1. PURPOSE:
   This Standard Operating Procedure (SOP) describes the process for obtaining an identified patient list for recruitment purposes through the Clinical Research Center’s use of the TriNetX Export ID Feature.

2. SCOPE:
   This SOP provides instruction and sets minimum standards regarding the process for submitting, reviewing, and releasing patient lists containing PHI for recruitment purposes.

   Prior to requesting patient lists, the project and recruitment plan must be approved by the Institutional Review Board (IRB) and a waiver of HIPAA authorization must be granted.

3. RESPONSIBLE INDIVIDUALS:
   This SOP applies to University Hospitals (UH) Principal Investigators (PIs) who are interested in identifying potential study participants for purposes of increasing recruitment for an under-enrolling study or identifying potential participants for a new study. This process is only available to UH PI’s who have submitted to the UH IRB.

4. DEFINITIONS:

   **TriNetX** is a global health research network that brings together healthcare organizations, biopharmaceutical companies, and contract research organizations to optimize clinical research and enable discoveries through the generation of real-world evidence.

   **Export ID** means re-identifying a de-identified patient list for recruitment.

   **UH Honest Broker** is the person from the Clinical Research Center who will receive the UH PI’s request for identification, re-identify the patients, and release the list to the investigator.

   **Protected Health Information (PHI)** means information created or received by a UH entity related to the past, present, or future physical or mental health or condition of a patient or payment for the provision of healthcare to a patient that is transmitted or maintained in any form or medium. PHI contains identifiers such as demographics, insurance information, medical record number, treating physician, admission date or photographic images, for which there is a reasonable basis to believe the information can be used to identify a patient. Any individually identifiable information of a person deceased more than 50 years is not PHI.
5. POLICY STATEMENT:
UH PI’s seeking patient lists for identifying eligible research participants must have IRB Approval and a waiver of HIPAA authorization. The release of PHI through the Export ID UH Honest Broker mechanism will be based on IRB approval of this method of recruitment for the specific study of interest. The UH PI will collaborate with the IRB to include this recruitment method in the protocol of interest. The release of PHI is intended to be used solely to identify prospective research participants. UH PI’s and study teams must recruit subjects in an ethical manner by following the IRB approved recruitment plan and all requirements outlined in the Investigator Manual.

6. PROCEDURES:
Export ID through TriNetX is a process where a UH designated Honest Broker can download a de-identified dataset and re-identify the patient cohort for recruitment purposes. The procedures below list the responsibilities of the UH PI and of the CRC Honest Broker.

1. The UH PI confirms that Part 1 of the UH CRC Feasibility Process has been completed before sending an Export ID request.
2. The UH PI confirms that the study has received IRB approval and a waiver for HIPAA authorization.
3. The UH PI and study team shall also confirm that obtaining a list of prospective research participants aligns with the IRB approved recruitment methods.
4. If the requirements above have been met, then the UH PI meets the criteria to send an electronic request for Export ID. The UH IRB Number and the approved CRC Feasibility Review form must be included in the request in order to retrieve the dataset.
5. The CRC Honest Broker will confirm IRB approval and waiver of HIPAA authorization.
6. The CRC Honest Broker will refresh the initial TriNetX feasibility query to update the number of eligible participants within UH for the research trial.
7. The CRC Honest Broker will request de-identified patient data from TriNetX and match synthetic IDs to medical record numbers behind the UH Firewall.
8. The CRC Honest Broker will match the medical record number to only the data elements authorized by the IRB on the HIPAA waiver.
9. The CRC Honest Broker will send the Export ID results to the Principal Investigator via UH e-mail within 3-5 business days. The email may not be forwarded to any other non-UH email address or to anyone that is not part of the study team. Results will include an excel file containing the data elements requested and approved by the

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IRB. The excel file will not exceed 5x anticipated accrual at local site and/or 500 patients, whichever is less.

a. By obtaining a patient list for recruitment through the Export ID process, the UH PI and study team attest that no patient will be contacted without prior approval from the providing physician, unless your recruitment plan specifically authorizes another process.

b. Patient lists received through this mechanism are confidential. PIs must agree that the Export ID list will not be shared with anyone outside of the IRB approved study team or sent to any non-UH email.

7. REFERENCES

   Link to Part 1 UH CRC Protocol Feasibility Research SOP SP-201: Protocol Feasibility Assessment
   UH Policy R-3 Uses and Disclosure of Protected Health Information (PHI for Research)

APPROVALS

Approved by Dr. Grace McComsey, Vice President of Research, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center - August 21, 2019
8. Appendix

A. Export ID Workflow Process