



# CLINICAL TRANSLATIONAL SCIENCE PILOT GRANT AWARDS

2023  
PILOT GRANT  
AWARDEES

UTILIZATION  
OF CHATGPT FOR  
KEY INFORMATION  
IN INFORMED  
CONSENT  
DOCUMENTS

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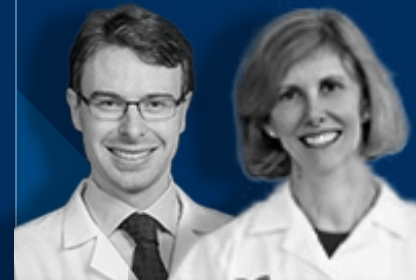
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CALEB SMITH, MPA

DEVELOPMENT OF  
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PAUL SWIECICKI, MD +  
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# UTILIZATION OF CHATGPT FOR KEY INFORMATION IN INFORMED CONSENT DOCUMENTS

## BACKGROUND

Informed consent is necessary in human research to ensure autonomy of research participants. The Key Information (KI) section of the consent document provides important information for the participant to make an informed decision about whether to join a study. Given the importance of the informed consent process, research investigators and IRBs invest substantial amounts of time in preparing and reviewing the consent materials.

Since the KI section was introduced as a new regulatory requirement in the 2018 Revised Common Rule, research investigators and IRBs have struggled to interpret and apply its content requirements. Complex information must be presented in a concise manner understandable to the research participants without oversimplifying or omitting important details found later in the full informed consent document. No standardized format has emerged, and KI sections differ in content and length (a single page to several pages) as interpreted by individual investigators. This variability leads to inefficiency during IRB review as IRBs evaluate the necessary level of content and require modifications from investigators. Participants may

also struggle with readability in the KI section and reconciling it with information provided later in the body of the consent document.

## CONCEPT

We will employ a large language model (LLM), such as ChatGPT, to draft KI sections for study-specific informed consent documents. The model will be trained using high-quality KI sections from existing informed consent documents and its output will be evaluated and adjusted by IRB experts. After a finetuning process, the model will produce KI sections of predetermined length, structure, required reading level and textual clarity.

To evaluate the readability and regulatory compliance of AI-generated KI sections, IRB Staff and Chairs will compare and score KI sections created by research investigators with those that are AI-generated, for the same consent document. If the scoring of a selected number of consent documents demonstrates substantial equivalency, invited research investigators will utilize the AI tool to develop the KI section of their consent document and submit it for review and approval by the IRB. The IRB will be blinded to the nature of the AI-generated materials at the time of review. After review of the materials, the IRB will be surveyed to assess the clarity of information, its compliance, and readability of the AI-generated KI section. If the graded level of satisfaction achieves a 75% or greater score, then the AI process will be recommended for routine utilization by research investigators.

## TEAM AND BUDGET

Our project team includes well-experienced IRB administrators, an IT professional, and research project manager to guide the process and assure regulatory compliance. We propose utilizing a student with experience in Transformer-based Large Language Models to assist with API query development. We also intend to use a small portion of the budget to pay for the necessary transaction costs as we interact with the OpenAI ChatGPT model.

## CONCLUSION

Utilizing AI natural language tools to create accurate, concise, and easily readable KI sections of the informed consent document benefits the research enterprise through standardization of information, a more efficient process for developing the materials, and increased comprehension for participants. This proof-of-concept project is a first step toward utilizing AI as a natural language solution for developing full informed consent materials. ■



JUDITH BIRK, JD

IRB Executive Director and HRPP Associate Director University of Michigan, Office of the Vice President for Research (OVPR)

# IDENTIFYING STRATEGIES FOR STRENGTHENING BEHAVIORAL AND SOCIAL SCIENCE RESEARCH (BSSR) STUDY CONDUCT

## SIGNIFICANCE:

Behavioral and Social Science Research (BSSR) is an integral part of translational science and its' value for prevention and management of health conditions and improving health equity is well established. BSSR accounts for 47% of human subjects R01s funded by NIH and 50% of new investigator-initiated trials at U-M.

Unlike biomedical research where a significant portion is initiated and supported by external sponsors, the vast majority of BSSR is investigator-initiated and requires additional institutional support and oversight. However, most of the institutional resources are designed to serve biomedical research and there is a critical gap in evidence about effective strategies for supporting and promoting high-quality BSSR.

