Appendix D. Hotline Site Visit Interview Protocol

Interviewee(s):

Interviewee(s) title and location:

Number to call if person is late or does not show:

Interviewee(s)' department (circle):

- 1. Implementation/operation of Health Care Safety Hotline (HCSH)
 - a. Director of Patient Safety/VP of Quality & Safety
 - b. Patient Safety Program Manager/point person to HCSH
- 2. Leadership/Governance
 - a. C Suite, CEO of hospital or health system, or board member
- 3. Quality and Safety for Medical Staff and/or Ambulatory Services
- 4. Marketing/Communications
- 5. Patient Relations and or Patient/Family Advisory Council members/VP Patient Experience
- 6. Legal/Risk Management
- 7. Human Subjects Protection

Clinic site location (circle):

XXX XXX

Date:

Time:

A. Introduction

Thank you for your time today. I am (introductions).

Facilitate introductions of the interviewee(s).

Ask if the interviewee(s) received the fact sheet and if they have any questions.

Review the purpose of the study (review fact sheet).

Explain the general purpose and format of the interview and the interviewee's role in this effort.

- 1. We are researchers from RAND, a nonprofit research institution, and from Tufts University and Brigham and Women's Hospital.
- 2. We are doing a research project funded by the Agency for Health Care Research and Policy (AHRQ), which is part of the federal government's Department of Health and Human Services.
- 3. The project is intended to learn about your organization's experiences with the Health Care Safety Hotline and how that may influence patients' experiences with health care.
- 4. We want to learn from you and your experiences in order to improve the current hotline and recommend lessons for other organizations that may want to implement a similar hotline in the future.
- 5. The discussion should take about 45 minutes. If you need to take a break at any time, please let us know.
- 6. Data will be reported so that neither you nor your organization can be identified. We will be aggregating the interviews across the pilot communities and reporting the information in aggregate form.
- 7. Your participation is voluntary, and you can decline to discuss any topic that we raise. Your names were provided to us today by your health care organization; however, we will not be reporting your participation to anyone outside of the research team.
- 8. We would like to record this discussion for note-taking purpose only. We will destroy the tape as soon as the notes have been completed. You do not have to agree to be taped; you can still participate in this conversation if you do not want to be taped.

May we record this discussion? (Circle: YES NO) \rightarrow *Turn on recorder*.

B. Background

- 1. For the record, can you please state your name and that you have consented to the interview?
- 2. What is your job within *[name of org]* and what role, if any, do you play in monitoring and/or improving patient safety?
- 3. What has been your involvement in the Health Care Safety Hotline so far, if any?

C. Decision to participate in the pilot

1. We want to learn a bit about how your organization decided to participate in the hotline pilot project. First, can you tell how you were involved in the decision to participate, if at all? [*If not involved, SKIP to Question 3.*]

Probe: What was your level of involvement in the decision to participate? Peripheral? Central?

2. OK, so now can you describe the process that *[name of org]* went through in deciding whether or not to participate? Please tell us about the people involved and the factors that were considered.

Probe: Who else was involved in making the decision to participate? When did they get involved? Who had to "sign off" on the decision?

Probe: Was there a champion?

Probe: What factors were considered in the decision process?

Probe: What pluses and minuses (or advantages and disadvantages) were perceived in the decision process?

Probe: [ASK EVERYONE BUT ESPECIALLY RISK MANAGEMENT] What about involving legal or risk management? Can you tell us anything about what risks were identified? Any concerns that emerged?

- 3. Were there any major "sticking points" or concerns that had to be overcome, before *[name of org]* decided to move forward with participating in the pilot?
- 4. So clearly, those sticking points were overcome. In the end, what would you say were the one or two primary motivators for deciding to participate in this pilot?

[Probe for both internal (e.g., reputation in the community) and external (pressures) factors. Come up with better terms.]

- 5. Thinking of your role as *[xxx]*, we are specifically interested in your view about the pluses and minuses in the decision to participate in the hotline. Can you tell us about your thoughts?
- 6. Was there anything unusual about how your organization decided to participate in the project, compared to how the organization usually decides to participate in other quality improvement or safety projects?

7. Here at *[name of org]*, you decided to limit the hotline to *[abc]* [see table below] and not include *[xyz]*. What factors were considered in that decision process?

ASK HUMAN-SUBJECTS PROTECTION OFFICE RESPONDENTS ONLY:

8. Can you tell us anything about how your IRB or human-subjects committee was involved? What was the process like for determining whether this project was quality improvement or research?

PROBE: Would the Human-Subjects Protection Office consider the project to be quality improvement if there was no evaluation component?

