Mayo Clinic
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To whom it may concern,

Re: Manuscript titled “Percutaneous Transluminal Angioplasty Balloons for Endoscopic Ultrasound-Guided Pancreatic Duct Interventions”

Corresponding Author: Dr. Vinay Chandrasekhara, Mayo Clinic, Rochester, MN, USA

This study was deemed exempt by the Institutional Review Board at Mayo Clinic. The HIPAA authorization requirement was **waived**. Individual **consent was not required** as the research only involved secondary collection and identifiable health information from medical record review.

We have attached the approved IRB application which indicates this.

Sincerely,

Jad AbiMansour, M.D.

Abimansour.jad@mayo.edu

Date: Tuesday, January 25, 2022 12:27:52 PM Print Close

Application Type
ID: 21-000942

For help selecting the application type, use the **IRB Wizard.** If you need assistance, submit a **ServiceNow ticket** or call the Research Service Center at 507-266-4000.

1. * **Select one:**
   Exempt

Title and Personnel

1. * **Full title:**
   Risk of post-sphincterotomy bleeding in patients with thrombocytopenia

2. Sponsor Protocol ID:

3. **Principal Investigator:**
   Students, fellows, residents, supplemental consultants, emeritus staff, and RTP personnel may not serve as PI or co-PI on new applications submitted to the IRB, unless approval has been received. Please review the Eligibility as Principal Investigator Policy for additional information and instructions to request approval.

   Vinay Chandrasekhara

Personnel:

	Last Name	MI	First Name	Location	Role	Edit	Consent	Notify	IRB Member	Disclosure Filed	Curr Discl	Positive Disclosure	COI Determination
View	AbiMansour		Pierre Jad	Mayo Clinic in Rochester, MN	Other Study Staff	yes	yes	yes	No	Yes	Yes	No	
View	Chandrasekhara		Vinay	Mayo Clinic in Rochester, MN	Principal Investigator	yes	yes	yes	No	Yes	Yes	No	
View	Garimella		Vishal	Mayo Clinic in Rochester, MN	Other Study Staff	no	no	no	No	Yes	Yes	No	

Research Plan

1. * **In simple (lay) language, describe the question(s) the research is designed to answer:**

This study will evaluate the risk of clinically significant bleeding after endoscopic sphincterotomy performed in patients who have low platelet counts.

2.

Attach the research protocol here:
IRB Protocol - ERCP Thrombocytopenia.docx(0.01)

Link to protocol templates

If this is a sponsor written protocol, and Mayo or other institution(s) covered by this application will conduct only a portion of the research activity, explain in the "Research Locations" section, question 2.

3. * **Is this an investigator-initiated protocol or sponsor-initiated protocol?**

- ○ Sponsor
- ● **Investigator**

Exempt Research

* **To qualify for exempt status, the research must be limited to activities in the following categories.**
Select the category(ies) that apply to the research:

1. ☐ Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

2. ☐ Research only including interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

3. ☐ Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects through verbal or written responses (including data entry) or audiovisual recording.

4. ☑ Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required **(e.g. medical records review)**

(Please use the Secondary Use of Information and/or Biospecimens (Chart Review) application type if your proposed research involves only research that meets this exempt category)

4.1 * **Select all that apply, and indicate the source of information/specimens below:**

- ☐ The identifiable private information or identifiable biospecimens are **publicly** available.
- ☐ Information, which may include information about biospecimens, is **recorded by the investigator so the human subjects' identity can NOT readily be ascertained** directly or through identifiers linked to the subjects, **AND** the subjects will not be contacted or re-identified.
- ☑ The research involves only collection and analysis of identifiable health information that is regulated under HIPAA. **(e.g. medical records review)**
- ☐ The research will be conducted by, or on behalf of, a federal entity and involves the use of federally generated nonresearch information, provided that the original collection was subject to specific federal

privacy protections and continues to be protected. (See informational text for the specific privacy protections)

4.2 * **Describe the source(s) of information/biospecimens and how you will access them.**
Electronic medical record (EPIC) accessed through Mayo clinic workstations

4.3 *__If identifiable private information__ **will be used, select all source(s) from which the information will be obtained.**

