Study Type and Performance Site Information

Type of study:

[ ] Standard or Expedited
[**x**] **Exempt**
[ ] Umbrella Review for funds release
[ ] Non-Human Subject Determination
[ ] Quality Improvement/Non-Research Determination
[ ] Request review by another IRB
[ ] Coordinating Center ONLY

Please indicate which Committee is most appropriate to review your project:

[ ] Social and Behavioral Sciences
[**x**] **Health Sciences**

Are there any international sites involved in this study in which the PI is responsible?

[ ] Yes
[**x**] **No**

Is this project cancer-related?

[ ] Yes
[**x**] **No**

Study Purpose and Description

Provide a brief abstract of the study in lay language. The IRB Committees are comprised of scientists with varied backgrounds, non-scientists, and community members.

Significant evidence suggests that Clinical Decision Support (CDS), when designed correctly and used effectively, can improve health care quality, safety, and effectiveness. Despite the promise of CDS, its adoption has faced challenges, including dissatisfaction among providers, shortages of trained CDS experts, high costs, limited research identifying necessary components for successful CDS implementation and challenges with terminology and value sets. Unintended consequences and safety issues have also been reported.

In the MALDIVES project, we propose the first comprehensive study of value set (lists of codes and corresponding terms, from National Library of Medicine (NLM)-hosted standard clinical vocabularies [such as SNOMED CT®, RxNorm, LOINC® etc.], that define clinical concepts), creation and maintenance, the development of novel and innovative machine learning and ontology-based approaches for improving value sets, and the creation of new open-source tools to help value set authors and users. Taken together these tools and techniques will improve clinical decision support and quality measurement, reduce alert fatigue and contribute to improvements in safety and quality.

Aim 1 involves studying value set creation processes, inventorying value set errors, and collecting value sets from provider organizations and the NLM Value Set Authority Center (VSAC). We will conduct a Rapid Assessment Process (RAP) via site visit to (1) map the processes and tools used at the site for creating value sets, (2) inventory value sets and associated CDS and CQMs at each site, (3) catalog value set errors, (4) identify how each value set error manifested itself in CDS and CQM malfunctions, (5) determine the cause of the value set failures using root cause analysis, and (6) identify data sources for machine learning in Aim 2.

Does your study fit into one or more of the listed categories of exemption (45 CFR 46.104)?

[ ] (d)(1) Research involving 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 such as: (1) Most research on regular and special education instructional strategies; or (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.
[**x**] **(d)(2) Research that only includes interaction involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following is met: (1) Information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained; or (2) Any disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk or; (3) The information obtained is recorded by the investigator in a manner that could identify the human subjects directly or through identifiers linked to the subjects.**
[ ] (d)(3): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met; (1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained; (2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk; or (3) The information obtained is recorded in a manner that could identify the human subjects directly or through identifiers linked to the subjects. Note: Children may not be included in research under this exemption.
[ ] (d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met: (1) The identifiable private information or biospecimens are publically available; or (2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or (3) The research involves only information, collection, and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA for the purposes of "health care operations" or "research", or for "public health activities and purposes" under HIPAA; or (4) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities.
[ ] (d)(5) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study public benefit or service programs for federally supported projects and most appropriately invoked with authorization by the funding agency, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or possible changes in methods or levels of payment for benefits or services under those programs.
[ ] (d)(6) or 21 CFR 56.104(d) Taste and food quality evaluation.
[ ] No category fits what I want to do.

Will you be recording or keeping any of the 18 HIPAA identifiers?

[ ] Yes
[**x**] **No**

Describe any procedures to be used during the study:

This aim of the study will employ a "rapid assessment process," or RAP. RAP allows teams to expeditiously gather, analyze, and interpret high quality ethnographic data. Compared to traditional ethnography, RAP streamlines the data collection, analysis, and interpretation processes, involves less time in the field, and provides timely feedback to internal stakeholders. RAP depends heavily on triangulation, which examines an issue by using multiple informants, data sources, perspectives, and data points to enhance the validity and reliability of both qualitative and quantitative data. Features of the RAP approach applied to value sets include: ● Develop data collection tools: Before the site visit, the team will develop a value set-oriented field manual, site profile, on-site surveys, and interview and observation guides. ● Gather preliminary data: Before the site visit takes place, the team will work with the liaison at the site to identify subjects to interview, gather artifacts (such as procedures, value set inventories, and software manuals), and receive demonstrations of the EHR software and value set authoring systems. ● Collect data during intensive site visit: During the site visits the team will collect data from interviews, field surveys, observations, documents collected from the field site, diagrams, photographs, and debriefings. The team will continually refine its data collection tools, identify new participant groups and observation sites, and write field notes immediately after observations and interviews. ● Analyze data quickly: Immediately after each site visit, the team will conduct rapid analysis, write a report for the site, and gather feedback from participants.