- D. "Pre-launch" period (from the decision to participate until February 2014)
 - 1. Let's talk for a bit about the time that we call "pre-launch," that is, between when *[name of org]* agreed to participate in the pilot and the actual launch in February 2014. How were you involved in this pre-launch period, if at all? **[Skip if not involved.]**
 - 2. In what department or group within your organization did responsibility for the prelaunch sit?
 - 3. What was the plan for the rollout?
 - 4. Within your unit, what kind of resources, support, or direction did you need to prepare to launch the pilot? What did you receive? What didn't you receive?
 - 5. Now let's talk about what you and your staff had to do to get ready for the launch. What were the biggest tasks or challenges that you and your staff faced?

Probe: Were these expected or unexpected?

Probe: What resources and support were needed vs. supplied?

Probe: Can you tell me about how participating in the hotline affected your unit's fiscal year budget? Did you have to reallocate funds from other projects?

- 6. Thinking about the organization as a whole, what about the things that *[name of org]* had to do to get ready for the launch. What were the biggest tasks or challenges the organization faced?
- 7. Now please tell us, from the perspective of your own unit, what challenges did you face that were different from the tasks or challenges that you just mentioned?

Probe for hospital, ambulatory, pharmacy.

Probe: Were these expected or unexpected?

E. Post-launch

OK, thank you for telling us about the pre-launch period. Now let's talk about how the pilot has gone since its launch, that is, the "post-launch" period.

1. For starters, how has it gone so far?

Probe: What are the biggest strengths or successes of the program so far? We also want to know about the weaknesses. It might help to think about this like a SWOT (strengths, weaknesses, opportunities, threats) analysis.

[Probes: Have you experienced any problems or issues that you had to work through?

- Any glitches on launch day
- Barriers to patients using the system
- Barriers to implementation or operation
- Barriers to marketing the HCSH
 - 2. What problems do you foresee going forward?
 - 3. Think back to the pluses and minuses that were considered during the decision to participate. Have your perceptions of the pluses and minuses changed since the decision to participate? If yes, how?

F. Reaction to the hotline within the organization

We now want to understand how the hotline has been received in *[name of org]*. Let's start by asking you about whether you think people in *[name of org]* are aware of the program?

- 1. How were employees and staff notified? Do you believe that most clinicians are adequately aware of the program?
- What has been the main reaction to participation in the hotline by hospital staff? Here is a list. Can you indicate whether they are generally positive or negative about the hotline?
 [Probe for reasons why for each group below. Mark "Not applicable" as needed.]
 - Physicians
 - Other clinical staff, including nurses
 - Pharmacy
 - Leadership such as the board or C-suite
 - Patients
 - Anyone else I missed?

3. To your knowledge, has *[name of site]* received any safety reports through the hotline? If yes, what happened? If no, what will happen?

Probe: have there been any glitches that we should know about?

G. [OPERATIONS ONLY]: Responding to hotline reports/ linking with other systems

- 1. How well does the hotline complement other existing safety reporting systems? Is it augmenting your ability to collect important information or is it redundant? (Or do you not know? Or is it too early to tell?)
- 2. How are you organizing the process of receiving reports from the hotline and responding to the reports?

Probe: How are the reports triaged?

- 3. How are the patient-relations department at the hospital and the physicians at ambulatory sites or pharmacies involved in reviewing the reports?
- 4. How do you handle patient-provided reports differently from reports that come from the Joint Commission or the state health department?

H. Lessons and advice

- 1. Are there aspects of the hotline that you would have preferred to be different in order to facilitate the integration of the pilot into your health system? Think about things like the culture, preferences, and current work styles and practices.
- 2. What advice would you give to another health system like yours about implementing the HCSH? What lessons have you learned so far that could be useful for others?
- 3. From what you know as of today, including what you could have done differently, how encouraging or discouraging would you be to other organizations thinking about starting a hotline?

[USE HANDOUT TO GAIN ANSWERS FROM EACH PARTICIPANT]

NAME: ____

[CIRCLE RESPONSE]

Very encouraging Somewhat encouraging Neutral Somewhat discouraging Very discouraging

NAME: ____

[CIRCLE RESPONSE]

Very encouraging Somewhat encouraging Neutral Somewhat discouraging Very discouraging

NAME: ____

[CIRCLE RESPONSE]

Very encouraging Somewhat encouraging Neutral Somewhat discouraging Very discouraging

ASK RISK MANAGEMENT, LEGAL, AND HUMAN-SUBJECTS RESPONDENTS ONLY:

4. Knowing what you know now about the risks, legal environment, and privacy issues, and once the research study is over, how would you recommend the hotline be structured in the future?

FOR EXAMPLE: Run out of a Patient Safety Organization?

A different type of organization?

A government agency or organization?

A not-for-profit or for-profit organization?

[Probes: What benefits and drawbacks might each of these have?]

I. Conclusion/followup

1. Thinking back about all the things you've told us, are there any areas that we failed to cover or important questions that we should have asked?

- 2. Are there any other ways that you believe the HCSH pilot will affect the organization, its patients, and providers either positively or negatively?
- 3. If you were going to summarize the most important points of our discussion today that relate to implementation of a safety hotline, what would they be?

Thank you for your time.