Seattle Children's
HOSPITAL • RESEARCH • FOUNDATION

Routing Instruction:
1 electronic copy to
irb@seattlechildrens.org

Form Information:
Form #: N/A
Form Owner: Laurie Bolton
Owning Dept: HSPP
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INSTITUTIONAL REVIEW BOARD

APPLICATION FOR "EXEMPT" DETERMINATION
OR
OTHER STATUS NOT REQUIRING IRB APPROVAL

The activities described in this application require IRB review for the purpose of making an IRB determination that any given activity qualifies for a status that does not require IRB approval.

Submit the completed application by email to: **irb@seattlechildrens.org**.
Questions should be directed to the IRB email or 206-987-7804.
The IRB determination will be documented in writing after review of the application.

Section I: Project and Contact Information

Project title:

Case Series: Allergic Eosinophilic Gastroenteritis Presenting as Duodenal Ulcerations

Principal investigator, degree, dept/division, and position

Kimberly Riehle, M.D. Department of General and Thoracic Surgery,

Telephone number, mailstop, and e-mail address

206-987-2794, OA.9.220, Kimberly.riehle@seattlechildrens.org

If this project receives funding, provide the following information: Grant title, name of grant PI, name of funding agency, and proposed (or awarded) funding period.

Section II: Forms/Attachments

☒ Attach all data collection forms/list of variables collected, surveys/questionnaires, or interview questions.
☐ If a protocol/research plan is available, attach for IRB review.
☐ If federally funded and Seattle Children's (or relying institution) is the prime awardee, attach a copy of the funding proposal

Section III: Project Summary

Briefly describe in lay language the purpose of the project and the benefits to be gained below.

Provide sufficient information so the IRB can determine if your project meets the criteria for exempt status/other status that does not require IRB approval.

Explain the sources of the data or specimens that will be used in this project.

If you are using existing*, anonymous** data or specimens, explain in detail what data or specimens you will receive for this research project. (*Existing is defined as on the shelf or in the records at the time of IRB application. **Anonymous means there is no way the data or specimens can be linked back to the individual. No direct identifiers or indirect identifiers can be recorded. If you receive any one of the 18 HIPAA identifiers, it is likely that your data/specimens will be considered identifiable. The list of 18 HIPAA identifiers is available for your reference at: NIH Privacy Rule in Research.)

Do not include multiple projects under one application. Each project should have its own application.

Project Summary:

Eosinophilic gastroenteritis (EGE) is a rare disorder of the immune system that is characterized by intestinal inflammation with a predominately eosinophilic infiltrate in the bowel wall. There are less than 300 total cases of this disease reported in the literature to date. EGE is known to cause mucosal ulceration and can present with a wide range of symptoms. The most common are abdominal pain, nausea, diarrhea, or gastric outlet obstruction. There are only two previous reports of a duodenal ulcer as the initial finding in patients with EGE, and only one of those was perforated.

This study is a case series of three patients with allergic eosinophilic gastroenteritis who presented with duodenal ulcers as the first sign of their disease. We aim to collect (from the SCH medical record) their demographic data, presenting signs/symptoms, clinical findings, imaging findings, pathology findings, and outcomes to report on this rare disease presentation.

Section IV: Category of Review

Check the category below that best applies to your project.
You may wish to review the OHRP Human Subjects Regulations Decision Charts for guidance on which category to choose. If your project does not fit within any of the categories described below, the project will likely require IRB approval. Application forms are available here or you may request an IRB consultation.

Categories that do not require IRB approval. Note that usually only **ONE** category should be selected**:**

☒ **"Not Research" under 45 CFR 46.102(d)**
Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
If this determination applies to your project, indicate why the project is not research (select at least one):

- ☐ Project is **not systematic**.
- ☐ Project is **not generalizable** (note: intent to publish suggests results will be generalizable).
- ☐ **Quality improvement** project that does NOT also meet the "research" definition above (see OHRP guidance)
- ☒ **Case report** involving 3 or fewer patients.
- ☐ **Other** (explanation required):

☐ **Research, but "Not Human Subjects" under 45 CFR 46.102(f)**
This overall project (including the work of any co-investigators at other institutions) does not involve obtaining: (1) data through intervention or interaction with the individual; OR (2) identifiable private information. Take note:

- The data/samples you intend to use cannot be collected for purposes of this research.
- Data/samples are not individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems (see OHRP guidance here)
  - If any of the 18 HIPAA identifiers will be obtained by investigators, it is likely the data/samples are considered identifiable. The 18 HIPAA identifiers are available here.
- This category cannot be applied to the use of de-identified leftover human specimens if they are used in a clinical investigation of an in vitro diagnostic device, which is under FDA regulation (see guidance here)

☐ **Human Subjects Research, but is "Exempt" from OHRP Requirements**

- Note that research involving prisoners (for example, juvenile detainees) or FDA regulated research cannot be exempt.

