknown
31.	AST:*	*(xxxxxxxx)* U/L		☐ Not Done/Unknown
32.	ALT:*	*(xxxxxxxx)* U/L		☐ Not Done/Unknown
33.	Serum lipase:*	*(xxxx)* mKat/L	*(xxxx)* U/L	☐ Not Done/Unknown
34.	Serum amylase:*	*(xxxx)* mKat/L	*(xxxx)* U/L	☐ Not Done/Unknown

Serology

35. Anti-HIV I/II:*

36. Anti-HTLV I/II:*

37. RPR-VDRL:*

38. Anti-CMV:*

39. HBsAg:*

40. Anti-HBC:*

Negative
Positive
Unknown
Not Done
Indeterminate
*Additional Options Listed Below

41. Anti-HCV:*

Negative
Positive
Unknown
Not Done
Indeterminate
*Additional Options Listed Below

Negative
Positive
Unknown
Not Done
Indeterminate
*Additional Options Listed Below

Terminal Hospitalization Information

42. Date and time of hospital admission: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

43. Duration of cardiac arrest: *(xxx)* minutes Unknown

44. Date and time of brain death: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

Pancreas Procurement Information

45. Cross clamp date and time: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

46. Date and time of pancreas recovery: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

47. Indicate all solutions used for pancreas preservation:

Check all that apply:

UW:

Two Layer:

Top Layer:
UW
Eurocollins
HTK
Celsior
Unknown
*Additional Options Listed Below

Bottom Layer:
PFC
Unknown
Other

If OTHER top layer, specify:

If OTHER bottom layer, specify:

Eurocollins:

HTK:

Celsior:

Unknown:

Other:

If OTHER, specify:

48. Duration of cold ischemia: *(xx)* Hour(s) **and** *(xx)* Minutes Unknown

Comments:

Additional Selection Options for CAD

Panc. # for this infusion (key field):
1
2
3
4
5
6
7
8
9

ABO blood group:*
A2
A1B
A2B
Unknown

Cause of death:*
Unknown

Mechanism of death:*
Drug intoxication
Gunshot wound
Intracranial hemorrhage/stroke
Seizure
Stab
Sudden infant death
None of the above
Unknown

Circumstances of death:*
Death from natural causes
None of the above
Unknown

Vasopress 1
midodrine hydrochloride (ProAmatine)
norephinephrine bitartrate (Noradrenaline, Levophed)
phenylephrine hydrochloride (Neo-Synephrine, Metasympatol)
Not Applicable
Other

Anti-HIV I/II:*
Cannot Disclose

Top Layer:
Other

Collaborative Islet Transplant Registry

(1) Living Allo-Donor (LAL)

Version: 4.02; 03-16-05

Infusion Date:
Panc. # for this infusion:

Donor Information

1. Donor type:

Islets
Stem/progenitor/precursor cell derived islets
Engineered cell line
Unknown
Other

2. Date of birth: *(mm/dd/yyyy)*

   If complete date of birth is unknown, enter donor's age at the time of the infusion: *(xx)* yrs ☐ Unknown

3. Gender:

Male
Female
Unknown

4. Ethnicity:

Non Hispanic or Latino
Hispanic or Latino
Unknown

5. Race: Indicate 'No', 'Yes', or 'Unknown' for each Race category.
   a. American Indian or Alaska Native: ☐ No ☐ Yes ☐ Unknown
   b. Asian: ☐ No ☐ Yes ☐ Unknown
   c. Black or African American: ☐ No ☐ Yes ☐ Unknown
   d. Indian Sub-continent: ☐ No ☐ Yes ☐ Unknown
   e. Mideast or Arabian: ☐ No ☐ Yes ☐ Unknown
   f. Native Hawaiian or Other Pacific Islander: ☐ No ☐ Yes ☐ Unknown
   g. White: ☐ No ☐ Yes ☐ Unknown
   h. Other: ☐ No ☐ Yes ☐ Unknown

   If OTHER, specify race:

6. Weight: *(xxx.x)* kg **OR** *(xxx.x)* lb ☐ Unknown

7. Height: *(xxx.x)* cm **OR** *(xxx.xx)* in ☐ Unknown

8. ABO blood group:

A
B
AB
O
A1
*Additional Options Listed Below

9. Rh:

Positive
Negative
Unknown

Donor Medical History

10. History of hypertension: ☐ No ☐ Yes ☐ Unknown

    a. If YES, duration:

    0-5 years
    6-10 years
    >10 years
    Unknown

    b. If YES, method of control:

    Diet: ☐ No ☐ Yes ☐ Unknown

    Diuretics: ☐ No ☐ Yes ☐ Unknown

    Other hypertensive medication: ☐ No ☐ Yes ☐ Unknown

11. History of alcohol dependency: ☐ No ☐ Yes ☐ Unknown

    If YES, continued use in the past six months: ☐ No ☐ Yes ☐ Unknown

12. History of diabetes: ☐ No ☐ Yes ☐ Unknown

    a. If YES, duration:

    0-5 years
    6-10 years
    >10 years
    Unknown

    b. If YES, is the donor insulin dependent: ☐ No ☐ Yes ☐ Unknown

    If YES, indicate number of years donor has been taking insulin:

    0-5 years
    6-10 years
    >10 years
    Unknown

Transfusion Information

13. During this hospitalization, total number of transfusion units given prior to surgery:

    0 units
    0-5 units
    6-10 units
    >10 units
    Unknown

14. Number of transfusion units given intraoperatively:

    0 units
    0-5 units
    6-10 units
    >10 units
    Unknown

HLA Typing

15. HLA typing conducted: ☐ No ☐ Yes ☐ Unknown

    If YES:

    a. Date typed: *(mm/dd/yyyy)*

    b. Class I:

    A (1): A (2):

    B (1): B (2):

    Bw4:

    Negative
    Positive
    Unknown or Not Determined
    Confirmed Blank

    Bw6:

    Negative
    Positive
    Unknown or Not Determined
    Confirmed Blank

c. Class II:
DR (1): DR (2):
DQ (1): DQ (2):

Pre-Donation Lab Data

16. Pre-donation laboratory information:

Items in blue (also double starred: **) should follow the procedures outlined in the CITR Guidelines for Metabolic Testing

If tests are used that do NOT follow CITR standards, record the result but do NOT check the 'CITR Standard Used' column.

	Standard Unit	International Unit	Not Done/Unknown	CITR Standard Used
a. Fasting blood glucose:	*(xxxx)* mg/dL	*(xx.xx)* mmol/L	☐	
b. HbA1c:	*(xx.x)* %		☐	
c. Basal plasma C-peptide:	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	
d. Peak stimulated C-peptide after meal:	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	
e. IV glucagon:				
1. Basal C-peptide before IV glucagon:	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	
2. Peak stimulated C-peptide after IV glucagon:	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	
f. Arginine Stimulation Test (AST):				
1. Basal C-peptide before IV arginine:**	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	☐
2. Peak stimulated C-peptide after IV arginine:**	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	☐
3. Acute C-peptide response to IV arginine:**	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	☐
4. Acute insulin response to IV arginine:**	*(xxx.x)* µU/mL		☐	☐
g. Intravenous Glucose Tolerance Test (IVGTT):				
1. Basal C-peptide before IV glucose:**	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	☐
2. Peak stimulated C-peptide after IV glucose:**	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	☐
3. Acute C-peptide response to IV glucose:**	*(xx.xx)* ng/mL	*(xx.xxx)* nmol/L	☐	☐
4. Acute insulin response to IV glucose:**	*(xxx.x)* µU/mL		☐	☐
5. AUC insulin derived from 0.5g/kg IVGTT:**	*(xxx.x)* µU/mL x min		☐	☐
6. K_G-Value derived from 0.5g/kg IVGTT:**	*(xxxx.xx)* K_G Value		☐	☐
h. Oral Glucose Tolerance Test (OGTT):				
1. 2-hr 75g OGTT plasma glucose:**	*(xxxx)* mg/dL	*(xx.xx)* mmol/L	☐	☐
2. AUC C-Peptide OGTT:**	*(xxx.xx)* ng/mL x min		☐	☐

i. Mixed Meal Test:				
1. AUC C-peptide MMTT:**	_____ *(xxx.xx)* ng/mL x min		☐	☐
2. Mixed meal stimulation index:**	_____ *(xx.x)* ng/mg	_____ *(xx.x)* pmol/mg	☐	☐

Serology

17. Anti-HIV I/II:
18. Anti-HTLV I/II:
19. RPR-VDRL:
20. Anti-CMV:
21. HBsAg:
22. Anti-HBC:
23. Anti-HCV:

Negative
Positive
Unknown
Not Done
Indeterminate
*Additional Options Listed Below

Hospitalization Information

24. Date and time of hospital admission: _____ *(mm/dd/yyyy)* _____ *(hh:mm)* ☐ Time unknown

Pancreas Procurement Information

25. Date and time of pancreas recovery: _____ *(mm/dd/yyyy)* _____ *(hh:mm)* ☐ Time unknown

26. Date and time pancreas placed in preservation: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

27. Indicate all solutions used for pancreas preservation:

Check all that apply:

UW:

Two Layer:

Top Layer: UW, Eurocollins, HTK, Celsior, Unknown, *Additional Options Listed Below

Bottom Layer: PFC, Unknown, Other

If OTHER top layer, specify:

If OTHER bottom layer, specify:

Eurocollins:

HTK:

Celsior:

Unknown:

Other:

If OTHER, specify:

