Survey to collect data on EHR Recruitment Process and Methods at CTSA institutions

INTRODUCTION
The Methods and Process Domain Task Force has established a workgroup to examine best practices in leveraging the power of Electronic Health Records (EHR) to facilitate investigators' identifying and contacting potential participants for consenting and enrollment in clinical research. The objective is to identify and disseminate such practices through publications and the development of materials to support such efforts across the CTSA consortium. This survey is being conducted as a quality improvement initiative and has been reviewed by the UNC-CH IRB and determined to be Not Human Subjects Research. No individuals or institutions will be identified in reports without the expressed interest and engagement of investigators from the CTSA's involved.

You are strongly encouraged to engage others at your CTSA (recruitment, informatics and regulatory staff) or institution (clinical trials office, data warehouse) in responding to the survey. Please coordinate internally when completing the survey to ensure that only one survey per CTSA institution is submitted.

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1. Institution specific questions:

a. Name of institution

Other institution _____

b. Name(s) of person(s) completing survey, position/role, email

i. Name _____

i. role

◯ Informatics
◯ Recruitment
◯ Regulatory
◯ Other

i. email _____

ii. Name _____

ii. role

◯ Informatics
◯ Recruitment
◯ Regulatory
◯ Other

ii. email _____

iii. Name _____

iii. role

◯ Informatics
◯ Recruitment
◯ Regulatory
◯ Other

iii. email _____

c. What is the name or type of EHR program that is used at your institution/Hospital?

☐ Epic
☐ Cerner
☐ Home grown
☐ Other (please specify)

Other EHR name _____

SURVEY

Imagine that Dr. Lee, a researcher at your institution, would like to participate in a NIH sponsored multicenter trial randomizing patients with type 2 diabetes treated only with metformin to one of four second line medications. For this study, Dr. Lee would like to utilize your Electronic Health Record (EHR) or data warehouse to identify patients from across your health care system who have been diagnosed with Type 2 diabetes and are treated only with metformin (among anti-hyperglycemic medications) in order to invite them to participate. He has a long list of inclusion and exclusion criteria. Dr. Lee approaches you to learn more about what informatics practices/tools are available at your institution for his study. He thinks he will need to identify thousands of patients to recruit 150 successfully.

INFORMATICS PRACTICES / TOOLS

Considering the above example of an investigator seeking recruitment support, answer the following questions (2-5) about the informatics tools and practices available at your institution:

2. For each of the informatics practices and tools listed below (a-g), use the scale provided to identify the extent to which the practices or tools have been implemented at your institution:

Scale:

No plans - no plans to implement such a tool or practice, or not applicable.
Exploration - actively considering a change; the purpose of exploration is to assess the need and make a decision on whether to proceed (or not).
Planning - preparing for implementation. Resources are being expended on active preparation.
Initial Implementation - actively engaged in implementing and supporting the system, implemented in some areas, and testing of an implemented tool or practice.
Fully Operational - implementation completed; the practice or tool is staffed and fully operational; being used as accepted practice.

Informatics practices / tools that offer recruitment support:

	No plans	Exploration	Planning	Initial Implementatio	Fully Operational	Not sure/Not applicable
a. Use of EHR patient portal (e.g., Epic MyChart) to notify patients of research opportunity	○	○	○	○	○	○
b. Electronic alerts to care providers of patient in clinic meeting eligibility	○	○	○	○	○	○

c. Electronic alerts to research team team if patient in clinic meets eligibility	○	○	○	○	○	○
d. Access to Data Warehouse via a staff member / analyst for eligibility criteria queries	○	○	○	○	○	○
e. Use of self-service tools (e.g., i2b2) to run de-identified queries (counts of potential subjects)	○	○	○	○	○	○
f. Researchers given direct query access to data warehouse through business intelligence tools	○	○	○	○	○	○
g. Use of EHRs to build registries to aid in recruitment	○	○	○	○	○	○

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3. For each of the informatics practices and tools listed below (a-g), what is the demand for these practices or tools by investigators at your institutions:

Scale:

Never - Very Rarely - Rarely - Occasionally - Frequently - Very Frequently - Not Sure/Not Applicable

Informatics practices / tools that offer recruitment support:

