OMB Control No. – 0693-0043 – NIST Generic Clearance for Usability Data Collections

Project title: Study of Electronic Health Record Usability PART 2 – Structured EHR Usability Interviews

FOUR STANDARD SURVEY QUESTIONS

1. Explain who will be surveyed and why the group is appropriate to survey.

The Information Technology Laboratory (ITL) of the National Institutes of Standards (NIST), will be working with participants consisting of clinical staff (e.g., physicians, nurses and radiology technicians) and non-clinical staff (e.g., hospital unit clerks) at study sites who interact directly with electronic health record (EHR) systems as part of their professional duties within one of the research sites. ITL will select research sites based on the EHR system that they use, their geographic location, and their availability to participate in the research study. Specifically, ITL aim to recruit a sample of research sites that use a variety of EHR vendors and at locations within close proximity to the research team's locations. ITL will recruit participants and remind them about the research opportunity via mass communication (i.e., recruitment posters and emails). Copies of the e-mail invitation and recruitment posted have been uploaded into ROCIS. Participation in this study will be open to all individuals, regardless of race, ethnicity, gender, or other personal characteristics. The aim of the recruitment strategy is inclusiveness and no EHR user will be denied the opportunity to participate as long as enrollment is open. The enrollment period will extend from TBD to May 27, 2012. This group is appropriate to survey because they will provide us with the necessary information to understand how individuals across a variety of professions and institutions use EHR systems.

2. Explain how the survey was developed including consultation with interested parties, pre-testing, and responses to suggestions for improvement.

The survey methodology was developed by the contractors and subcontractors in consultation with the team from the National Institute for Standards and Technology (NIST). Key personnel from the contracting organization, Wiklund Research & Design (WR&D), developed the first draft of the survey. WR&D sent the survey via email to the subcontracting organizations (Vanderbilt University, Design Science and University of Wisconsin) for review and comments. All subcontractors were given approximately two weeks to submit comments to WR&D. WR&D incorporated the subcontractors' suggestions for improvement and provided NIST with a draft for feedback. The final draft of the survey reflects the feedback that WR&D received from NIST. Notably, all of the suggestions for improvement were incorporated into the document.

While WR&D did not conduct formal pre-testing of the survey questions and methodology,

several of the subcontractors are clinicians who interact directly with EHR systems and could assess the appropriateness of the survey as qualified participants. Moreover, the contractors and subcontractors developed the survey based on materials from previous usability studies that had proved to be an effective means to obtain information about users' interactions with health information technology (HIT).

3. Explain how the survey will be conducted, how customers will be sampled if fewer than all customers will be surveyed, expected response rate, and actions your agency plans to take to improve the response rate.

The prime- and sub-contractors will conduct structured usability interviews to understand how end-users interact with EHR systems to accomplish clinical and non-clinical tasks. Users of EHR systems will be invited to participate in a usability interview at their convenience via recruitment posters and emails. Depending on the goals of the structured interview, the role of the participant, and the participant's experience with EHR, the interview will consist of the usability data collection questions (*filename: Structured usability interview questions*). The structured usability interview will be audio recorded. ITL will obtain written informed consent from the participant to conduct the interview and audio record the session. Each structured usability interview will last up to 75 minutes. The research staff (no more than 2 interviewers) will take notes during the structured usability interview. General demographic information but not user identity will be collected. NO identifying information about EHR users or patients, or patients' protected health information (PHI) will be captured.

Data Management: Structured usability interview responses will be audio recorded and transcribed. Once the transcription has been reviewed and edited, the audio recording will be destroyed. The transcription and electronic versions of the researchers' notes will be stored in a secure electronic database. All structured usability interview data will undergo a cleaning process to ensure both respondent and affiliated institution anonymity and confidentiality. For example, participant's narrative responses will be reviewed and edited by authorized research project staff to remove any participant or patient names or other identifying text (e.g., patient's PHI).

NIST will *not* have access to any of the raw data. Instead, the prime- and sub-contractors' will analyze the accumulated narrative data to create Summary Reports that are completely devoid of identifying information or characteristics. Only the Summary Reports will be provided to *anyone* outside the research team. Therefore, NIST will never possess any information that is traceable to individual participants, specific commercial vendors, or specific healthcare entities.

The research team (Wiklund Research & Design and members of the subcontracting organizations) expects that approximately 90% of recruited participants will attend his/her scheduled structured interview session. ITL will attempt to improve the response rate by recruiting 10% more participants than our target sample size at each research site. ITL will

use validated survey design approaches to tailor the content of surveys (e.g., length) to optimize response rates (D.A. Dillman, 2008, Mail and Internet Surveys: The Tailored Design Method; Wiley: Hoboken, NJ).

4. Describe how the results of the survey will be analyzed and used to generalize the results to the entire customer population.

The research team will collate and integrate descriptive data with coded qualitative findings from all participants. ITL will analyze the results by looking for trends in the data overall and across different clinical roles (e.g., physician, nurse, resident, administrative secretary) and departments/facility types (e.g., intensive care unit, clinic, emergency room). Based on the observed data trends, ITL will develop a narrative description of user characteristics, use environments, EHR-related tasks, functions, goals, and best practices. ITL will measure associations between variables (e.g., between amount of EHR use and satisfaction with EHR). The findings yielded from this survey will help inform continuing research, guidelines, and policy. The results will generalize to the entire population of EHR users to the extent a representative sample of users can be obtained. In cases where the data cannot be generalized to the entire EHR user population, they may be generalized to specific EHR user groups (e.g., most common tasks performed by EHR users in intensive care units).