28. Duration of cold ischemia: *(xx)* Hour(s) **and** *(xx)* Minutes Unknown

Comments:

Additional Selection Options for LAL

Panc. # for this infusion (key field):
1
2
3
4
5
6
7
8
9

ABO blood group:
A2
A1B
A2B
Unknown

Anti-HIV I/II:
Cannot Disclose

Top Layer:
Other

Collaborative Islet Transplant Registry

(1) Living Auto-Donor (LAU)

Version: 3.01; 03-16-05

Infusion Date:
Panc. # for this infusion:

Donor Information

1. Donor type:
   - Islets
   - Stem/progenitor/precursor cell derived islets
   - Engineered cell line
   - Unknown
   - Other

2. Is the donor on prescription narcotics: ☐ No ☐ Yes ☐ Unknown ☐ Cannot Disclose
   If YES, year started: ☐ *(xxxx)* ☐ Unknown

Medical History

3. History of hypertension: ☐ No ☐ Yes ☐ Unknown
   a. If YES, duration:
      - 0-5 years
      - 6-10 years
      - >10 years
      - Unknown

   b. If YES, method of control:
      Diet: ☐ No ☐ Yes ☐ Unknown
      Diuretics: ☐ No ☐ Yes ☐ Unknown
      Other hypertensive medication: ☐ No ☐ Yes ☐ Unknown

4. History of alcohol dependency: ☐ No ☐ Yes ☐ Unknown
   If YES, continued use in the past six months: ☐ No ☐ Yes ☐ Unknown

5. History of diabetes: ☐ No ☐ Yes ☐ Unknown
   a. If YES, duration:
      - 0-5 years
      - 6-10 years
      - >10 years
      - Unknown

   b. If YES, is the donor insulin dependent: ☐ No ☐ Yes ☐ Unknown
      If YES, indicate number of years donor has been taking insulin:
      - 0-5 years
      - 6-10 years
      - >10 years
      - Unknown

Pancreatectomy Information

6. Was a pancreatectomy performed on the recipient: ☐ No ☐ Yes ☐ Unknown
   If YES,
   a. Type of pancreatectomy:
      - Total (100%)
      - Completion (95-99%)
      - Partial (<95%)
      - Unknown

   b. Pancreatectomy performed for the treatment of:
      - Pancreatitis
      - Other
      - Unknown

   If PANCREATITIS:
   1. Date of pancreatitis diagnosis: ☐ *(mm/dd/yyyy)* ☐ Unknown

2. Cause of pancreatitis:

Small duct disease
Biliary (gall stones)
Alcoholism
Pancreas divisum
Familial pancreatitis
*Additional Options Listed Below

If OTHER, specify:

3. Did the recipient have previous surgery for pancreatitis:

None
Drainage
Sphincterotomy
Sphincterplasty
Distal pancreatectomy
*Additional Options Listed Below

If OTHER, specify:

Hospitalization Information

7. Date and time of hospital admission: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

Pancreas Procurement Information

8. Date and time of pancreas recovery: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

9. Date and time pancreas placed in preservation: *(mm/dd/yyyy)* *(hh:mm)* Time unknown

10. Indicate all solutions used for pancreas preservation:

Check all that apply:

UW:

Two Layer:

Top Layer:
UW
Eurocollins
HTK
Celsior
Unknown
*Additional Options Listed Below

Bottom Layer:
PFC
Unknown
Other

If OTHER top layer, specify:

If OTHER bottom layer, specify:

Eurocollins:

HTK:

Celsior:

Unknown:

Other:

If OTHER, specify:

11. Duration of cold ischemia: *(xx)* Hour(s) **and** *(xx)* Minutes Unknown

Comments:

Additional Selection Options for LAU

Panc. # for this infusion (key field):
1
2
3
4
5
6
7
8
9

Cause of pancreatitis:
Duct occlusion
Unknown
Other

Did the recipient have previous surgery for pancreatitis:
Pancreaticojejunostomy
Pancreaticoduodenectomy (Whipple)
Unknown
Other

Top Layer:
Other

Collaborative Islet Transplant Registry

(2) Islet Processing/Testing (IPT)

Version: 4.00; 03-16-05

Infusion Date:
Panc. # for this infusion:
Processing Date:

1. Pancreas procurement team:

Unrelated to processing/infusion team
Related to processing/infusion team
Unknown

2. Islet processing and testing center:

CITR center, where infusion took place
Another facility not located or affiliated with the transplant center
Unknown

Islet Processing Information

3. Collagenase type: (Check all that apply)

a. Liberase HI: ☐
b. Serva: ☐
c. Collagenase P: ☐
d. Sigma blend: ☐
e. NB1: ☐
f. Unknown: ☐
g. Other: ☐

If OTHER, specify:

4. Collagenase lots and concentrations:

	Lot 1	Lot 2	Lot 3
Collagenase type:	Liberase HI Serva Collagenase P Sigma blend NB1 *Additional Options Listed Below	Liberase HI Serva Collagenase P Sigma blend NB1 *Additional Options Listed Below	Liberase HI Serva Collagenase P Sigma blend NB1 *Additional Options Listed Below
Collagenase lot number:			
Lot number unknown:	☐	☐	☐
Final collagenase concentration:	*(xx.xx)* mg/ml	*(xx.xx)* mg/ml	*(xx.xx)* mg/ml
Concentration unknown:	☐	☐	☐

5. Was Pulmozyme used during processing: ☐ No ☐ Yes ☐ Unknown

6. Islet purification:

None
Density gradient
Unknown
Other

a. If DENSITY GRADIENT, specify:

Discontinuous
Continuous
Continuous followed by discontinuous
Unknown

b. If OTHER, specify:

7. Islet pretreatment:
Check all that apply:

a. None: ☐

b. Culture: ☐

If islets were cultured, indicate the duration: *(xxx)* hours *(xx)* minutes ☐ Unknown

c. Cryopreservation: ☐

d. Irradiation: ☐

e. Gene Transfer: ☐

f. Unknown: ☐

g. Other: ☐

If OTHER, specify:

Comments on islet pretreatment:

Islet Product Characterization for Total Final Islet Preparation

For the following questions, indicate the most IMMEDIATE pre-infusion information only:

8. Total packed cell volume: *(xxx.x)* mL ☐ Not Done/Unknown
9. Percent trapped islets: *(xxx)* % ☐ Not Done/Unknown
10. Total islet count: *(xxxxxxx)* ☐ Not Done/Unknown
11. Time of Islet Equivalent count:

Post Digestion
Post Purification (Pre culture/cryo)
Post culture/cryo
Unknown
Other

If OTHER, specify time:

12. Total number of Islet Equivalents: *(xxxxxxx)* IEQ ☐ Not Done/Unknown
13. Total number of beta cells: *(xxx)* x 10^6 ☐ Not Done/Unknown
14. Total insulin content: *(xxxx)* µg ☐ Not Done/Unknown
15. Total DNA content: *(xxxxx)* µg ☐ Not Done/Unknown

Islet Microbiology Results

Test	Result	If POSITIVE, specify:
16. Gram stain:	No Organism Seen / Positive / Unknown / Missing	Gram negative / Gram positive / Unknown
17. Aerobic culture:	No Growth / Positive / Unknown / Not Done	

18. Anaerobic culture: [No Growth / Positive / Unknown / Not Done] [ ]

19. Fungal culture: [No Growth / Positive / Unknown / Not Done] [ ]

20. Mycoplasma: [No Growth / Positive / Unknown / Not Done] [ ]

21. Total endotoxin units in final preparation: ☐ < [ ] *(xxxx.xx)* EU ☐ Not Done/Unknown

22. Islet purity:
    a. Percent dithizone positive cells: [ ] *(xxx)* % ☐ Not Done/Unknown
    b. Percent beta cells: [ ] *(xxx)* % ☐ Not Done/Unknown

23. Islet viability:
    a. Test: [Fluorescein Diacetate/Propidium Iodide / Equivalent fluorochromes / Trypan Blue / Other]
    If OTHER, specify: [ ]
    b. Result: [ ] *(xxx)* % ☐ Not Done/Unknown

24. Islet potency:
    Stimulation index: [ ] *(xx.x)* ☐ Not Done/Unknown

25. Mouse bioassay conducted: ☐ No ☐ Yes ☐ Unknown

If YES,

a. Indicate your time to function definition (check all that apply):

Blood glucose permanently < 200 mg/dL: ☐

Insulin permanently > 5 µU/L: ☐

C-peptide permanently > 1 ng/mL: ☐

Other: ☐

If OTHER, specify: [ ]

b. For each group of mice infused please indicate the mouse model used, number of mice infused, islet equivalents per kilogram, percent of mice with functioning grafts, and average number of days to function after infusion:

Mouse Model Used	Number of Mice Infused	IEQs/kg	% of Mice with Functioning Grafts	Average Days to Function
[Nude/Athymic / SCID / NOD/SCID / Rag/Knock-out / Not Done/Unknown / *Additional Options Listed Below]	[ ] *(xx)*	[ ] *(xxxxxx)*	[ ] *(xx)*	[ ] *(xxxx)*
[Nude/Athymic / SCID / NOD/SCID / Rag/Knock-out / Not Done/Unknown / *Additional Options Listed Below]	[ ] *(xx)*	[ ] *(xxxxxx)*	[ ] *(xx)*	[ ] *(xxxx)*

Nude/Athymic
SCID
NOD/SCID
Rag/Knock-out
Not Done/Unknown
*Additional Options Listed Below

(xx) (xxxxxx) (xx) (xxxx)

Nude/Athymic
SCID
NOD/SCID
Rag/Knock-out
Not Done/Unknown
*Additional Options Listed Below

(xx) (xxxxxx) (xx) (xxxx)

Nude/Athymic
SCID
NOD/SCID
Rag/Knock-out
Not Done/Unknown
*Additional Options Listed Below

(xx) (xxxxxx) (xx) (xxxx)

Comments: (Include any comments on the answers provided on the form)

Comments: (Include any additional test results, etc)

Additional Selection Options for IPT

Panc. # for this infusion (key field):
1
2
3
4
5
6
7
8
9

Coll type Lot 1
Other
Unknown

Mouse model 1
Other

Collaborative Islet Transplant Registry

(3a) Pre Infusion (PRE)

Version: 4.02; 03-16-05

Infusion Date:

1. Date person was listed by transplant center for this islet infusion: _____ *(mm/dd/yyyy)*

2. Type of infusion:
   - Autograft
   - Allograft
   - Xenograft

   If infusion was XENOGRAFT, then stop here, save, and submit the data.