- [x] Medical records from the location(s) covered by this application (i.e. Mayo, or another organization relying on Mayo IRB)
- [ ] Clinical database from the location(s) covered by this application (i.e. Mayo, or another organization relying on Mayo IRB)
- [ ] Another separately approved IRB application(s)
- [ ] External source
- [ ] Other
- [ ] None of the Above (Information will not be obtained or used)

a.) * **Describe ALL information that will be collected:**
(include data elements, type of subjects for which data will be collected, etc.)
Data will be collected from patients with platelet counts < 150,000/mL who have undergone ERCP at the Mayo Clinic from Jan 1 2020 to Jan 1 2021. Collected data will include demographics (age, sex, BMI), baseline laboratory values (platelets, INR, aPTT, Cr, hemoglobin), comorbidities (CKD, heart failure, malignancy), medication list, procedure information (duration, indications, interventions performed), outcomes (post operative labwork, blood transfusion, rehospitalization, repeat procedures performed).

b) * **Select all that apply to the use of information.**

- [ ] The identifiable private information is **publicly available (clinical records or databases are NOT publicly available)**
- [x] The information will be recorded by the investigator in such a manner that the **identity of the human subjects cannot readily be ascertained** directly or through identifiers linked to the subjects; the investigator **will not contact the subjects; AND** the investigator **will not re-identify the subjects**
- [ ] The research involves **only information collection** and analysis involving the investigator's use of identifiable health information when that use is **regulated under HIPAA (e.g. medical chart review)**
- [ ] The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities (additional specifications apply per 45 CFR 46.104(d)(4)(iv))
- [ ] None of the above

c) * **Check all subject identifiers that will be recorded with the __Information__ in your research dataset.**
NONE of the above identifiers will be recorded or maintained in the research dataset.

If the research involves only the receipt of de-identified materials, complete the Human Subjects Research Wizard to determine if this application needs to be submitted to the IRB.

4.4 *__If biospecimens__ **will be used, which of the following apply?**
None of the above (Biospecimens will not be obtained or used)

5. - [ ] Research and demonstration projects conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve or otherwise examine public benefit or service programs.

6. ☐ Taste and food quality evaluation and consumer acceptance studies.

Funding/Other Support

1. * **Select all sources of funding or other support. Other support includes material goods, such as drugs or devices, equipment, supplies, etc., provided to conduct the research:**

- ☐ Industry/Commercial Entity
- ☐ Federal
  (Federal funding may involve support from NIH, NCI, and other government agencies and includes Career Development Awards (K Awards), and Training Grants)
  NIH Grant & Funding Activity Codes
- ☐ External Foundations
- ☐ Institutional Funding (e.g. Mayo Clinic or other institution covered by this application)
- ☑ **No funding/support required**

If no specific funding/support is required, explain:

To be conducted by GIH fellow during research time

2. * **Department of Defense (DoD) involvement in your research (check all that apply):**

- ☐ The research is funded by a component of DoD, and the investigator or institution is primary awardee.
- ☐ The research involves cooperation, collaboration, or other type of agreement with a component of DoD.
- ☐ The research uses property, facilities or assets of a component of DoD.
- ☐ The subject population will intentionally include personnel (military and/or civilian) from a component of DoD, or data or specimens from DoD personnel.
- ☑ **None of the above.**

3. * **Will subjects receive payment (remuneration) for taking part in the research, or be offered reimbursement for expenses related to taking part in the research?**

○ Yes ● **No**

If non-monetary incentives will be offered to subjects, mark this question 'No', and attach a description of the incentives in 'Contact Materials (After Enrollment)'.

4. * **Do you have a related budget or funding proposal (pending or active) in the Grants and Contracts (GnC) module?**

○ Yes ● **No**

Explain and/or attach budget/funding documentation:
No funding/support required

Attach other budget documentation:

Name	Version	Date Created	Date Modified

There are no items to display

Research Locations

1.

* **Select the Mayo location(s) where subject interactions and/or interventions will be conducted.**
(Examples: recruitment, research visits/examinations, specimen collection.)

This is intended to define locations at which interested individuals may enroll and take part in the research.
For medical record review or archived specimen studies, mark only the location(s) where the research activity is occurring. (This may differ from the locations where data or samples originated)

Mayo Clinic in Rochester, MN

2. **Click ADD to specify location(s) listed above that will conduct only a portion of the subject interactions/interventions, or will conduct modified or additional interactions/interventions at that location.**
(Examples: research phases/cohorts/ procedures limited to specific locations, additional use of radiation at a select location.)