	Never	Very Rarely	Rarely	Occasionally	Frequently	Very Frequently	Not Sure/Not Applicable
a. Use of EHR patient portal (e.g., Epic MyChart) to notify patients of research opportunity	○	○	○	○	○	○	○
b. Electronic alerts to care providers of patient in clinic meeting eligibility	○	○	○	○	○	○	○
c. Electronic alerts to research team team if patient in clinic meets eligibility	○	○	○	○	○	○	○
d. Access to Data Warehouse via a staff member / analyst for eligibility criteria queries	○	○	○	○	○	○	○
e. Use of self-service tools (e.g., i2b2) to run de-identified queries (counts of potential subjects)	○	○	○	○	○	○	○

f. Researchers given direct query access to data warehouse through business intelligence tools	◯	◯	◯	◯	◯	◯	◯
g. Use of EHRs to build registries to aid in recruitment	◯	◯	◯	◯	◯	◯	◯

Other EHR approaches and metrics

4. Are there other EHR informatics approaches to facilitate patient recruitment that you have considered, piloted or fully implemented at your institution?

◯ No
◯ Yes, but details are unavailable at this point
◯ Yes (describe below)

Other EHR approaches _____

5. Do you have metrics, tracking processes or evidence of impact of informatics tools / innovations on EHR based recruitment?

◯ No
◯ Yes, but details are unavailable at this point
◯ Yes (describe below)

Describe metrics process _____

REGULATORY and WORKFLOW

For his study of Type 2 diabetes, Dr. Lee also needs to learn more about the workflow process he should expect if he uses the EHR to aid in recruitment. A workflow process might include the following steps:

- Regulatory review and approval is obtained (i.e., IRB, HIPAA, Data Warehouse)
- Investigator works with informatics staff to generate a database of potential participants
- Select data elements are assessed to determine which patients meet inclusion / exclusion criteria
- Investigators reach out to patients or their providers to determine if they are interested in study participation

Please answer the following questions (6-10) based on the Regulatory Requirements and Workflow Process at your institution for investigators seeking EHR data for recruitment purposes.

6. Does your institution have one or more established workflow processes for cohort recruitment into clinical research, which leverages the power of EHR to identify large numbers of potential participants analogous to the above description of a workflow process?

◯ No (skip questions 7 & 8).
◯ Piloting such a program
◯ Yes.

If yes, provide any details or particular innovations that might be relevant to our workgroup's work. _____

7. Are there substantive restrictions of such workflow processes beyond regulatory reviews and approvals?

◯ No
◯ Yes

Please describe those restrictions _____

8. Are there different approaches to the above description of regulatory and workflow process either implemented or piloted at your institution?

◯ No
◯ Yes

Please describe those approaches _____

9. Are there other insights on using the EHR to facilitate research recruitment at your institution that might be useful for our committee to consider and potentially include in our "best practice" report?

◯ No
◯ Yes

Please describe other insights _____

10. Once the researcher receives the list of potential research participants, what recruitment practices are allowed at your institution, with IRB approval? (Check all that apply)

☐ Investigators are allowed to call potential participants directly
☐ Investigators are allowed to use the EHR to build a registry of potential participants for recruitment
☐ Investigators are allowed to contact patients who have opted in to an institutional research registry
☐ Investigators are allowed to contact patients unless the patients have opted out of institutional research communication
☐ Investigator contact with potential participants allowed only after introduction of PCP or clinic/practice
☐ Investigator allowed to approach potential participants in clinic who have been previously identified
☐ Contact with potential participants allowed only if researcher is an MD who works with the study population
☐ Letter or email may be sent to potential participants inviting them to the research study
☐ Letter may be sent from researcher if it provides an explanation about how s/he got the potential participant's name
☐ Other (specify) _____

Please specify _____

We asked you to respond to Questions 2-10 in the context of a particular hypothetical scenario, Dr. Lee's Type 2 diabetes study. Would any of your answers have been substantially different if:

11. Dr. Lee's study focused on a rare disease?

◯ No - my answers would still be the same
◯ Yes - one or more of my answers would be substantially different

Please describe briefly _____

12. Dr. Lee's study focused on cancer?

◯ No - my answers would still be the same
◯ Yes - one or more of my answers would be substantially different

Please describe briefly _____

13. Dr. Lee's study focused on pediatric conditions?

◯ No - my answers would still be the same
◯ Yes - one or more of my answers would be substantially different

Please describe briefly _____

14. Contact information

We would like to potentially contact you to obtain additional details concerning the processes in place at your institution. If you are willing to be contacted, please indicate here. Name:

_____

email: _____