3. Was there a simultaneous transplant within 7 days of this islet infusion: ☐ No ☐ Yes *If YES, complete the Non Islet Transplant Form (NIT).*

   If YES, indicate the type of simultaneous transplant:
   - Kidney
   - Hematopoietic stem cells (HSC)
   - Kidney-HSC
   - Kidney-Liver
   - Kidney-Liver-HSC
   - *Additional Options Listed Below

   If OTHER, specify: _____

4. Indicate the one primary source of payment for the islet infusion and all secondary forms of payment:

Source	Primary	Secondary
a. Medicare:	☐	☐
b. Medicaid:	☐	☐
c. US/State Gov't Agency:	☐	☐
d. Private Insurance:	☐	☐
e. HMO/PPO:	☐	☐
f. Self:	☐	☐
g. Donation:	☐	☐
h. Institutional Contribution:	☐	☐
i. Non-government Research Grant Funding:	☐	☐
j. Dept. of Veterans' Affairs:	☐	
k. Pending:	☐	☐
l. Provincial Gov't (Canada):	☐	☐
m. Non-US/Canada Gov't:	☐	☐

Specify country: _____

5. Employment status:
   - Working full time
   - Working part time by choice
   - Working part time due to disease
   - Working part time, reason unknown
   - Not working by choice
   - *Additional Options Listed Below

6. Weight: _____ *(xxx.x)* kg **OR** _____ *(xxx.x)* lb ☐ Unknown

7. Height: _____ *(xxx.x)* cm **OR** _____ *(xxx.x)* in ☐ Unknown

8. Record recipient's Visual Acuity for both eyes in either feet or meters:

	Right Eye (OD) ☐ Not Done/Unknown	Left Eye (OS) ☐ Not Done/Unknown
Visual Acuity in feet	(xx) / (xxx.x) feet	(xx) / (xxx.x) feet
OR		
Visual Acuity in meters	(x) / (xx.xx) meters	(x) / (xx.xx) meters

9. Blood Pressure (SBP/DBP): (xxx) / (xxx) mmHg ☐ Unknown

10. Is the recipient currently taking blood pressure medication specifically for the control of hypertension: ☐ No ☐ Yes ☐ Unknown

If YES, indicate all medications:

Click here to view a list of medication names and categories.

a. ACE inhibitors: ☐ No ☐ Yes ☐ Unknown
b. Alpha adrenergic blockers: ☐ No ☐ Yes ☐ Unknown
c. Angiotensin II receptor blockers: ☐ No ☐ Yes ☐ Unknown
d. Beta adrenergic blockers: ☐ No ☐ Yes ☐ Unknown
e. Calcium channel blockers: ☐ No ☐ Yes ☐ Unknown
f. Centrally acting agents: ☐ No ☐ Yes ☐ Unknown
g. Diuretics: ☐ No ☐ Yes ☐ Unknown
h. Vasodilators: ☐ No ☐ Yes ☐ Unknown
i. Unknown: ☐ No ☐ Yes ☐ Unknown
j. Other: ☐ No ☐ Yes ☐ Unknown

If OTHER, specify:

11. Is the recipient currently taking lipid lowering medication: ☐ No ☐ Yes ☐ Unknown

If YES, indicate all agents:

Click here to view a list of medication names and categories.

a. Bile acid sequestrants: ☐ No ☐ Yes ☐ Unknown
b. Cholesterol absorption inhibitors: ☐ No ☐ Yes ☐ Unknown
c. Fibric acid derivatives: ☐ No ☐ Yes ☐ Unknown
d. HMG CoA reductase inhibitors: ☐ No ☐ Yes ☐ Unknown
e. Neomycin: ☐ No ☐ Yes ☐ Unknown
f. Nicotinic acid: ☐ No ☐ Yes ☐ Unknown
g. Probucol: ☐ No ☐ Yes ☐ Unknown
h. Unknown: ☐ No ☐ Yes ☐ Unknown
i. Other: ☐ No ☐ Yes ☐ Unknown

If OTHER, specify:

12. Did the recipient experience any severe hypoglycemic episodes (requiring the assistance of another person) in the 12 months prior to this islet infusion (or since 30 days after last infusion if prior infusion was within 12 months): ☐ No ☐ Yes

If YES:

a. Total number of severe hypoglycemic episodes (requiring the assistance of another person): 1-2 / 3-5 / 6 or more / Unknown
b. Total number of severe hypoglycemic episodes (requiring the assistance of another person): (xxxx) ☐ Unknown
c. Total number of severe hypoglycemic episodes (requiring the assistance of another person) resulting in the loss of consciousness and/or seizures: (xxx) ☐ Unknown

13. Total number of hospital admissions in the past 12 months (or since 30 days after last infusion if prior infusion was within 12 months): (xxx) ☐ Unknown

Total number of hospitalized days in the past 12 months (or since 30 days after last infusion if prior infusion was within 12 months): (xxx) ☐ Unknown

14. Indicate average daily insulin requirement (including basal, bolus and correction sliding scale) given before this infusion: (xxx) total units ☐ Unknown

If insulin treatment required before this infusion:

a. Use of an insulin pump: ☐ No ☐ Yes ☐ Unknown

b. Number of injections per day: _____ *(xx)* ☐ Unknown

c. Is the duration of intensive therapy known: ☐ No ☐ Yes

1. Duration of intensive therapy: _____ *(xx)* [Weeks / Months / Years]

15. Prior to infusion, not including induction therapy, was the recipient on immunosuppression: ☐ No ☐ Yes ☐ Unknown

16. Secondary complications at the time of the islet infusion and year of onset:

Complication	Response	Year of onset	Year Unknown
a. Hypoglycemia:	No occurrence / Reduced awareness / Unawareness / Unknown	*(xxxx)*	☐
b. Peripheral neuropathy:	No occurrence / Asymptomatic / Symptomatic / Disabling / Unknown	*(xxxx)*	☐
c. Autonomic neuropathy:	No occurrence / Asymptomatic / Symptomatic / Disabling / Unknown	*(xxxx)*	☐
d. Nephropathy:	No occurrence / Microalbuminuria / Macroalbuminuria / End stage renal disease / Stable allograft / *Additional Options Listed Below		☐
e. CAD:	No / Yes / Unknown	*(xxxx)*	☐
f. CVA:	No / Yes / Unknown	*(xxxx)*	☐
g. PVD:	No / Yes / Unknown	*(xxxx)*	☐
h. Treated hypertension:	No / Yes / Unknown	*(xxxx)*	☐

	Right Eye (OD)	Year of onset	Year Unknown	**Left Eye (OS)**	Year of onset	Year Unknown
i. Retinopathy:	None / Non Proliferative / Proliferative / Unknown	*(xxxx)*	☐	None / Non Proliferative / Proliferative / Unknown	*(xxxx)*	☐
j. Diabetic macular edema:		*(xxxx)*	☐		*(xxxx)*	☐

None
Mild
Moderate
Severe
Unknown

None
Mild
Moderate
Severe
Unknown

17. Eye surgery performed:

Surgery	Right Eye (OD)	Year of surgery *(xxxx)*	Year Unknown	Left Eye (OS)	Year of surgery *(xxxx)*	Year Unknown
a. Laser photocoagulation for proliferative diabetic retinopathy:	No / Yes / Unknown	*(xxxx)*	☐	No / Yes / Unknown	*(xxxx)*	☐
b. Laser photocoagulation for diabetic macular edema:	No / Yes / Unknown	*(xxxx)*	☐	No / Yes / Unknown	*(xxxx)*	☐
c. Vitrectomy:	No / Yes / Unknown	*(xxxx)*	☐	No / Yes / Unknown	*(xxxx)*	☐
d. Other:	No / Yes / Unknown	*(xxxx)*	☐	No / Yes / Unknown	*(xxxx)*	☐

18. Has the recipient ever experienced the following diabetes related foot problems (or since last infusion):

a. Ulcers: ☐ No ☐ Yes ☐ Unknown
b. Lower limb amputation: ☐ No ☐ Yes ☐ Unknown
c. Foot deformity: ☐ No ☐ Yes ☐ Unknown
d. Dysesthesia: ☐ No ☐ Yes ☐ Unknown

19. Have any of the following events occured in the past 12 months (or since last infusion if prior infusion was within 12 months):

a. Orthostatic hypotension: ☐ No ☐ Yes ☐ Unknown
b. Gastroparesis: ☐ No ☐ Yes ☐ Unknown
c. Constipation: ☐ No ☐ Yes ☐ Unknown
d. Diabetic diarrhea: ☐ No ☐ Yes ☐ Unknown
e. Fecal incontinence: ☐ No ☐ Yes ☐ Unknown
f. Diabetic bladder dysfunction: ☐ No ☐ Yes ☐ Unknown
g. Sexual dysfunction: ☐ No ☐ Yes ☐ Unknown

20. Pre infusion autoantibody data:

a. GAD 65: ☐ Negative ☐ Positive ☐ Not Done/Unknown
b. IA-2: ☐ Negative ☐ Positive ☐ Not Done/Unknown
c. Insulin: ☐ Negative ☐ Positive ☐ Not Done/Unknown
d. ICA: < / > *(xxx)* JDF units ☐ Not Done/Unknown

21. Most recent serum date and result for PRA (Class I/T cell): *(mm/dd/yyyy)* *(xxx)* % ☐ Not Done/Unknown

If this infusion was an AUTOGRAFT, question 22 should be skipped.

