Site Participation Application

Site Enrollment Process

Site Eligibility

Any healthcare facility in the United States that provides care for patients diagnosed and/or treated for pancreatic disease is eligible to participate in NPF's National Patient Registry (NPR) at this current time.

Site Enrollment

To become a participating site of the NPR, the healthcare institution must complete the following steps:

- Appoint a qualified individual as the Site PI
    - Site Investigator responsibilities are outlined on the following page
    - Required to complete the Site Investigator Agreement (Appendix E of the protocol)
- Assign a qualified study member as the Site Coordinator/ Administrator
    - Role serves as a designated site contact for the local site
- Complete the **Site Participation Application** (pg. 5 of this document)
- Obtain IRB and/or Ethics Committee (EC) approval
    - Approval from the central IRB or local site's institutional IRB (or EC)
    - The site must submit the protocol and supporting documentation to the IRB for review and approval.
    - To facilitate the site's preparation for IRB review, NPF has prepared templates for the supporting documentation (e.g. Informed Consent form, recruitment materials). These forms should be modified as needed. The participating sites will submit the NPF's NPR protocol.
    - If approved, then a copy of the IRB approval letter, as well as the supporting documents, must be submitted by the local site to NPF.
    - Participating sites must submit IRB-approved documents to NPF on an annual basis (e.g. Continuing Review).
        - A lapse in IRB site approval will result in immediate suspension, including data entry capability.
    - The local site is responsible for obtaining and maintaining all IRB documentation. All site IRB documentation is subject to NPF audit at any time during site participation.
    - Any fees associated with IRB services related to the local site are the responsibility of the participating site/ investigator.
- Training in HSP, GCP, and health information security and privacy awareness (e.g. HIPAA for Research)

    - Copies of training documentation/ certification must be submitted for all site investigators and study staff
- Financial Disclosure and Conflict of Interest
    - In accordance with 21 CFR 54, all site investigators and study personnel must submit a financial disclosure and conflict of interest statement. Form should be obtained from the central IRB or institutional IRB.
- Agreements
    - All site agreements/ participation documents are provided in the Standard Operating Procedures (SOP) of the NPR.
        - Business Associate Agreement
        - Terms of Use Policy
        - Site Participation Agreement (i.e. National Patient Registry for Pancreatic Disease Participation Agreement)
    - These agreements are between the local participating site and NPF.
    - All signed agreements must be submitted to NPF prior to site activation.
- Activation
    - After the site has completed the above requirements and been approved by NPF, the site user(s), including the site investigators and/or study personnel, will be required to complete and submit the Site User Access Request Form (provided in the SOP) to request for access to the NPR.
    - Once NPF reviews and approves each site user's request for access, the site user will receive a notification via e-mail that will contain navigation instructions to the secured web-based NPR application, along with the individual's user name (e.g. institutional e-mail address) and initial password.
        - Upon initial login, the site user will be immediately prompted to change their password.

Site Investigator Responsibilities

The responsibilities of the Site PI are outlined as follows:

- Conducts study in accordance with applicable federal, state, and local regulations, including the DHHS regulations (e.g. 45 CFR 46, 160, and 164), and complies with applicable FDA regulations (e.g. 21 CFR 50, 56, and 312.2(b)(iv)), as well as GCP guidelines
- Required to provide adequate oversight at the local site to ensure proper supervision, training of staff, resource management, and study conduct
- Any responsibility delegated by the Site PI to members of the study team continues to be performed under the Site PI's delegation and the Site PI retains final accountability
- Responsible for all communication with NPF and the IRB/EC regarding the study at their local site, but may delegate another study staff member as the designated contact person

- Evaluates the feasibility of the study design based on site-specific considerations (e.g. staff availability, study population, security considerations, and space allocation)
- Certifies that the local site's study personnel are adequately qualified to conduct the study
- Ensures the local site's study team is trained on study procedures (both study specific and general operating procedures)
- Accountable for all local site submissions to the IRB for review (e.g. HIPAA Authorization form development, annual continuing review report, study amendments/ modifications/ changes) and submits in a timely fashion to ensure a lapse does not occur with the IRB approval date
- Ensures that any changes to the IRB-approved study documents are not initiated at the local site prior to IRB approval
- Provides up-to-date copies of the protocol to all site co-investigators and/or other site personnel responsible for study conduct
- Provides NPF with copies of all IRB/EC actions related to registry activities at the local site
- Maintains compliance with the IRB-approved protocol at the local site
- Reports any protocol deviations to NPF in a timely fashion
- Responsible for implementing and maintaining quality control and quality assurance systems related to registry data and activities
- Ensures the accuracy, completeness, and timeliness of data reported to the NPR
- Assures appropriate safeguarding of subject's privacy and confidentiality
- Maintains adequate and accurate study records that are readily available for inspection by the sponsor (NPF), internal and external monitors, and/or regulatory agencies
- Required to submit the Site Investigator Agreement (Appendix E of the protocol) to NPF prior to local site activation

Site Participation Application Form

Site/ Reporting Facility Information

How does the site plan to obtain IRB approval?

☐ NPF's Central IRB (Schulman IRB)

☐ Local IRB/ EC

☐ Other (please specify):_____

Type of Medical Facility:

☐ General/ Acute Care Hospital

☐ Hospital-based Outpatient Facility or Clinic

☐ Healthcare System/ Multi-hospital system

☐ Healthcare Network

☐ Academic Medical Center

☐ Rural Health Clinic

☐ Cancer Center

☐ Private Outpatient Office or Group Practice

☐ Research Center

☐ Industry

☐ Other (please specify):_____

Name of Institution/ Practice: _____

Street Address:_____

City:_____

State:_____ Postal Code:_____

Country:_____

Website:_____

Site Principal Investigator

Title (Mr./ Ms./ Mrs./ Dr.):_____

First Name:_____

Last Name:_____

Position:_____

Department:_____

Street Address:_____

State:_____ Postal Code:_____

Mail Code (if applicable):_____

Country:_____

Phone #:_____ Extension (if applicable):_____

Fax Number:_____

E-mail:_____

Primary Contact Information (Site Coordinator/ Administrator)

Title (Mr./ Ms./ Mrs./ Dr.):_____

First Name:_____

Last Name:_____

Position:_____

Department:_____

Street Address:_____

State:_____ Postal Code:_____

Mail Code (if applicable):_____

Country:_____

Phone Number:_____

Extension (if applicable):_____

Fax Number:_____

E-mail:_____