We will also conduct remote interviews with a purposive sample of 10-12 value set authors and stewards (including government agencies, government contractors, medical specialty societies, vendors, etc.), as well as 10 additional interviews of VSAC staff, clinical terminologists, terminology vendors, and EHR vendors, following the RAP process. Where appropriate, we may also request demonstrations of tools, or sample documents and procedures to review.

Will children be the subjects of your study?

[ ] Yes
[**x**] **No**

Recruitment

Describe the specific steps to be used to identify and/or contact prospective participants. (If applicable, also describe how you have access to lists of potential participants.)

We will use our site liaisons, including Dr. Wright at VUMC and Dr. Walsh for Memorial Hermann sites, to identify initial participants at each site and will snowball sample from these initial interviewees to ensure we are being inclusive of anyone who might work on value sets or in a related area. We have established relationships with our participating sites, and we are certain that we can successfully identify and recruit the intended subjects without issue. We plan to recruit 3-5 clinical leaders, 3-6 technical leaders, and 1-2 database administrators at each site for the rapid assessment. The RAP is meant to be quick but in-depth and efficient, and we intend to spend the 2-3 days at each site immersed in observations and interviews with relevant personnel that we hope to maintain contact with in the event that follow-up questions emerge as we move to the other Aims.

As part of Aim 1, we also intend to interview 10-12 value set stewards (including from government agencies, government contractors, medical specialty societies, vendors, etc.) and around 10 people who may work for the Value Set Authority Center, or are clinical terminologists, terminology vendors, and EHR vendors. These will be single, one-hour structured interview sessions, and our study team has relationships with many of the organizations we will recruit from, so recruitment is anticipated to go smoothly.

Identify the criteria for inclusion and exclusion and explain the procedures that will be used to determine eligibility. If psychiatric/psychological assessments will be conducted (e.g., depression or suicidal ideation screenings), state who will administer, his/her experience, and how risks will be managed.

We will include employees of participating study sites (VUMC, Memorial Hermann) who work in areas related to creation, maintenance, use, and governance of value sets and clinical decision support systems, including leadership. All clinical and informatics leaders, database administrators, and value set authors and stewards who are willing to participate in the study, may be selected for this study.

Exclusion: Those who do not work in areas related to creation, maintenance, use, and governance of value sets and CDS systems.

Describe how the selection of participants is equitable in relation to the research purpose and setting.

All eligible clinical and informatics leaders, database administrators, and value set authors and stewards who are willing to participate in the study, may be selected for this study.

Please indicate whether you plan to enroll any of the populations indicated below:

[ ] VU Medical Students/trainees
[ ] Students
[ ] Elderly/Aged - targeted
[**x**] **Subordinates/Employees**
[ ] Females of childbearing potential
[ ] Terminally ill participants
[ ] Healthy Volunteers
[ ] Other
[ ] Minorities

Please identify ALL applicable recruitment methods:

[ ] N/A
[ ] Flyers
[ ] Internet
[ ] Letter
[ ] Departmental Research Boards,
[ ] Mass E-mail Solicitation/Research Notifications Email Distribution List
[ ] Newspaper
[ ] Posters
[ ] ResearchMatch (IRB 090207)
[ ] Radio
[ ] Telephone
[ ] Television
[ ] Social Media
[ ] EHR-Based Recruitment
[ ] EMR Recruitment - Existing provider relationship
[**x**] **Other**

Please describe other:

Targeted email to specific informatics leaders, database administrators, and value set authors and stewards from the study team.

Will the study provide compensation to research participants? Please be advised, any resident of a country subject to U.S. comprehensive territorial sanctions or any person designated on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals list of prohibited individuals related to national security or foreign policy cannot accept any compensation for participation.

[ ] Yes
[**x**] **No**

Conflict of Interest Disclosure

Is there a potential conflict of interest for the Principal Investigator or key personnel? • The PI is responsible for assuring that no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research and no arrangement has been entered into where the amount of compensation will be affected by the outcome of the research. • Assessment should include anyone listed as Principal Investigator, or other research personnel on page 1 of this application. Please note that ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children). Do not consider the combined ownership of all investigators.

[ ] Yes
[**x**] **No**