Location	Description
There are no items to display	

3. **Add other Mayo Clinic location(s) (not included in question 1) conducting research activities that do not involve subject interactions/interventions.**
(Examples: analysis of information/specimens, regulatory/administrative reporting.)

Location	Research Activities to be Conducted	Other
There are no items to display		

4. * **Is this a multi-center trial for which a location covered by this application will serve as a coordinating/lead center?**
○ Yes ● **No**

5. * **Will research staff covered by this application conduct the research at a location for which Mayo Clinic IRB is not the IRB of record?**
○ Yes ● **No**

6. **Check this box if the application includes request(s) for the Mayo Clinic IRB to serve as the IRB of record for a Relying Organization(s).**
☐

7. * **Will a local physician or other provider/medical center ("local provider") perform subject interventions or procedures for the purpose of this research, without participating as a research location?**
○ Yes ● **No**

Subject Population

1.

* **Specify the maximum number of subjects to be accrued at the location(s) covered by this application.**
2000

For retrospective data or biospecimens review, "Subjects" refers to the number of individuals whose information or biospecimens will be reviewed.

2.

* **Will additional individuals be screened in order to reach the maximum accrual specified above?**
○ Yes ● **No**

3.

* **Will there be any interaction or intervention with the research subjects? Interaction may occur in person or remotely, such as by mailed surveys or phone calls.**

○ Yes ● **No**

Describe how you will access the information or biospecimens:

> Retrospective review of electronic medical records

4.

* **Age range of subjects**

Minimum Age:

18 **years**

Maximum Age (if applicable):

years

5.

* **Protected research populations – check all populations expected to be included:**

☐	Pregnant women, fetuses or neonates	Subpart B
☐	Prisoners	Subpart C
☐	Children	Subpart D
☐	Adults lacking capacity to consent	
☑	**None of the above**	

Confidentiality

1. * **Describe measures that will be used to maintain confidentiality of subjects' information and/or biospecimens.**

Data will be extracted from EHR using secure Mayo Clinic workstations. No identifying information will be stored after extraction from the medical record. Data will be stored on secure, Mayo clinic intranet and encrypted. Access will be restricted to those named in this application. Data will not be shared or transferred at any time.

2. * **Is the research covered by a Certificate of Confidentiality (CoC)?**

○ Yes ● **No**

NIH Certificate of Confidentiality resources

Protected Health Information (HIPAA)

Studies utilizing identifiable private health information (PHI) or coded PHI (with ability to link to specific subjects) require HIPAA authorization or Waiver of HIPAA authorization. (**Example: Medical Chart Reviews**)

1. * **Indicate how HIPAA authorization will or will not be obtained for this research: (check all that apply)**

Health Insurance Portability and Accountability Act (HIPAA)
Informed Consent and the Research Subject

- [x] **Waiver of HIPAA authorization requested.**
- [ ] HIPAA authorization will be obtained using a standalone HIPAA form.
- [ ] HIPAA authorization does not apply because no protected health information is being recorded or used.
- [ ] HIPAA authorization is not required because the research involves receipt of a limited data set from an external party with a data use agreement in place.

If multiple boxes are selected, explain how each applies to the research:

2. * **Will information and/or specimens be shared with an external party?**
   - ○ Yes
   - ● **No**

HIPAA Authorization Waiver

1. * **All research data will be treated in a confidential manner and the same precautions used to protect patient clinical data will be employed.**
   - ● **True** ○ False

2. * **All subject identifiers will be destroyed upon completion of the research.**
   - ● **True** ○ False

3. * **Subject identifiers will not be reused or disclosed to any other person or entity for research, unless required by law, for authorized conduct and oversight of the research, or for other IRB-approved research.**
   - ● **True** ○ False

4. * **The research could not practicably be conducted without the waiver or alteration; and the research could not practicably be conducted without access to and use of the PHI.**
   - ● **True** ○ False

Supporting Documents

1. **Attach supporting documents:**

Name	Version	Date Created	Date Modified
There are no items to display			

You have reached the end of the IRB portion of the application.

Complete the questions on the following pages to provide information required for Mayo Clinic's Research Systems and Research Resources.

Your application **IS NOT SUBMITTED** until you press the Submit button on the next page.

Submission to the IRB may only be done by the Principal Investigator.

Click 'Continue' to submit the application for review.