STANDARD OPERATING PROCEDURE (SOP)

Preparing Pancreas Section for Histology

Version: QA-007-03
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1.0 Objective

1.1 To define the preparation of pancreas section in paraffin for histology processing for use in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored research in the Integrated Islet Distribution Program (IIDP).

2.0 Scope and Applicability

2.1 This SOP applies to all IIDP islet distribution centers using funds from the NIDDK to manufacture purified human pancreatic islets for basic research studies for IIDP approved investigators.

3.0 Responsibilities

3.1 It is the responsibility of each IIDP center to follow the procedures listed in this SOP and to work to the best of their ability to follow all requirements.

3.2 Managers and supervisors are responsible for assuring that all technicians are properly trained in the correct procedure for this SOP and that equipment and facilities are in good working order.

3.3 Laboratory personnel are responsible for reading and understanding the SOP and for performing the tasks in accordance with this SOP.

3.4 It is the responsibility of the IIDP CC to both follow and ensure adherence to the procedures outlined in this SOP. In order to accomplish this, the IIDP CC will interact with the relevant personnel from each of the participating centers.

4.0 Definitions

4.1 Integrated Islet Distribution Program (IIDP): The IIDP is a program commissioned and funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK Project Scientist and Program Official, the External Evaluation Committee and the CC at City of Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.

4.2 IIDP Coordinating Center (CC): Joyce Niland, Ph.D. is the Principal Investigator for the IIDP CC and leads staff from the Department of Diabetes and Cancer Discovery Science, Diabetes and Metabolism Research Institute at COH to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.
4.3 City of Hope Pathology Core Laboratory (COH-PCL): The COH-PCL will be responsible for sectioning and staining all IIDP pancreas samples. Original blocks and stained and unstained sections will be kept on file and will be made available for any investigator that requires additional pancreas sections for future or confirmatory studies.

5.0 Materials

5.1 The following equipment and supplies are necessary to prepare a pancreas sample for histology and shipping to the IIDP CC.

5.1.1 Sterile scissors, forceps, and suture or clips to seal the pancreas once the sample is taken.

5.1.2 Sterile trimming pan with UW (whatever process is used for cleaning the pancreas of extraneous tissue and fat.)

5.1.3 40ml pre-filled specimen jar with 20ml of 10% Neutral Buffered Formalin (NBF)
Fisher 22 899 402

5.1.4 15ml – Phosphate Buffered Saline (PBS)

5.1.5 15ml – 70% Ethyl Alcohol (ETOH)

5.1.6 Waste container for formalin disposal

5.2 Histology Log Sheet

5.2.1 Mailer for sending paraffin block to COH – Uline Cat# S-7887

5.2.2 3oz. frozen cold pack for shipping sample - Uline S-13376
6.0 Procedures

6.1 Assemble all items described in 5.0-Materials

6.1.1 Label the Histology Log Sheet with the following:
6.1.1.1 Center Name: select drop-down and choose appropriate center name
6.1.1.2 Center ID: field will be populated based on selected Center Name, select the appropriate Center ID
6.1.1.3 RRID: enter only the numeric portion of the RRID
6.1.1.4 Date of Isolation: enter the date in MM/DD/YYYY format
6.1.1.5 Specimen code: this field will be auto-populated based on the data entered for Center ID, RRID and Isolation Date. Please ensure that all fields are entered appropriately so that the specimen code can be populated

6.1.2 Label specimen jar with Center name, UNOS #, and date of isolation.

6.2 After cleaning of the pancreas, the center should take a 1cm x 1cm sample of the pancreas from the neck of the pancreas. The hole should be clamped or sutured to prevent enzyme leakage, if necessary. Note: Confirm taking of histology sample on question 5 of the Characterization of Islets for Distribution Information page of the Quick Broadcast.

6.3 Place sample in pre-filled 30ml specimen jar with 15ml of NBF for 24±8 hours.

6.4 Record Start of Fixation Date/Time on Histology Log Sheet.

6.5 After fixation time is complete, decant NBF into appropriate waste container, rinse once with 15ml of PBS, and hold in 15ml of 70% ETOH.

6.6 Record End of Fixation Date/Time on Histology Log Sheet.

6.7 Send sample to your histology lab for embedding in paraffin block with appropriate paperwork.

6.8 Upon return of embedded sample in paraffin block, label the paraffin block with specimen code from the histology log sheet. The block should be carefully packaged and sent to the IIDP for staining and analysis in labeled shipping box.
6.8.1 The IIDP expects to receive embedded tissue within 10 days of the isolation. If several samples are processed within a few days, samples may be consolidated for shipping and cost savings.

6.8.2 Samples should be packaged in IIDP supplied mailers with a frozen 3 oz. ice pack in order to keep paraffin from melting in warm weather.

6.8.3 Complete Electronic Histology Log Sheet accordingly to step 6.1, ship date, and FedEx Tracking Number, email to Julie Hom at jhom@coh.org. Print a copy to include the log sheet in the shipment to IIDP.

6.8.4 Samples should be sent by FedEx with a copy of the Histology Log Sheet, to:

Julie Hom  
Integrated Islet Distribution Program (IIDP)  
City of Hope  
Department of Diabetes and Cancer Discovery Sciences  
1500 East Duarte Road, BRC 2016.11  
Duarte, CA  91010  
T: 626-218-4174

6.8.4.1 Date of the shipment of the sample to IIDP should be completed on Question 4 on the Preliminary Assessments data form: It is important to log in the date when the samples are actually shipped so that the IIDP can actually track the shipment and be alerted if the shipment is not received. Samples must be sent and date must be entered before reimbursement for distributed islets will provided.

6.8.5 Once sample is received, IIDP will enter the date the paraffin block was received confirm the assigned specimen code on the Histology Log Sheet, and send the sample to COH-PCL for sectioning and staining. Note: Details for IIDP Procedure provided in Admin-008 SOP.

6.8.6 Samples will be collected, catalogued and stored by IIDP. Every two weeks the collected samples will be organized, PCL paperwork completed, and delivered to COH-PCL for sectioning and staining.
6.8.7 Samples will be batched for sectioning and staining, every 2 weeks in 10 sample batches by COH-PCL.

6.8.8 Each sample will be consecutively cut and stained with Hematoxylin & Eosin, and Anti-Insulin & Anti-Glucagon per COH-PCL protocols.

6.9 Stained slides will be scanned by Dr. Muirhead’s lab and images will be uploaded to the IIDP website where each will be posted with the appropriate broadcast.

6.10 Extra unstained slides can be requested by both centers and investigators for additional stains as needed.

7.0 References

7.1 nPOD Histology Procedure, SOP 70.1; 5/10/12

7.2 City of Hope Pathology Core Lab: SOPs for Histology Sampling, Processing and Staining.

8.0 Attachments

8.1 Histology Log Sheet (Fillable)