22. Peak serum date and result for PRA (Class I/T cell): *(mm/dd/yyyy)* *(xxx)* % ☐ Not Done/Unknown

Comments:

Additional Selection Options for PRE

If YES, indicate the type of simultaneous transplant:
Other

Employment status:
Not working due to disease
Not working, unable to find employment
Not working, reason unknown
Retired
Student
Employment status unknown
Not applicable, less than 5 years old

Nephropathy
Unknown

Collaborative Islet Transplant Registry

(3b) Pre Infusion Lab Info (PRL)

Version: 2.02; 03-16-05

Infusion Date:

1. Pre infusion laboratory information (Most recent lab results prior to infusion):

		Standard Unit	International Unit	Not Done/ Unknown
a. Fasting blood glucose:	☐ <	☐ *(xxxx)* mg/dL	☐ *(xx.xx)* mmol/L	☐
b. HbA1c:		☐ *(xx.x)* %		☐
c. ALT:	☐ <	☐ *(xxxx)* U/L		☐
d. AST:	☐ <	☐ *(xxxx)* U/L		☐
e. Alkaline phosphatase:	☐ <	☐ *(xxxx)* U/L		☐
f. Total bilirubin:		☐ *(xx.x)* mg/dL	☐ *(xxx)* µmol/L	☐
g. Total cholesterol:	☐ <	☐ *(xxx)* mg/dL	☐ *(xx.xx)* mmol/L	☐
h. HDL:		☐ *(xxx)* mg/dL	☐ *(xx.xx)* mmol/L	☐
i. LDL:		☐ *(xxx)* mg/dL	☐ *(xx.xx)* mmol/L	☐
j. Triglycerides:		☐ *(xxxx)* mg/dL	☐ *(xx.xx)* mmol/L	☐
k. Serum creatinine:		☐ *(xx.x)* mg/dL	☐ *(xxxx)* µmol/L	☐
l. Calculated creatinine clearance:		☐ *(xxx)* mL/min/1.73m^2	☐ *(x.xx)* mL/s/1.73m^2	☐

2. Metabolic assessment pre infusion:

Items in blue (also double starred: **) should follow the procedures outlined in the CITR Guidelines for Metabolic Testing

If tests are used that do NOT follow CITR standards, record the result but do NOT check the 'CITR Standard Used' column.

		Result	Units	Not Done/ Unknown	CITR Standard Used
a. Basal plasma C-peptide:	☐ <	☐ *(xx.xx)*	ng/mL nmol/L	☐	
b. Peak stimulated C-peptide after meal:	☐ <	☐ *(xx.xx)*	ng/mL nmol/L	☐	
c. IV glucagon:					
1. Basal C-peptide before IV glucagon:	☐ <	☐ *(xx.xx)*	ng/mL nmol/L	☐	
2. Peak stimulated C-peptide after IV glucagon:	☐ <	☐ *(xx.xx)*	ng/mL nmol/L	☐	
d. Arginine Stimulation Test (AST):					

1. Basal C-peptide before IV arginine:**	☐ <	(xx.xx)	ng/mL nmol/L	☐	
2. Peak stimulated C-peptide after IV arginine:**	☐ <	(xx.xx)	ng/mL nmol/L	☐	☐
3. Acute C-peptide response to IV arginine:**		(xx.xx)	ng/mL nmol/L	☐	☐
4. Acute insulin response to IV arginine:**		(xxx.x)	µU/mL	☐	☐
e. Intravenous Glucose Tolerance Test (IVGTT):					
1. Basal C-peptide before IV glucose:**	☐ <	(xx.xx)	ng/mL nmol/L	☐	
2. Peak stimulated C-peptide after IV glucose:**	☐ <	(xx.xx)	ng/mL nmol/L	☐	☐
3. Acute C-peptide response to IV glucose:**		(xx.xx)	ng/mL nmol/L	☐	☐
4. Acute insulin response to IV glucose:**		(xxx.x)	µU/mL	☐	☐
5. AUC insulin derived from 0.5 g/kg IVGTT:**		(xxx.x)	µU/mL x min	☐	☐
6. K_G-Value derived from 0.5 g/kg IVGTT:**		(xxxx.xx)	K_G Value	☐	☐
f. Oral Glucose Tolerance Test (OGTT):					
1. 2-hr 75g OGTT plasma glucose:**		(xxxx.x)	mg/dL mmol/L	☐	☐
2. AUC C-peptide OGTT:**		(xxx.xx)	ng/mL x min	☐	☐
g. Mixed Meal test:					
1. AUC C-peptide MMTT:**		(xxx.xx)	ng/mL x min	☐	☐
2. Mixed meal stimulation index:**		(xx.x)	pmol/mg ng/mg	☐	☐

3. Pre infusion serology:

		Negative	Positive	Indeterminate	Unknown	Not Done
HIV						
	Screening	☐	☐	☐	☐	☐
	Confirmation	☐	☐	☐	☐	☐
CMV		Negative	Positive	Indeterminate	Unknown	Not Done
	IgG	☐	☐	☐	☐	☐
	IgM	☐	☐	☐	☐	☐
	DNA	☐	☐	☐	☐	☐
Hepatitis B		Negative	Positive	Indeterminate	Unknown	Not Done
	Core antibody	☐	☐	☐	☐	☐

	Surface antigen	☐	☐	☐	☐	☐
	HBV DNA	☐	☐	☐	☐	☐
Hepatitis C		Negative	Positive	Indeterminate	Unknown	Not Done
	Antibody screen	☐	☐	☐	☐	☐
	RIBA test	☐	☐	☐	☐	☐
	HCV RNA	☐	☐	☐	☐	☐
EBV		Negative	Positive	Indeterminate	Unknown	Not Done
	IgG	☐	☐	☐	☐	☐
	IgM	☐	☐	☐	☐	☐
	DNA	☐	☐	☐	☐	☐

Comments:

Collaborative Islet Transplant Registry

(4a) Infusion (TRN)

Version: 2.02; 03-16-05

Infusion Date:

1. Number of prior islet infusions: _____ *(x)*
   If prior islet infusion, date of last infusion: _____ *(mm/dd/yyyy)*

2. Protocol information:
   a. IND number: _____ ☐ Not Applicable
   b. Protocol number: _____ ☐ Not Applicable

3. This infusion was performed as: [Outpatient / Inpatient / Unknown]

   If it was an INPATIENT procedure:
   a. Admission date: _____ *(mm/dd/yyyy)*
   b. Discharge date: _____ *(mm/dd/yyyy)*

Day 0 Data (Infusion Day)

4. IEs planned for infusion: _____ *(xxxxxxx)* IEQ ☐ Unknown
5. IEs infused: _____ *(xxxxxxx)* IEQ ☐ Unknown
6. Packed cell volume infused: _____ *(xx.xx)* mL ☐ Unknown
7. Was an immunobarrier device used: [No / Yes / Unknown]

   If YES, specify the device: [Microencapsulation / Macroencapsulation / Micro and Macro Encapsulation / Unknown / Other]

   If OTHER, specify: _____
8. Infusion site: [Liver / Spleen / Kidney capsule / Intraperitoneal cavity / Subcutaneous / *Additional Options Listed Below]

   If OTHER, specify infusion site: _____

   If the infusion site is LIVER:
   Infusion technique: [Open/Laparoscopy / TIPS / Percutaneous / Unknown / Other]

   If OTHER, specify technique: _____

   Number of passes (attempts) necessary to obtain adequate access for islet infusion: _____ *(xx)* ☐ Unknown

   Pre infusion portal pressure: _____ *(xx)* mmHg **OR** _____ *(xxx)* cmH_20 ☐ Unknown

   Peak portal pressure: _____ *(xx)* mmHg **OR** _____ *(xxx)* cmH_20 ☐ Unknown

Closure portal pressure: ☐ *(xx)* mmHg **OR** ☐ *(xxx)* cmH_20 ☐ Unknown

9. Total daily units of insulin at Day 0 (Infusion Day) including basal, bolus and correction sliding scale: ☐ *(xxxxxx)* total units

Day 7 and Day 30 Data: Graft Function Summary

10. Total daily units of insulin at post infusion **Day 7**, including basal, bolus and correction sliding scale: ☐ *(xxxxxx)* total units

11. Was a subsequent infusion given prior to **Day 30**: ☐ No ☐ Yes

12. Total daily units of insulin at post infusion **Day 30**, including basal, bolus and correction sliding scale: ☐ *(xxxxxx)* total units

13. HbA1c value at Day 30: ☐ *(xx.x)* % ☐ Unknown

For questions 14-16, C-peptide and glucose levels should be taken from the same sample, or at least drawn at the same time.

