IRB #2076923 MU

Human Subjects Research Determination Form (Including QI Projects) #349033

Submission date: **10/26/2021**
Submitted by: **Song, Xing**

1. Human Subjects Research Determination

1. Project Investigators

Role	Investigator	Department	Consent personnel role	Primary contact	Truman VA Hospital personnel
Principal Investigator	Song, Xing	Health Mgmt & Informatics	Non-Consenting Personnel	☑	☐

2. Contact Information

Principal investigator

Song, Xing

Job title	PROF, AST
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

Primary contact

Song, Xing

Job title	PROF, AST
Department	Health Mgmt & Informatics
Division	Medicine
Business unit	University of MO-Columbia

3. Project Title:

Predicting Outcomes in Children with Ulcerative Colitis

4. Describe the purpose of your project.

Note: If you are using an investigational invitro diagnostic device on biospecimens, you must complete the IRB application, even if the biospecimens are unidentified.

Ulcerative colitis (UC) is a chronic intestinal disorder, a type of inflammatory bowel disease (IBD). there is currently a lack of guidance to clinicians as to which children are going to do well with these medications and who needs more medication exposure or surgery. To address this important issue, a clinical trial of standardized medical therapy was launched enrolling 428 children newly diagnosed with UC at 29 pediatric medical centers in North America (Predicting Response to Standardized Pediatric Colitis Therapy: The PROTECT Study). The PROTECT study collected clinical, genetic, environment and immune factors along with biospecimens including blood, stool, and colonic tissue. It was anticipated that a combination of clinical,

genetic, and immunologic tests performed at diagnosis can construct a valuable predictive model for personalized medicine which can be implemented to improve clinical outcomes such as early and late remission on 5-ASA only without the concurrent use of steroid medications. Along this line, state-of-art machine learning algorithms can ultimately utilize the PROTECT study data and more accurately predict clinical outcomes.

5. What do you intend to do with the data collected?

We seek to reuse the de-identified data on GROUSE (IRB #2057285) as an external data source to validate the machine learning model and demonstrate its generalizability

6. Quality Improvement Activities VS Human Subject Research Determination

A. Do you consider the activities you will perform to be Quality Improvement instead of human subject research?

If yes, you will be prompted with additional questions.

○ Yes ● No

7. De-Identified Biospecimens and/or Information

A. Does this project involve analyzing de-identified, secondary information?

● Yes ○ No

B. Does the project involve analyzing de-identified biospecimens (and possibly corresponding de-identified health information) obtained through pathology, an MU associated repository, or another source?

○ Yes ● No

C. Identifiers

Select all potential identifiers that may be accessed and/or included in the research records for the study.

- ☐ Names
- ☐ Dates
- ☐ Postal Addresses
- ☐ Phone Numbers
- ☐ Fax Numbers
- ☐ Email Addresses
- ☐ Social Security Numbers
- ☐ Medical Record Numbers
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☐ License or Certificate Numbers
- ☐ Vehicle ID Numbers
- ☐ Web URLs
- ☐ IP Addresses
- ☐ Biometric Identifiers
- ☐

Facial Photos or Images

☐ Any other unique identifier

☑ No identifiers (none of the above apply)

D. Does the study involve analyzing de-identified information that will be de-identified by a third party unrelated to the research?

○ Yes ● No

E. Describe the de-identification process including (a) information about how these data or biospecimens are already publicly or commercially available in de-identified form, OR (b) what process a third-party has available to provide the information or biospecimens in a de-identified form.

We will reuse the de-identified data collected for GROUSE project (IRB #2057285) from GPC sites to support the analysis

8. DHHS Human Subject Research

A project falls under DHHS regulations if it is research and involves human subjects. The questions below will assist in making this determination.

A. Is the project a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?

This is the DHHS definition of research. MU defines a "systematic investigation" as an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. MU defines "generalizable knowledge" as those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program.

● Yes ○ No

B. Human Subject

The following questions break down this definition to assist in making this determination.

i. Will investigators conduct research about living individuals?

"About" means the information and/or biospecimens collected must be about the living individuals. It may not necessary to obtain IRB approval if the study is about a particular policy, agency, program, technology, technique, or best practice. If information collected is not about the human subject themselves, but rather about an external topic, then it doesn't meet the definition of human subject including "...about whom..".

● Yes ○ No

ii. Will you obtain information or biospecimens through intervention or interaction with the individual, and use, study, or analyze the information or biospecimens?

Intervention *includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.* ***Interaction*** *includes communication or interpersonal contact between investigator and subject.*

○ Yes ● No

iii. Will you obtain identifiable private information or biospecimens?

Private information *includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).* ***Identifiable private information or biospecimens*** *is when the identity of the subject is or may be readily ascertained by the investigator or associated with the information or biospecimen.*

○ Yes ● No

Note: If you marked yes to (A) research and yes to (i) living human subjects and yes to (ii) and/or (iii), the activity is human subjects research requiring an IRB application. Please exit this form and complete the IRB Application under IRB Forms.

C. The following activities have been deemed NOT human subject research. Please select from any of the following if it applies to the proposed activities:

☐ **Publicly or commercially available information/data** with no restrictions on the use of the information.

☐ **Publicly or commercially available biospecimens** with no restrictions on the use of biospecimens.

☐ **Public health surveillance activities,** including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

☐ Collection and analysis of information, biospecimens, or records by or for **criminal justice agency** for activities authorized by law or court solely for criminal justice or criminal investigative purposes.

☐ Authorized operational activities (as determined by each federal agency) in support of **intelligence, homeland security, defense, or other national security missions**.

☐ **Scholarly and journalistic activities focused on a person/family/group** (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

9. FDA Human Subject Research - Clinical Investigations

A project falls under FDA regulations if it is research and involves human subjects. The questions below will assist in making this determination.

A. Does the project involve a test article regulated by the FDA?

A test article is any product that is regulated by the FDA, including: food, dietary supplements, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, or certain electronic products used for human health care.

○ Yes ● No

NOTE: ***Registered Nurses as PI or Co-I*** *: If you are a Registered Nurse and Employee of MU Health Care, please contact Sean Pridgeon, Coordinator of EBP and Nursing, for additional information regarding MU Health Care project tracking at pridgeons@health.missouri.edu.*

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