A major element of dissonance between biomedical and behavioral study conduct is the emphasis on study monitoring. For biomedical research, close monitoring of adverse events and protocol deviations is critical to study rigor. In particular, understanding the risks of drugs and devices to study participants while participating in a trial is a main goal for FDA regulation and approval. For behavioral research, which typically involve low to moderate risk to participants, there is often less emphasis on study monitoring. Further, BSSR investigators get variable training on how to track adverse events and protocol deviations in trials. These investigators come from various backgrounds with discipline-specific training in BSSR conduct. Lastly, there are differing requirements from the many external sponsors of these BSSR studies. The

University of Michigan Office of Research Compliance Review (ORCR) audits studies across all 19 U-M school and colleges, including behavioral studies, and from these audits, there appears to be opportunity for improvement. However, it is not clear what the optimal strategies are to improve behavioral study conduct. For example, it may be that systems need some adaptation to adjust audits more appropriately based on best practices for behavioral study conduct. In addition, or alternatively, it may be that behavioral researchers and staff need training in developing stronger study monitoring and record keeping plans. The proposed project will use a participatory approach by leveraging the expertise of BSSR researchers, BSSR support staff, research compliance professionals, and lessons learned from post-approval audits to identify issues from behavioral trials conduct. This group will help identify strategies for developing solutions to better support that would meet their needs to accelerate the progress of BSSR studies within our institution and nationally.

## AIM 1: CHARACTERIZE ISSUES SEEN BY REGULATORY COMPLIANCE ON POST-APPROVAL AUDITS OF BEHAVIORAL STUDIES.

**METHOD:** Working closely with regulatory compliance officials, our team will generate reports of the types and prevalence of regulatory issues over the last 1-5 years of all behavioral studies that have been audited by ORCR. The span of time for tracking issues (here estimated from 1-5 years) depends on the number of audits performed and the number of studies audited. We would hope to review at least 50 trial audits for this characterization. Types of prevalence of issues will be examined based on characteristics such as the PI's years of experience, PI's home department, discipline, and type of grant funding the trial and amount of funding using descriptive statistics (t-tests/chi-square).

## AIM 2: ENGAGE STAKEHOLDER GROUP IN EXAMINING REGULATORY COMPLIANCE ISSUES OF BEHAVIORAL STUDIES.

**METHOD:** We will present data from Aim 1 to members of the stakeholder group. Given findings from Aim 1, we may purposively sample groups that have high versus low regulatory compliance issues (like novice versus experienced PIs) and using focus groups and structured interviews, we will perform thematic analysis on perspectives from different stakeholders regarding perceived barriers and potential solutions to issues. ■



SANA KHOURY- SHAKOUR, PHD

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# AUTOMATIC TRANSLATIONAL RESEARCH DETECTION AND CHARACTERIZATION

Researchers at the University of Michigan Medical School are working on a groundbreaking project to improve the way we understand and evaluate translational research, which involves turning scientific discoveries into real-world applications like new treatments or therapies. Currently, this field faces challenges due to unclear definitions and methods.

To tackle these issues, the team has developed a new model using the National Library of Medicine's PubMed database, which contains over 30 million biomedical research publications. This model helps them to automatically identify and categorize around 30,000 active biomedical research topics, giving a clearer picture of the scientific communities studying them.

The researchers have also created a quantitative definition of translational research, focusing on the exchange of ideas between research communities. They plan to use this definition to create a network of translational research spanning over 20 years and 1.5 billion references.

**This project has important implications for funding agencies, universities, and researchers, as it can help direct resources to projects with the greatest potential for real-world impact.** By analyzing the exchanges between research communities, they can better understand the practical implications of their work and focus on the most promising areas for translation.

In short, this project aims to revolutionize how we evaluate the process of turning scientific discoveries into practical applications, potentially leading to more efficient research and better health outcomes for everyone. ■



CALEB SMITH, MPA

Director, Research Intelligence &  
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# DEVELOPMENT OF A CLINICAL TRIAL TRANSLATIONAL MEDICINE (CTTM) CONCIERGE SERVICE

The University of Michigan is a leader in investigator initiated clinical trials (IITs). However, principal investigators (PIs) face significant hurdles in performing correlative studies on clinical trial specimens. We are developing a Clinical Trial Translational Medicine (CTTM) Concierge Service.

**This proposed service aims to provide a comprehensive, streamlined approach to managing the logistics and conducting correlative studies on investigator-initiated clinical trial specimens.**

Our hypothesis is that formation of a CTTM Concierge Service will expedite translational research and enhance the impact of IITs. The objective of this pilot is to evaluate the impact of utilization on IITs. The primary endpoint would be the rate of completed TM objectives in IIT's, which would be assessed pre- and post- implementation.

The design of the CTTM Concierge Service is aimed to assist IITs as each point of their life cycle, from protocol development to trial operation and finally study completion. The service will establish a consultative service for protocol development to help PIs identify the best assays to fit their translational objectives and specimen requirements prior to protocol development. In addition, it aims to provide the PI with a single point of contact for managing logistics, guidance on the use of shared resources, and access to novel assays or specimen requirements before protocol development. This service will aim to address the identified challenges and provide PIs with the necessary support to conduct correlative studies successfully. ■



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