Test	**Day 7**		Day 7 Result	Units	**Day 30**		Day 30 Result	Units
14. Fasting plasma glucose:	No / Yes / Unknown		*(xxxx.x)*	mg/dL / mmol/L	No / Yes / Unknown		*(xxxx.x)*	mg/dL / mmol/L
15. Fasting C-peptide:	No / Yes / Unknown	☐ <	*(xx.xx)*	ng/mL / nmol/L	No / Yes / Unknown	☐ <	*(xx.xx)*	ng/mL / nmol/L
16. Peak stimulated C-peptide:	No / Yes / Unknown	☐ <	*(xx.xx)*	ng/mL / nmol/L	No / Yes / Unknown	☐ <	*(xx.xx)*	ng/mL / nmol/L
17. Was insulin administered prior to stimulation test:	No / Yes / Unknown	How far in advance:	*(xx)* hr	*(xx)* min	No / Yes / Unknown	How far in advance:	*(xx)* hr	*(xx)* min

18. Total number of hospitalized days from islet infusion date to Day 30 post infusion (or until day of subsequent infusion if subsequent infusion was within 30 days): ☐ *(xx)* ☐ Unknown

19. Did the recipient experience any severe hypoglycemic episodes (requiring the assistance of another person) in the 30 days post infusion (or until day of subsequent infusion if subequent infusion was within 30 days): ☐ No ☐ Yes ☐ Unknown

If YES:

a. Total number of severe hypoglycemic episodes (requiring the assistance of another person): 1-2 / 3-5 / 6 or more / Unknown

b. Total number of severe hypoglycemic episodes (requiring the assistance of another person): ☐ *(xxx)* ☐ Unknown

c. Total number of severe hypoglycemic episodes (requiring the assistance of another person) resulting in the loss of consciousness and/or seizures: ☐ *(xxx)* ☐ Unknown

20. Did any adverse events (Grade 3, 4, or 5) occur during the first 30 days post infusion: ☐ No ☐ Yes ☐ Unknown

If YES, complete the Adverse Event form for each event.

21. Is recipient compliant with protocol regulated medications/therapy at Day 30: ☐ No ☐ Yes ☐ Unknown

Comments:

Additional Selection Options for TRN

Infusion site:
Intramuscular
Epiploic flap
Omental pouch
Other

Collaborative Islet Transplant Registry

(4b) Induction Therapy (IND)

Version: 3.01; 03-16-05

Infusion Date:

1. **Peri-infusion Immunosuppression Therapy**

a. Were any chemical immunosuppressants given peri-infusion: ☐ No ☐ Yes ☐ Unknown ☐ Not Applicable

If YES, indicate doses:

Chemical Immunosuppressants:

Immuno Med	Specify Medication	First Dose Day	Day Unknown	First Day Dose (mg/day)	Dose Unknown	Day 30 Dose (mg/day)	Dose Unknown		Day 30 Trough Level (ng/mL)	Trough Unknown
Sirolimus: No / Yes		(xx)	☐	(xx.xx)	☐	(xx.xx)	☐	< ☐	(xxxx.xx)	☐
Tacrolimus: No / Yes		(xx)	☐	(xx.xx)	☐	(xx.xx)	☐	< ☐	(xxxx.xx)	☐
Cyclosporine: No / Yes	Generic / Neoral / Sandimmune / Other / Unknown	(xx)	☐	(xxxx)	☐	(xxxx)	☐	< ☐	(xxxx.xx)	☐
MMF: No / Yes		(xx)	☐	(xxxx)	☐	(xxxx)	☐			
Steroid: No / Yes	Prednisone / Methylprednisolone / Other / Unknown	(xx)	☐	(xxxx.x)	☐	(xxxx.x)	☐			
DSG: No / Yes		(xx)	☐	(xxxx)	☐	(xxxx)	☐			
Everolimus: No / Yes		(xx)	☐	(xxxx)	☐	(xxxx)	☐			
Other medication 1: No / Yes		(xx)	☐	(xxxx.x)	☐	(xxxx.x)	☐			
Other medication 2: No / Yes		(xx)	☐	(xxxx.x)	☐	(xxxx.x)	☐			
Other medication 3: No / Yes		(xx)	☐	(xxxx.x)	☐	(xxxx.x)	☐			
Other medication 4: No / Yes		(xx)	☐	(xxxx.x)	☐	(xxxx.x)	☐			
Other medication 5: No / Yes		(xx)	☐	(xxxx.x)	☐	(xxxx.x)	☐			

b. Were any T cell antibodies given peri-infusion: ☐ No ☐ Yes ☐ Unknown ☐ Not Applicable

If YES, indicate doses:

T Cell Antibodies:

	Specify Medication	First Dose Day	Day Unknown	# Dose Days	Days Unknown	Total Dose (mg)	Total Unknown
Antibody 1:		(xx)	☐	(xx)	☐	(xxxx)	☐

	Anti-thymocyte (Thymoglobulin) Lymphocyte immune globulin (ATGAM) Antilymphocyte globulin (Minnesota ALG) Basiliximab (Simulect) Daclizumab (Zenapax) *Additional Options Listed Below						
If OTHER, specify:							
Antibody 2:	Anti-thymocyte (Thymoglobulin) Lymphocyte immune globulin (ATGAM) Antilymphocyte globulin (Minnesota ALG) Basiliximab (Simulect) Daclizumab (Zenapax) *Additional Options Listed Below	(xx) ☐		(xx) ☐		(xxxx) ☐	
If OTHER, specify:							
Antibody 3:	Anti-thymocyte (Thymoglobulin) Lymphocyte immune globulin (ATGAM) Antilymphocyte globulin (Minnesota ALG) Basiliximab (Simulect) Daclizumab (Zenapax) *Additional Options Listed Below	(xx) ☐		(xx) ☐		(xxxx) ☐	
If OTHER, specify:							

c. Were any cytokine inhibitors or cytokines given peri-infusion: ☐ No ☐ Yes ☐ Unknown ☐ Not Applicable

If YES, indicate doses:

Cytokine Inhibitors and Cytokines:

		First Dose Day	Day Unknown	# Dose Days	Days Unknown	Total Dose (mg)	Dose Unknown
Soluble IL-1 Receptor:	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
IL-1 Receptor Antagonist:	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
Anti-IL-6:	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
Anti TNF α (Infliximab):	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
Soluble Anti TNF (Etanercept):	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
Other 1 (specify):	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
Other 2 (specify):	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐
Other 3 (specify):	No Yes	(xx)	☐	(xx)	☐	(xxx)	☐

Adjunctive Therapy:

2. Was any other protocol-regulated medication/therapy given peri-infusion: ☐ No ☐ Yes ☐ Unknown

If YES, indicate all medications/therapies:

a. Antibiotics: ☐ No ☐ Yes ☐ Unknown
b. Anticoagulants (Lovenox): ☐ No ☐ Yes ☐ Unknown
c. Antifungals: ☐ No ☐ Yes ☐ Unknown
d. Antivirals: ☐ No ☐ Yes ☐ Unknown
e. Arcabose (Precose): ☐ No ☐ Yes ☐ Unknown
f. Aspirin: ☐ No ☐ Yes ☐ Unknown
g. Heparin: ☐ No ☐ Yes ☐ Unknown
h. Iron Supplements (Feosol): ☐ No ☐ Yes ☐ Unknown
i. Metformin: ☐ No ☐ Yes ☐ Unknown
j. Nicotinamide: ☐ No ☐ Yes ☐ Unknown

k. Pentoxifylline: ☐ No ☐ Yes ☐ Unknown

l. Pioglitazone: ☐ No ☐ Yes ☐ Unknown

m. Protonix (pantoprazole): ☐ No ☐ Yes ☐ Unknown

n. Rosiglitazone: ☐ No ☐ Yes ☐ Unknown

o. Vitamins: ☐ No ☐ Yes ☐ Unknown

p. Zofran (ondansetron hydrochloride): ☐ No ☐ Yes ☐ Unknown

q. Other: ☐ No ☐ Yes ☐ Unknown

If OTHER, specify:

Comments:

Additional Selection Options for IND

Antibody 1 choice
Muromonab-CD3 (Orthoclone OKT3)
hOKT3g-1 (Ala-Ala)
Alemtuzumab (Campath)
Other
Not Applicable

Collaborative Islet Transplant Registry

(5a) Follow-up Post First Infusion (FOI)

Version: 1.01; 03-16-05

Infusion Date:
Assessment Date:

1. Is the recipient currently taking insulin: ☐ No ☐ Yes ☐ Unknown

2. **Indicate results closest to this assessment. (C-peptide and glucose levels should be taken from same sample or at least drawn at the same time):**

		Standard Units	International Units	Not Done/Unknown
a. Fasting blood glucose:	☐ <	_____ *(xxxx)* mg/dL	_____ *(xx.xx)* mmol/L	☐
b. Basal plasma C-peptide:	☐ <	_____ *(xx.xx)* ng/mL	_____ *(xx.xxx)* nmol/L	☐
c. HbA1c:		_____ *(xx.x)* %		☐

Comments:

Collaborative Islet Transplant Registry

(5b) Follow-up Post Last Infusion (FOL)

Version: 4.00; 03-16-05

Infusion Date:
Assessment Date:

1. Weight: ☐ *(xxx.x)* kg **OR** ☐ *(xxx.x)* lb ☐ Unknown

2. Record recipient's Visual Acuity for both eyes in either feet or meters:

	Right Eye (OD) ☐ Not Done/Unknown	**Left Eye (OS)** ☐ Not Done/Unknown
Visual Acuity in feet	☐ *(xx)* / ☐ *(xxx.x)* feet	☐ *(xx)* / ☐ *(xxx.x)* feet
OR		
Visual Acuity in meters	☐ *(x)* / ☐ *(xx.xx)* meters	☐ *(x)* / ☐ *(xx.xx)* meters

3. Blood Pressure (SBP/DBP): ☐ *(xxx)* / ☐ *(xxx)* mmHg ☐ Unknown

4. Is the recipient currently taking blood pressure medication specifically for the control of hypertension: ☐ No ☐ Yes ☐ Unknown

If YES, indicate all medications:

Click here to view a list of medication names and categories.

a. ACE inhibitors: ☐ No ☐ Yes ☐ Unknown
b. Alpha adrenergic blockers: ☐ No ☐ Yes ☐ Unknown
c. Angiotensin II receptor blockers: ☐ No ☐ Yes ☐ Unknown
d. Beta adrenergic blockers: ☐ No ☐ Yes ☐ Unknown
e. Calcium channel blockers: ☐ No ☐ Yes ☐ Unknown
f. Centrally acting agents: ☐ No ☐ Yes ☐ Unknown
g. Diuretics: ☐ No ☐ Yes ☐ Unknown
h. Vasodilators: ☐ No ☐ Yes ☐ Unknown
i. Unknown: ☐ No ☐ Yes ☐ Unknown
j. Other: ☐ No ☐ Yes ☐ Unknown

If OTHER, specify: ☐

5. Is the recipient currently taking lipid lowering medication: ☐ No ☐ Yes ☐ Unknown

If YES, indicate all agents:

Click here to view a list of medication names and categories.

a. Bile acid sequestrants: ☐ No ☐ Yes ☐ Unknown
b. Cholesterol absorption inhibitors: ☐ No ☐ Yes ☐ Unknown
c. Fibric acid derivatives: ☐ No ☐ Yes ☐ Unknown
d. HMG CoA reductase inhibitors: ☐ No ☐ Yes ☐ Unknown
e. Neomycin: ☐ No ☐ Yes ☐ Unknown
f. Nicotinic acid: ☐ No ☐ Yes ☐ Unknown
g. Probucol: ☐ No ☐ Yes ☐ Unknown
h. Unknown: ☐ No ☐ Yes ☐ Unknown
i. Other: ☐ No ☐ Yes ☐ Unknown

If OTHER, specify: ☐

6. Did the recipient experience any severe hypoglycemic episodes (requiring the assistance of another person) since the last CITR assessment: ☐ No ☐ Yes

If YES:

a. Total number of severe hypoglycemic episodes (requiring the assistance of another person): ☐ (1-2, 3-5, 6 or more, Unknown)
b. Total number of severe hypoglycemic episodes (requiring the assistance of another person): ☐ *(xxx)* ☐ Unknown
c. Total number of severe hypoglycemic episodes (requiring the assistance of another person) resulting in the loss of consciousness and/or seizures: ☐ *(xxx)* ☐ Unknown

7. Total number of hospital admissions since last CITR assessment: ☐ *(xx)* ☐ Unknown

If one or more hospital admissions:
Total number of hospitalized days: ☐ *(xxx)* ☐ Unknown

Total number of islet infusion related hospitalization days: _____ *(xxx)* ☐ Unknown

Insulin Administration

8. Was insulin administered at the last CITR assessment: ☐ No ☐ Yes ☐ Unknown
9. Was insulin administered for more than 14 consecutive days at any time between the last CITR assessment and this CITR assessment: ☐ No ☐ Yes ☐ Unknown
10. At this CITR assessment, is the recipient currently taking insulin: ☐ No ☐ Yes ☐ Unknown

IF YES to questions 8, 9, OR 10, complete the Insulin Administration Form

11. Since the last CITR assessment, has the recipient been treated for islet graft dysfunction or suspected islet graft dysfunction: ☐ No ☐ Yes ☐ Unknown

If YES, complete the Islet Graft Dysfunction (IGD) form.

Maintenance Immunosuppression

12. Were immunosuppressants used for maintenance: ☐ No ☐ Yes ☐ Unknown

Immuno Med	Specify Medication	Dose (mg/day)	Dose Unknown		Trough Level (ng/mL)	Trough Unknown
Sirolimus: No / Yes		_____ *(xx.xx)*	☐	☐ <	_____ *(xxxx.xx)*	☐
Tacrolimus: No / Yes		_____ *(xx.xx)*	☐	☐ <	_____ *(xxxx.xx)*	☐
Cyclosporine: No / Yes	Generic / Neoral / Sandimmune / Other / Unknown	_____ *(xxxx)*	☐	☐ <	_____ *(xxxx.xx)*	☐
MMF: No / Yes		_____ *(xxxx)*	☐			
Daclizumab: No / Yes		_____ *(xxxx)*	☐			
Steroid: No / Yes	Prednisone / Methylprednisolone / Other / Unknown	_____ *(xxxx.x)*	☐			
DSG: No / Yes		_____ *(xxxx)*	☐			
Everolimus: No / Yes		_____ *(xxxx)*	☐			
Other medication 1: No / Yes		_____ *(xxxx.x)*	☐			
Other medication 2: No / Yes		_____ *(xxxx.x)*	☐			
Other medication 3: No / Yes		_____ *(xxxx.x)*	☐			
Other medication 4: No / Yes		_____ *(xxxx.x)*	☐			
Other medication 5: No / Yes		_____ *(xxxx.x)*	☐			

13. Were any protocol regulated anti-hyperglycemic medications or other protocol regulated therapies (except antibiotic, antiviral, and antifungal prophylaxis) given since the last CITR assessment: ☐ No ☐ Yes ☐ Unknown

If YES, how many (select medications below): _____ *(x)*

Medication 1: Chromium picolinate / Vitamins / Pentoxifylline / Other — If OTHER, specify: _____

Medication 2: Chromium picolinate / Vitamins / Pentoxifylline / Other — If OTHER, specify:

Medication 3: Chromium picolinate / Vitamins / Pentoxifylline / Other — If OTHER, specify:

Medication 4: Chromium picolinate / Vitamins / Pentoxifylline / Other — If OTHER, specify:

Medication 5: Chromium picolinate / Vitamins / Pentoxifylline / Other — If OTHER, specify:

14. Were any malignancies newly diagnosed since last CITR assessment: ☐ No ☐ Yes ☐ Unknown

If YES:

a. Indicate date of diagnosis: *(mm/dd/yyyy)* ☐ Unknown

b. Indicate diagnosis: text **OR** ICD-9 code ☐ Unknown

c. Was the malignancy:
- Transplanted from donor
- Recurrence of a pre transplant malignancy
- Post transplant malignancy occurred since last CITR assessment
- Unknown
- Other

15. Has the recipient experienced any adverse events (Grade 3, 4, or 5) since last CITR assessment, including portal vein thrombosis or complications at the site of the islet graft infusion: ☐ No ☐ Yes ☐ Unknown

If YES, complete the Adverse Event (AEF) form for each event that occurred.

16. Has the recipient received a transplant since the last CITR assessment (other than an islet infusion): ☐ No ☐ Yes ☐ Unknown

If YES, complete the Non Islet Transplant (NIT) form for each transplant.

17. What is the current status of each of the following secondary complications:

a. Hypoglycemia:
- No occurrence
- Reduced awareness
- Unawareness
- Unknown

b. Peripheral neuropathy:
- No occurrence
- Asymptomatic
- Symptomatic
- Disabling
- Unknown

c. Autonomic neuropathy:
- No occurrence
- Asymptomatic
- Symptomatic
- Disabling
- Unknown

d. Nephropathy:
- No occurrence
- Microalbuminuria
- Macroalbuminuria
- End stage renal disease
- Stable allograft
- *Additional Options Listed Below

e. CAD:
- No
- Yes
- Unknown

f. CVA:
- No
- Yes
- Unknown

g. PVD:
- No
- Yes
- Unknown

h. Treated hypertension:
- No
- Yes
- Unknown

	Right Eye (OD)	Left Eye (OS)
i. Retinopathy:	None / Non Proliferative / Proliferative / Unknown	None / Non Proliferative / Proliferative / Unknown
j. Diabetic macular edema:	None / Mild / Moderate / Severe / Unknown	None / Mild / Moderate / Severe / Unknown

18. Eye surgery performed for treatment of diabetic retinopathy since the last CITR assessment:

Surgery	Right Eye (OD)	Year of surgery *(xxxx)*	Left Eye (OS)	Year of surgery *(xxxx)*
a. Laser photocoagulation for proliferative diabetic retinopathy:	No / Yes / Unknown		No / Yes / Unknown	
b. Laser photocoagulation for diabetic macular edema:	No / Yes / Unknown		No / Yes / Unknown	
c. Vitrectomy:	No / Yes / Unknown		No / Yes / Unknown	
d. Other:	No / Yes / Unknown		No / Yes / Unknown	

19. Has the recipient experienced the following diabetes related foot problems since the last CITR assessment:
    a. Ulcers: ☐ No ☐ Yes ☐ Unknown
    b. Lower limb amputation: ☐ No ☐ Yes ☐ Unknown
    c. Foot deformity: ☐ No ☐ Yes ☐ Unknown
    d. Dysesthesia: ☐ No ☐ Yes ☐ Unknown

