

INSTITUTIONAL INTERVIEW GUIDE

Introduction

We are conducting this interview as part of the SCANNER research project. SCANNER stands for Scalable National Network for Effectiveness Research. Before investing in developing and implementing such a network to share patient clinical information for comparative effectiveness research across multiple institutions, we are relying on the expertise of people like yourself who work in the field to give us feedback on the challenges you face and requirements you have.

We are interested in 1) how you currently handle patient and clinical information for research as well as 2) your opinions and preferences for the use of a network for research purposes.

A. Interview Questions – All

1. Tell me about your role here.
2. In your role, how involved are you in privacy and security issues which include privacy of clinical or personal health information and security of systems that protect data.
 - a. Can you give me an example of how you have been involved with privacy and security issues?
[IF TECHNICAL SECURITY EXPERIENCE, GO TO SECURITY SECTION]
3. In your role, how involved are you in human subjects research? For example, are you or have you been a researcher, IRB or compliance committee member, administrator who sets policy governing research, responsible for systems or processes that researchers rely on to collect, analyze research data?
 - a. Can you give me an example of how you are usually involved with human subjects research?
[IF IRB EXPERIENCE, GO TO IRB SECTION]
4. What issues come to mind first for you in privacy of clinical or research data?
 - a. Probe for security if they haven't mentioned
 - b. Probe for privacy if they haven't mentioned of clinical research or data?
5. Now, thinking about information technology and how it is used to collect clinical or research data and share it electronically between institutions, do other issues around privacy and security come up for you?
 - a. Examples of technology for data collection might include mobile devices like cell phones, smart phones or tablets
 - b. Examples of electronically sharing data might be health information exchanges or peer to peer networks where one user can access data directly from another users's computer.

Now, I'd like to describe the SCANNER concept and hear your feedback on it.

The purpose of SCANNER is to build a trusted computer network that allows institutions to collect patient information from electronic health records and clinical data repositories and share it with others in the network to perform comparative effectiveness studies. The network would be governed by rules and policies agreed upon by the institutions in each particular research project. So, we will build it to allow the flexibility for each set of partners to set their own rules per project.

Given this description,

6. *Opinions and preferences regarding proposed privacy and security policies.* HANDOUT
 - a. What do you think about this? What is your first reaction?
 - b. What are the advantages and disadvantages of such a network?
 - c. What are the challenges, barriers to developing such a network?

[Place standup demo on table-front and back should be same picture]

I'm going to take you through a high level walk-through of how SCANNER might work. As I give you this tour, please share your thoughts at any point about:

- whether you or your facility would have specific requirements
- what issues arise for you
- [Stop after each page and reiterate the questions]

7. Portal, p. 1: Identity Management: How do you handle identity management? [Notes: In enterprise IT, identity management is about establishing and managing the roles and access privileges of individual network users. ID management systems provide IT managers with tools and technologies for controlling user access to critical information within an organization.]

8. User Multi-Factor Authentication, p. 4: What types of user authentication do you currently use? Do you have policies regarding what is allowed?

9. Data Request, p. 8: Do or your facility have specific requirements related to who is allowed access to particular data sets? How do you manage those requirements?

10. View & Download Data, p. 9: Do you or your facility have specific requirements related to viewing and downloading research data sets? Do any issues come to mind related to this?

11. Site and Global Results, p. 12. Do you or your facility have specific requirements related to analyzing shared research data sets? Do any issues come to mind related to this?

12. Data governance which encompasses the people, processes, and [information technology](#) required to create a consistent and proper handling of an organization's data across the business enterprise. Some organizations' goals for data governance might include:

- Decreasing the risk of regulatory fines
- Improving [data security](#)
- Designating accountability for information quality

13. Do you have any questions or comments after walking through this SCANNER demo?

In our last few questions I will ask you to think policies that SCANNER might need to implement. For these questions, please assume that your institution is a participating member of the network (which it is) that both contributes and uses research data from the network.

14. If this were your data being contributed to SCANNER for comparative effectiveness research, what would your concerns be, if any?
 - a. Given those concerns what would you expect SCANNER to do to protect your privacy?
 - b. Examples might be: auditing, tracking and monitoring access to data, who can have access, etc.
15. Who do you think should be able to be a member of SCANNER? You might think of members in terms of types of organizations, individuals, or roles.
16. Based on what you've heard about SCANNER today, are there any issues that you would like to raise? Is there anything else you want to discuss that we haven't already?

B. Additional Questions for IRB or Compliance

1. *IRB issues*
 - a. How would your IRB approval process be impacted in a project that shared data across a network such as SCANNER?
 - b. Have you had differences between partnering institutions' IRBs? If so, how did you manage those differences?
 - c. What should we be concerned about using data (outside of consent) from vulnerable populations or sensitive health information, e.g. secondary use
2. What information would you need from the partner institution's IRB protocol?
3. Tell me about IRB audits: who would be included, for example a partner institution, or for SCANNER, what type of documentation?
4. Tell me about Compliance audits: who would be included, for example a partner institution, or for SCANNER, what type of documentation?

C. Additional Questions for IT

1. What IT security standards do you have in place today? [Get copies if this is documented]
 - a. User Access
 - i. User Authentication
 - ii. Monitoring and audit
 - iii. Access control – based on identity, role, data content
 - iv. Patient matching verification
 - b. data center security audit or certification requirements
2. What do you want to know about the security of the other institutions with which you are sharing data?
3. How do you handle security of sensitive data?
 - c. Do you have preferred methods for de-identification or pseudonimization that you use in the institution today.

- d. How do you handle redaction of sensitive data from records, for example, meta-tagging sensitive data, excluding records with sensitive data, summarizing or transform it, excluding notes and unstructured text

Thank you for your time.