Research Team Members (Only required for exempt research):

Name and Degree	Position	Dept/ Division	Telephone Number	Email	Human Subjects Training Date & Type/Location	Member of Children's Workforce* - Yes or No

***Children's workforce = Children's employee, Children's University Medical Group (CUMG) employee, Resident/Fellow working at Children's.**

Exempt Categories, 45 CFR 46.101(b):

☐ 1. **45 CFR 46.101(b)(1):** Research conducted in established or commonly accepted educational settings that involve normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

☐ 2. **45 CFR 46.101(b)(2):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

***Note**: This category does not apply to research involving minors if survey or interview procedures will be used. This category does not apply to research involving minors and observation of public behavior except when the investigators do not participate in the activities being observed. You may also need to submit a HIPAA authorization if collecting protected health information.*

☐ 3. **45 CFR 46.101(b)(3):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2), if:(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

***Note:** Use of this category is **rare** at Seattle Children's.*

☐ 4. **45 CFR 46.101(b)(4):** Research involving the collection or study of existing **check all that apply:** ☐ data, ☐ documents, ☐records, ☐pathological specimens or ☐ diagnostic specimens, if these sources are **(check the one that applies):** ☐ publicly available or if ☐ the information is **recorded** in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Notes: *The investigator may view/use identifiable private information, but may not record it with the information collected for the research. This category does not apply to psychiatric records. You may also need to request a waiver of HIPAA authorization below.*

☐ 5. **45 CFR 46.101(b)(5):** Research and demonstration projects which are conducted by or subject to the approval of DHHS department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Note: *Use of this category is **rare** at Seattle Children's.*

☐ 6. **45 CFR 46.101(b)(6):** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: *Use of this category is **rare** at Seattle Children's.*

☐ **Human subjects research, but Seattle Children's is "Not Engaged" in Research**
Seattle Children's employees or agents are not "engaged" in human subjects research. If you have questions about the involvement of multiple institutions in the project, it is strongly suggested that you request a consultation (see consult request information above). For information about "engagement", you may wish to review the OHRP guidance.

Check the boxes below to confirm that Seattle Children's employees or agents will **NOT** do any of the following for this project:

☐ obtain data about individuals for research purposes through intervention or interaction with them;
☐ obtain individually identifiable private information for research purposes;
☐ obtain the informed consent of human subjects; OR
☐ receive a direct HHS award to support any such research, even if all human subjects activities will be performed by agents or employees of another institution

If you cannot confirm the preceding statements are all true, you may be "engaged" in human subjects research. If still feel you are not "engaged in human subjects research", then **include an explanation why.**

Section V: HIPAA Compliance

HIPAA rules apply if the investigator is part of a covered entity and is collecting/using/receiving protected health information (PHI) for research purposes, regardless of whether OHRP and/or FDA regulations apply to the project.

☑ **N/A**: Activity does not involve access, collection, use, or receipt of protected health information.
☐ **Waiver of Authorization**: If you are accessing participant PHI through a medical record and are not interacting with the participant, you should request a waiver of HIPAA authorization. For a waiver, complete the regulatory criteria below:

1. Explain why the use or disclosure of PHI involves no more than a **minimal risk to privacy** of individuals, based on, at least the presence of the following elements:
   a. An adequate plan to **protect the identifiers** from improper use and disclosure:
   b. An adequate plan to **destroy identifiers at earliest opportunity** consistent with conduct of research:
   c. Assurances that **PHI will not be reused or disclosed** to any other party or entity, except as required by law or for authorized oversight of the research:
2. Explain why the research could not **practicably** be conducted without the **waiver** of authorization:
3. Explain why the research could not **practicably** be conducted without access to and use of the **PHI**:

If you requested a HIPAA Waiver above, are all members of the research team part of Seattle Children's "**work force**" (defined as Children's employee, Children's University Medical Group (CUMG) employee, Resident/Fellow working at Children's)?

☐ Yes, all members of the research team are Seattle Children's "work force, therefore HIPAA tracking is not required. Please proceed to the next Section.

☐ No, one or more members of the research team are not Seattle Children's "work force", therefore **HIPAA Tracking** is **required**.
When you share PHI with researchers who are not part of Children's work force, the disclosures of PHI must be tracked.
➔ *Page 8 of the IRB Information sheet on HIPAA and research explains the tracking requirements for disclosures.*

☐ **Authorization Form**: If you are collecting PHI and interacting with the participant, you must ask participants to sign a HIPAA authorization form. Be sure to include the HIPAA template form with your submission.

Section VI: SFI Compliance Certification

By virtue of the signature provided in the section below, I attest that all research team members responsible for the design, conduct or reporting of the research have submitted the required Significant Financial Interest (SFI) disclosures to the Office of Research Compliance.

Section VII: Principal Investigator's Statement:

I certify that the information provided in this application is correct, and to the best of my ability to judge, that this research qualifies for exemption or other status not requiring IRB approval. I agree that any future changes to this activity/project will be submitted using a modification request form, before implementation of the changes, to the IRB for review/approval.

Signature Submitted from PI's email account. **Date** 7/3/14
(Optional signature if submitted from PI's e-mail account.)

IRB Concurrence

7/13/14

IRB Signature:_____ **Date**_____

IRB Decision: ☑ Not Research ☐ Not Human Subjects Research

☐ Exempt; Category ___ ☐ Not Engaged in Human Subjects Research

HIPAA Determinations:

☑ N/A

☐ Waived per 45 CFR 164.512(i)). HIPAA Tracking Required: ☐ No ☐ Yes

☐ Authorization Required

Patient Number	Age	Gender	Abdominal pain	nausea	emesis
1					

diarrhea constipation early satiety UGI CT Endoscopy WBC

Other labs Procedure Operation pathology steroids GI cocktail Food allergy

Diet restrictic follow up recurrent sym