20. Have the following events occurred since the last CITR assessment:
    a. Orthostatic hypotension: ☐ No ☐ Yes ☐ Unknown
    b. Gastroparesis: ☐ No ☐ Yes ☐ Unknown
    c. Constipation: ☐ No ☐ Yes ☐ Unknown
    d. Diabetic diarrhea: ☐ No ☐ Yes ☐ Unknown
    e. Fecal incontinence: ☐ No ☐ Yes ☐ Unknown
    f. Diabetic bladder dysfunction: ☐ No ☐ Yes ☐ Unknown
    g. Sexual dysfuction: ☐ No ☐ Yes ☐ Unknown

21. Current employment status of islet transplant recipient:
    Working full time / Working part time by choice / Working part time due to disease / Working part time, reason unknown / Not working by choice / *Additional Options Listed Below

22. Since the last CITR assessment, has the recipient been compliant with protocol regulated medications/therapy:
    No / Yes / Unknown / Not Applicable

Comments:

Additional Selection Options for FOL

Nephropathy:
Unknown

Current employment status of islet transplant recipient:
Not working due to disease
Not working, unable to find employment
Not working, reason unknown
Retired
Student
Employment status unknown
Not applicable, less than 5 years old

Collaborative Islet Transplant Registry

(5b) Follow-up Post Last Infusion Lab Info (FUL)

Version: 1.02; 03-16-05

Infusion Date:
Assessment Date:

Laboratory Information

1. **Indicate results closest to this assessment. (C-Peptide and glucose levels should be taken from same sample or at least drawn at the same time):**

		Standard Units	International Units	Not Done/Unknown
a. Fasting blood glucose:	☐ <	*(xxxx)* mg/dL	*(xx.xx)* mmol/L	☐
b. HbA1c:		*(xx.x)* %		☐
c. ALT:	☐ <	*(xxxx)* U/L		☐
d. AST:	☐ <	*(xxxx)* U/L		☐
e. Alkaline phosphatase:	☐ <	*(xxxx)* U/L		☐
f. Total bilirubin:		*(xx.x)* mg/dL	*(xxx)* µmol/L	☐
g. Total cholesterol:	☐ <	*(xxx)* mg/dL	*(xx.xx)* mmol/L	☐
h. HDL:		*(xxx)* mg/dL	*(xx.xx)* mmol/L	☐
i. LDL:		*(xxx)* mg/dL	*(xx.xx)* mmol/L	☐
j. Triglycerides:		*(xxxx)* mg/dL	*(xx.xx)* mmol/L	☐
k. Serum creatinine:		*(xx.x)* mg/dL	*(xxxx)* µmol/L	☐
l. Calculated creatinine clearance:		*(xxx)* mL/min/1.73m^2	*(x.xx)* mL/s/1.73m^2	☐

Metabolic Assessment of Islet Infusion Function

2. Indicate results closest to this assessment:

Items in blue (also double starred: **) should follow the procedures outlined in the CITR Guidelines for Metabolic Testing

If tests are used that do NOT follow CITR standards, record the result but do NOT check the 'CITR Standard Used' column.

		Result	Units	Not Done/Unknown	CITR Standard Used
a. Basal plasma C-peptide:	☐ <	*(xx.xx)*	ng/mL nmol/L	☐	
b. Peak stimulated C-peptide after meal:	☐ <	*(xx.xx)*	ng/mL nmol/L	☐	
c. IV glucagon:					
1. Basal C-peptide before IV glucagon:	☐ <	*(xx.xx)*	ng/mL nmol/L	☐	
2. Peak stimulated C-peptide after IV glucagon:	☐ <	*(xx.xx)*	ng/mL nmol/L	☐	

d. Arginine Stimulation Test (AST):					
1. Basal C-peptide before IV arginine:**	☐ <	☐ (xx.xx)	ng/mL nmol/L	☐	
2. Peak stimulated C-peptide after IV arginine:**	☐ <	☐ (xx.xx)	ng/mL nmol/L	☐	☐
3. Acute C-peptide response to IV arginine:**		☐ (xx.xx)	ng/mL nmol/L	☐	☐
4. Acute insulin response to IV arginine:**		☐ (xxx.x)	µU/mL	☐	☐
e. Intravenous Glucose Tolerance Test (IVGTT):					
1. Basal C-peptide before IV glucose:**	☐ <	☐ (xx.xx)	ng/mL nmol/L	☐	
2. Peak stimulated C-peptide after IV glucose:**	☐ <	☐ (xx.xx)	ng/mL nmol/L	☐	☐
3. Acute C-peptide response to IV glucose:**		☐ (xx.xx)	ng/mL nmol/L	☐	☐
4. Acute insulin response to IV glucose:**		☐ (xxx.x)	µU/mL	☐	☐
5. AUC insulin derived from 0.5 g/kg IVGTT:**		☐ (xxx.x)	µU/mL x min	☐	☐
6. K_G-Value derived from 0.5 g/kg IVGTT:**		☐ (xxxx.xx)	K_G value	☐	☐
f. Oral Glucose Tolerance Test (OGTT):					
1. 2-hr 75g OGTT plasma glucose:**		☐ (xxxx.x)	mg/dL mmol/L	☐	☐
2. AUC C-peptide OGTT:**		☐ (xxx.xx)	ng/mL x min	☐	☐
g. Mixed Meal test:					
1. AUC C-peptide MMTT:**		☐ (xxx.xx)	ng/mL x min	☐	☐
2. Mixed meal stimulation index:**		☐ (xx.x)	pmol/mg ng/mg	☐	☐

Comments:

Collaborative Islet Transplant Registry

(5b) Insulin Administration (INS)

Version: 2.01; 03-16-05

Infusion Date:
Assessment Date:

Complete the following table recording insulin use for this recipient during the current CITR assessment period. The start date is the date the participant began taking insulin. This could be as early as the date of last CITR assessment. The end date is either the date the recipient stopped taking insulin or the current CITR assessment date, if the recipient is currently on insulin. If there were multiple periods of insulin use (insulin administered > 14 days), record each period in a separate row. Average total daily insulin requirement is the total number of units given divided by the total number of days (e.g., Day 1-Day 9: 10 units per day, Day 10-Day 19: 5 units per day = 7.4.). More information and examples are included in the CITR Internet Data Entry System User's Guide.

1. Total number of periods of insulin use greater than 14 days (include periods of use that span the last assessment date or this assessment date even if those periods were less than 14 days): _____ *(xx)*

Insulin Use

Episode #	Start Date	End Date	Average Total Daily Insulin Requirement (units)	Reason	If OTHER, specify
1	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
2	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
3	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
4	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
5	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
6	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
7	*(mm/dd/yyyy)*	*(mm/dd/yyyy)*	*(xx.x)*	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	

8	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
9	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
10	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
11	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
12	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
13	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
14	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	
15	(mm/dd/yyyy)	(mm/dd/yyyy)	(xx.x)	Delayed graft function Drug toxicity Infection Rejection episode Partial rejection episode *Additional Options Listed Below	

Comments:

Additional Selection Options for INS

Insulin reason 1
Surgery
Per protocol
Marginal function
Insufficient islet mass
Unknown
Other

Collaborative Islet Transplant Registry

(6) Islet Graft Dysfunction (IGD)

Version: 2.01; 03-16-05

Infusion Date:
Date of graft dysfunction:

1. Indicate the presumed primary reason and then all secondary reason(s) why this is an islet graft dysfunction or suspected dysfunction:

Reasons	Primary	Secondary
Primary nonfunction	☐	☐
Insufficient islet mass	☐	☐
Islet exhaustion	☐	☐
Rejection	☐	☐
Autoimmune reaction	☐	☐
Transplant center staff discontinued medication	☐	☐
Recipient discontinued medication by self	☐	☐
Insulin resistance	☐	☐
Drug toxicity	☐	☐
Dietary non-compliance	☐	☐
Weight gain	☐	☐
Infection (e.g., CMV)	☐	☐
Unknown	☐	☐
Other	☐	☐

If OTHER, specify:

2. Outcome or resolution of the dysfunction:

Full recovery
Partial recovery
Complete dysfunction
Unknown

Comments:

If FULL RECOVERY, indicate date of full recovery: *(mm/dd/yyyy)*

If COMPLETE DYSFUNCTION, indicate date of failure: *(mm/dd/yyyy)*

3. Immediately prior to dysfunction, was the recipient on immunosuppression therapy: ☐ No ☐ Yes ☐ Unknown

If YES, indicate all current immunosuppression therapies the recipient was on and the dose given:

Immuno Med	Specify Medication	Dose (mg/day)	Dose Unknown	Trough level (ng/mL)	Trough Unknown
Sirolimus: No Yes		*(xx.xx)* ☐		*(xxxx.xx)* ☐	
Tacrolimus: No Yes		*(xx.xx)* ☐		*(xxxx.xx)* ☐	

Cyclosporine: No / Yes — Generic / Neoral / Sandimmune / Other / Unknown — (xx.xx) ☐ — (xxxx.xx) ☐

MMF: No / Yes — (xxxx) ☐

Steroid: No / Yes — Prednisone / Methylprednisolone / Other / Unknown — (xxxx.x) ☐

Other medication 1: No / Yes — (xxxx.x) ☐

Other medication 2: No / Yes — (xxxx.x) ☐

Other medication 3: No / Yes — (xxxx.x) ☐

Other medication 4: No / Yes — (xxxx.x) ☐

Other medication 5: No / Yes — (xxxx.x) ☐

4. In response to an islet graft dysfunction or suspected dysfunction, were any **anti rejection therapies** used: ☐ No ☐ Yes ☐ Unknown

