Waivers of Consent, Assent, HIPAA Authorization

A waiver of consent AND a waiver of HIPAA authorization is included in IRB approval for all retrospective studies including medical chart review in accordance with Stanford University Medical Center Institutional Review Board policies and scope of practice. Copies of the Waiver of Consent and HIPAA Authorization statements pertaining to this study are included below. See IRB Approval letter for confirmation of IRB Committee (Review includes Ethics Considerations) Certification and approval of these waivers, which are part of the IRB protocol.

Waivers

Waiver of HIPAA Authorization

Consent Information Type:* Waiver of HIPAA Authorization

Title:* Waiver of HIPAA Authorization

Before answering the following questions, click here to learn about HIPAA and the authorized use of identifiable protected health information (PHI).

a) **Specify the PHI (protected health information). PHI is health information linked to HIPAA identifiers (see link above). List BOTH health information AND HIPAA identifiers. If you are using STARR , use Data Privacy Attestation to ensure that your request will match your IRB-approved protocol. Be consistent with information listed in section 3a.**
Patient Name, Medical Record Number, Age, Gender, ERCP procedure and technique, ERCP procedure date, hospital course after ERCP

b) **Complete the following:**

- **Yes** / **No** — **Do you certify that the use or disclosure of the protected health information involves no more than a minimal risk to the privacy of individuals?**
- **Yes** / **NO** — **Do you certify that the research could not practically be conducted without the waiver?**
- **Yes** / **No** — **Do you certify that you have adequate written assurances that 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 project, or for other research for which the use or disclosure of protected health information would be permitted?**
- **Yes** / **No** — **Do you certify that the research could not practically be conducted without access to and use of the protected health information?**

c) **Describe an adequate plan to protect any identifiers from improper use and disclosure.**
REDCAPs (HIPAA compliant) database will be used to store data and data collection will be carried out only on encrypted Stanford computers. Stored data will be password protected and only available to the immediate research team directly listed on this protocol.

d) **Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.**
The MRNs will be coded using study IDs as soon as data collection is complete.

Waivers

Waiver of Consent

Consent Information Type:* Waiver of Consent

Title:* Waiver of Consent

1) ◉ True ○ False **The research involves no more than minimal risk to the participants because it involves materials (data, documents, records) that have been or will be collected, and precautions will be taken to ensure that confidentiality is maintained.**

2) ◉ True ○ False **The waiver will not adversely affect the rights and welfare of the participants because procedures are in place to protect confidentiality, and information learned during the study will not affect the treatment of participants.**

3a) ◉ True ○ False **The research could not practicably be carried out without the requested waiver because it would require contacting patients, and contact information is not readily available.**

3b) ○ True ○ False **The research could not practicably be carried out without using identifiable private information or identifiable biospecimens because the information comes from various sources or identifiers cannot be removed from the source data.**

4) ◉ True ○ False **Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation. We do not anticipate that there would be any information to share with participants.**

STANFORD UNIVERSITY

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David D Oakes, M.D. (650) 723-5215
CHAIR, PANEL ON MEDICAL HUMAN SUBJECTS (650) 725-8013

Certification of Human Subjects Approvals

Date: October 16, 2018

To: Monique Theresa Barakat, MD, PhD, Medicine - Gastroenterology and Hepatology
Robert Jeffrey Huang MD, Subhas Banerjee MD, Mohit Girotra

From: David D Oakes, M.D., Administrative Panel on Human Subjects in Medical Research

eProtocol Title: Analysis of Goff Transpancreatic Septotomy Technique Performed in ERCPs

eProtocol #: 36658 **IRB 8 (Registration #:** 6208)

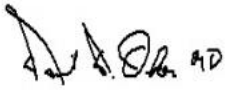
The IRB approved human subjects involvement in your research project on 10/16/2018. **'Prior to subject recruitment and enrollment, if this is: a Cancer-related study, you must obtain Cancer Center Scientific Review Committee (SRC) approval;** a CTRU study, you must obtain CTRU approval; a VA study, you must obtain VA R and D Committee approval; and **if a contract is involved, it must be signed.'**

This protocol has been approved under the Extended Approval Process and **approval does not expire**. Proposed changes to approved research must still be reviewed and approved prospectively by the IRB. No changes may be initiated without prior approval by the IRB, except where necessary to eliminate apparent immediate hazards to subjects. (Any such exceptions must be reported to the IRB within 10 working days.) Unanticipated problems involving risks to participants or others and other events or information, as defined and listed in the Report Form, must be submitted promptly to the IRB. (See Events and Information that Require Prompt Reporting to the IRB at http://humansubjects.stanford.edu.) It is your responsibility to report the completion of the protocol to the IRB within 30 days.

Please remember that all data, including all signed consent form documents, must be retained for a minimum of three years past the completion of this research. Additional requirements may be imposed by your funding agency, your department, HIPAA, or other entities. (See Policy 1.9 on Retention of and Access to Research Data at http://doresearch.stanford.edu/policies/research-policy-handbook)

This institution is in compliance with requirements for protection of human subjects, including 45 CFR 46, 21 CFR 50 and 56, and 38 CFR 16.

Waiver of Individual Authorization for recruitment under 45 CFR 164.512(i)(2)(ii)(A),(B),(C), pursuant to information provided in the HIPAA section of the protocol application.



David D Oakes, M.D., Chair

Approval Period: 10/16/2018 - (Does Not Expire)
Review Type: EXPEDITED - MODIFICATION
Funding: None
Expedited Under Category: 5
Assurance #: FWA00000935 (SU), FWA00000934 (SHC)