If YES, indicate the medication(s), dose and number of days used:

	Medication	Dose (mg/day)	Dose Unknown	# of Days Used	# of Days Unknown
a.	Anti TNF alpha (Infliximab) / Anti-IL-6 / Arcabose (Precose) / Cyclosporine / Heparin / *Additional Options Listed Below	(xxxx.xx)	☐	(xxx)	☐
b.	Anti TNF alpha (Infliximab) / Anti-IL-6 / Arcabose (Precose) / Cyclosporine / Heparin / *Additional Options Listed Below	(xxxx.xx)	☐	(xxx)	☐
c.	Anti TNF alpha (Infliximab) / Anti-IL-6 / Arcabose (Precose) / Cyclosporine / Heparin / *Additional Options Listed Below	(xxxx.xx)	☐	(xxx)	☐
d.	Anti TNF alpha (Infliximab) / Anti-IL-6 / Arcabose (Precose) / Cyclosporine / Heparin / *Additional Options Listed Below	(xxxx.xx)	☐	(xxx)	☐

5. In response to an islet graft dysfunction or suspected dysfunction, were any **antibody therapies** used: ☐ No ☐ Yes ☐ Unknown

If YES, indicate the antibody, dose and number of days used:

	Specify Antibody	Dose (mg/day)	Dose Unknown	# of Days Used	# of Days Unknown
a. Antibody 1:	Alemtuzumab (Campath) Basiliximab (Simulect) Daclizumab (Zenapax) Muromonab-CD3 (Orthoclone OkT3) Polyclonal (Thymoglobulin) *Additional Options Listed Below	*(xx)*	☐	*(xxx)*	☐
If OTHER, specify:					
b. Antibody 2:	Alemtuzumab (Campath) Basiliximab (Simulect) Daclizumab (Zenapax) Muromonab-CD3 (Orthoclone OkT3) Polyclonal (Thymoglobulin) *Additional Options Listed Below	*(xx)*	☐	*(xxx)*	☐
If OTHER, specify:					
c. Antibody 3:	Alemtuzumab (Campath) Basiliximab (Simulect) Daclizumab (Zenapax) Muromonab-CD3 (Orthoclone OkT3) Polyclonal (Thymoglobulin) *Additional Options Listed Below	*(xx)*	☐	*(xxx)*	☐
If OTHER, specify:					

6. Were there any adverse events (Grade 3, 4 or 5) associated with the dysfunction: ☐ No ☐ Yes ☐ Unknown

If YES, complete the Adverse Event (AEF) form for each event.

7. Local transplant center's criteria or reason why this is an islet graft dysfunction:

Comments:

Additional Selection Options for IGD

Therapy 1
IL-1 Receptor Antagonist
IL-2
Metformin
MMF
Nicotinamide
Other
Pentoxifylline
Proglitazone
Rosiglitazone
Sirolimus
Soluble Anti TNF (Etanercept)
Soluble IL-1 Receptor
Steroid
Tacrolimus
Not Applicable

Antibody 1
hOKT3y-1 (ala-ala)
Other
Not Applicable

Collaborative Islet Transplant Registry

(6) Non Islet Transplant (NIT)

Version: 1.03; 03-16-05

NIT Date:

Donor Information for Non Islet Transplants

For every non islet transplant, complete one of these forms. Complete the Non Islet Transplant Follow-up Form (NIF) at least once per year for functional status of the transplant.

1. Type of transplant:

Kidney
Liver
Lung
Intestine
Bone Marrow
*Additional Options Listed Below

If OTHER, specify:

2. Donor type:

Living
Deceased
Unknown

3. Specify UNOS Donor ID: ☐ Not Available ☐ Not Applicable
4. Specify CORR Donor ID: ☐ Not Available ☐ Not Applicable

If UNOS ID provided, all '*' questions may be skipped. Make sure to answer all red questions.

5. ABO blood group:*

A
B
AB
O
A1
*Additional Options Listed Below

HLA Typing

6. HLA typing conducted:* ☐ No ☐ Yes ☐ Unknown

If YES:

a. Date typed:* *(mm/dd/yyyy)*

b. Class I:*

A (1):* A (2):*

B (1):* B (2):*

Bw4 :*

Negative
Positive
Unknown or Not Determined
Confirmed Blank

Bw6 :*

Negative
Positive
Unknown or Not Determined
Confirmed Blank

c. Class II:

DR (1):* DR (2):*

DQ (1):* DQ (2):*

Serology

7. Anti-HIV I/II:*
8. Anti-HTLV I/II:*
9. RPR-VDRL:*
10. Anti-CMV:*
11. HBsAg:*
12. Anti-HBC:*
13. Anti-HCV:*

Negative
Positive
Unknown
Not Done
Indeterminate
*Additional Options Listed Below

Comments:

Additional Selection Options for NIT

Type of transplant:
Simul. Islet/Kidney
Simul. Islet/Kid/BM
Simul. Islet/Liver
Simul. Islet/Liver/BM
Simul. Islet/Kid/Liver
Simul. Islet/Liver/Kid/BM
Simul. Islet/Lung
Simul. Islet/Heart/Lung
Pancreas
Other

ABO blood group:*
A2
A1B
A2B
Unknown

Anti-HIV I/II:*
Cannot Disclose

Collaborative Islet Transplant Registry

(6) Non Islet Transplant Follow-up (NIF)

Version: 2.00; 03-16-05

NIT Date:
Assessment Date:

1. Functional status of non islet transplant at this assessment:

Full functioning
Partial functioning
Failed
Unknown
Not Applicable

If FAILED:

a. Failure date: *(mm/dd/yyyy)*

b. Specify cause:

c. Was the failure treated: ☐ No ☐ Yes

d. Was drug toxicity experienced: ☐ No ☐ Yes

Comments:

Collaborative Islet Transplant Registry

(6) Adverse Event (AEF)

Version: 1.02; 03-16-05

Date of AE onset:
CTCAE term:

1. Was AE expected: ☐ No ☐ Yes

2. Did the AE meet the definition of a serious adverse event (SAE)? ☐ No ☐ Yes

If 'YES,' check all that apply:

a. Death: ☐
b. Life threatening: ☐
c. Inpatient hospitalization: ☐
d. Prolongation of existing hospitalization: ☐
e. Persistent or significant disability/incapacity: ☐
f. Congenital anomaly/birth defect: ☐

3. Severity of AE:
- Severe (Grade 3)
- Life threatening (Grade 4)
- Fatal (Grade 5)

4. Relationship to islet infusion:
- Unrelated
- Unlikely
- Possible
- Probable
- Definite

5. Relationship to immunosuppression therapy or protocol regulated treatment product:
- Unrelated
- Unlikely
- Possible
- Probable
- Definite

6. Was treatment required or modified:
- No treatment or modification of treatment required for AE
- Required additional treatment for AE
- Current treatment modified based on AE
- Required additional treatment and current treatment modified based on AE
- Other

If OTHER, specify:

7. Outcome of AE:
- Resolved, no residual effects
- Resolved, with sequelae
- Persistent condition, Alive
- Death, related to AE
- Unrelated persistent condition at time of death

If AE resolved, indicate date of resolution: *(mm/dd/yyyy)*

If AE is persistent, indicate date of last assessment: *(mm/dd/yyyy)*

8. Narrative of adverse event:

Collaborative Islet Transplant Registry

(6) Death (DTH)

Version: 2.00; 03-16-05

1. Date of death: _____ *(mm/dd/yyyy)* ☐ Unknown

2. Primary cause of death:
   a. Specify primary cause of death: _____
   b. Categorize primary cause of death:
   - Cardiovascular
   - Cerebrovascular
   - Infection
   - Malignancy
   - Not Obtainable
   - *Additional Options Listed Below

3. Was the death related to the islet infusion procedure: ☐ No ☐ Yes ☐ Unknown

4. Was the death related to the islet infusion immunosuppressive therapy: ☐ No ☐ Yes ☐ Unknown

5. Was recipient hospitalized at time of death: (hospitalization=24 or more hours from admission to expiration) ☐ No ☐ Yes ☐ Unknown

6. Was recipient currently taking insulin at time of death: ☐ No ☐ Yes ☐ Unknown
   If YES, record average daily insulin requirement including correction sliding scale: _____ *(xxx)* total units ☐ Unknown

7. Was an autopsy performed: ☐ No ☐ Yes ☐ Unknown
   If YES, is the autopsy report available: ☐ No ☐ Yes

Comments: _____

Additional Selection Options for DTH

Categorize primary cause of death:
Other
Trauma/Accidental
Unknown cause

Collaborative Islet Transplant Registry

(6) Lost to Follow-up (LTF)

Version: 1.02; 03-16-05

Date of last CITR contact:

1. Type of last known contact:

Transplant follow-up at CITR center
Follow-up at primary care office or other health care provider
Telephone contact
Returned mail contact form
Abstracted information from hospital records or physician patient charts
*Additional Options Listed Below

If OTHER, specify:

Comments:

Additional Selection Options for LTF

Type of last known contact:
Other

Collaborative Islet Transplant Registry

(6) Transfer (TNF)

Version: 1.02; 03-16-05

Transfer Date:

1. Date of last CITR contact by previous transplant center: *(mm/dd/yyyy)*
2. Name of new transplant center:
3. Date of first assessment at new transplant center: *(mm/dd/yyyy)*
4. Was the transfer confirmed with the new center's Transplant Coordinator: ☐ No ☐ Yes

Comments: