



2184 Morris Ave, Union, NJ 07083

<http://www.DigiDMS.com>

support@DigiDMS.com

Phone: 908.688.8810, Fax: 877.733.4305

EHR Usability Test Report of DigiDMS EHR Version 19.0

*Report based on ISO/IEC 25062:2006 Common Industry Format for
Usability Test Reports*

DigiDMS EHR 19.0

Date of Usability Test: September 1st, 2018
Date of Report: Tuesday September 4, 2018
Report Prepared by: DigiDMS Inc.
Tushar Desai, Director
(413) 822-9340
Tushar@DigiDMS.com
2184 Morris Ave,
Union, NJ 07083

Contents

EXECUTIVE SUMMARY	5
INTRODUCTION	11
METHOD.....	11
PARTICIPANTS	11
STUDY DESIGN	13
TASKS	14
PROCEDURES.....	16
TEST LOCATION	17
TEST ENVIRONMENT.....	17
TEST FORMS AND TOOLS	17
PARTICIPANT INSTRUCTIONS.....	18
USABILITY METRICS.....	18
DATA SCORING.....	19
RESULTS	21
DATA ANALYSIS AND REPORTING	21
DISCUSSION OF THE FINDINGS	26
APPENDICES	28

Preface

About this Document

This document demonstrates that user-centered design (UCD) process(es) were applied to all of the safety-enhanced design referenced certification criterion for which corresponding capabilities are being presented for certification.

This Document explains Test procedure for Certification Criteria;
§170.315(g)(3) Safety-enhanced design.

This document focuses on requirement of User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria:

- § 170.315 (a)(1) Computerized Provider Order Entry (CPOE) – medications
- § 170.315 (a)(2) CPOE – laboratory
- § 170.315 (a)(3) CPOE – diagnostic imaging
- § 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE
- § 170.315 (a)(5) Demographics
- § 170.315 (a)(6) Problem List
- § 170.315 (a)(7) Medication List
- § 170.315 (a)(8) Medication Allergy List
- § 170.315 (a)(9) Clinical Decision Support
- § 170.315 (a)(14) Implantable Device List
- § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
- § 170.315 (b)(3) Electronic Prescribing

Document Owner: DigiDMS, Inc.

Target Audience

The document is intended for DigiDMS Inc. employees and ONC- Authorized Certification Body (ACB) and Authorized Test Lab (ATL) Body.

Assumptions

Not Available

Contact Information

DigiDMS, Inc.
2184 Morris Ave,
Union, NJ-07083
Ph: (877)-1.866DGDMS,
(908)-688-8810
Fax: (877) - 733 - 4305

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EXECUTIVE SUMMARY

A usability test of DigiDMS EHR product, version 19.0, Ambulatory EHR was conducted on Saturday September 1st, 2018 in Union, NJ by DigiDMS, Inc using online meeting tool 'WebEx'. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR under Test (EHRUT). During the usability test, 8 healthcare providers, 2 Medical Assistants and 2 Practice Manager matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 12 tasks typically conducted on an EHR;

- § 170.315 (a)(1) CPOE – medications
- § 170.315 (a)(2) CPOE – laboratory
- § 170.315 (a)(3) CPOE – diagnostic imaging
- § 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE
- § 170.315 (a)(5) Demographics
- § 170.315 (a)(6) Problem List
- § 170.315 (a)(7) Medication List
- § 170.315 (a)(8) Medication Allergy List
- § 170.315 (a)(9) Clinical Decision Support
- § 170.315 (a)(14) Implantable Device List
- § 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
- § 170.315 (b)(3) Electronic Prescribing

During the 60 Minutes one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form; they were instructed that they could withdraw at any time. Most of the Participants had prior experience with the EHR and few participants did not have prior experience with the EHR. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data electronically. The administrator did not give the participant assistance in how to complete the task during live test of each task.

Participant screens recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and type of errors
- Path deviations
- Participant's verbalizations
- Participant's satisfaction ratings of the system

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire, system usability scale questionnaire. None of the participants were compensated with for their time. Various recommended metrics, in accordance with the examples set forth in the NIST Guide to the process, Approach for improving the usability of Electronic Health Records, were used to evaluate the usability of the **DigiDMS EHR 19.0**.

Following is a summary of the performance and rating data collected on the **DigiDMS EHR 19.0**.

Task\ Measure	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5 = Very Easy Likert Scale
	#	Mean (SD)%	Deviations (Observed/Optimal)	Mean (SD)	Deviations (Observed/Optimal)	Mean (SD)%	Mean (SD)
§ 170.315 (a)(5) Demographics							
Record new patient's with preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	11	90.90% (0.30)	14/10	60 (22.60)	60/30	9.09% (0.30)	4.75 (0.45)
Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity,	11	100% (0)	3/3	40 (10.80)	40/20	0% (0)	4.75 (0.45)
Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	11	100% (0)	2/2	20 (7.65)	20/10	0% (0)	4.75 (0.45)
§ 170.315 (a)(6) Problem List							
Record a problem to the problem list	12	91.66% (0.28)	10/9	55 (10.80)	55/25	8.3% (0.28)	5 (0)
Change a problem on the problem list	12	100% (0)	4/3	20 (4.05)	20/8	0% (0)	5 (0)
Display the active problem list	12	100% (0)	1/1	8 (1.15)	8/6	0% (0)	5 (0)
Display the historical problem list	12	100% (0)	1/1	8 (1.49)	8/6	0% (0)	5 (0)
§ 170.315 (a)(8) Medication Allergy List							
Record a medication allergy	11	100% (0)	9/9	30 (5.07)	30/25	0% (0)	4.83 (0.38)
Change a medication allergy	11	100% (0)	3/3	8 (1.6)	8/8	0% (0)	4.83 (0.38)

Display the active medication allergy list	11	100% (0)	1/1	6 (1)	6/6	0% (0)	4.83 (0.38)
Display the historical medication allergy list	11	100% (0)	1/1	6 (0.75)	6/6	0% (0)	4.83 (0.38)
§ 170.315 (a)(7) Medication List							
Record a medication to the medication list	12	83.33 % (0.38)	20/18	60 (11.67)	60/40	16.6% (0.38)	4 (0.85)
Change a medication on the medication list	12	100% (0)	6/6	20 (5.29)	20/10	0% (0)	4 (0.85)
Display the active medication list	12	100% (0)	2/1	11 (3.21)	11/5	0% (0)	4 (0.85)
Display the historical medication list	12	100% (0)	1/1	10 (2.6)	10/5	0% (0)	4 (0.85)
§ 170.315 (b)(3) Electronic Prescribing							
Create new prescription	12	75% (0.45)	40/30	100 (7.9)	100/90	25% (0.45)	4 (0.73)
Change prescription (dosage or duration)	12	100% (0)	10/10	60 (11.67)	60/20	0% (0)	4 (0.73)
Cancel prescription	12	100% (0)	5/5	12 (1.27)	12/10	0% (0)	4 (0.73)
Refill prescription	12	100% (0)	6/6	10 (2.6)	10/10	0% (0)	4 (0.73)
Receive fill status notification	12	100% (0)	3/3	10 (2.6)	10/10	0% (0)	4 (0.73)
Request and receive medication history information	12	100% (0)	5/4	15 (0.95)	15/10	0% (0)	4 (0.73)
§ 170.315 (a)(1) CPOE – medications							
Record medication via CPOE	12	75% (0.45)	40/30	100 (7.9)	100/90	25% (0.45)	4 (0.73)
Change medication via CPOE	12	100% (0)	10/10	60 (11.67)	60/20	0% (0)	4 (0.73)
Display changed CPOE medication order	12	100% (0)	9/7	14 (2.33)	14/10	0% (0)	4 (0.73)
§ 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE							
Using CPOE, trigger a drug-drug interaction by entering a new medication order	12	100% (0)	40/30	100 (7.9)	100/90	0% (0)	4 (0.73)
Using CPOE, trigger a drug-allergy interaction by entering a new medication order	12	100% (0)	40/30	100 (7.9)	100/90	0% (0)	4 (0.73)

Adjust the severity level of a displayed drug-drug interaction	12	100% (0)	6/6	14 (2.33)	14/10	0% (0)	4 (0.73)
§ 170.315 (a)(2) CPOE – laboratory							
Record Lab order via CPOE	12	100% (0)	10/10	40 (9.81)	40/35	0% (0)	4.25 (0.45)
Change Lab order via CPOE	12	100% (0)	2/2	15 (2.66)	15/10	0% (0)	4.25 (0.45)
Display changed CPOE Lab order	12	100% (0)	1/1	6 (0.51)	6/5	0% (0)	4.25 (0.45)
§ 170.315 (a)(3) CPOE – diagnostic imaging							
Record Imaging order via CPOE	12	100% (0)	10/8	40 (5.40)	40/35	0% (0)	4.75 (0.45)
Change Imaging order via CPOE	12	100% (0)	4/4	10 (2.6)	10/10	0% (0)	4.75 (0.45)
Display changed CPOE Imaging order	12	100% (0)	1/1	8 (1.15)	8/5	0% (0)	4.75 (0.45)
§ 170.315 (a)(14) Implantable Device List							
Record UDI	12	100% (0)	10/7	20 (4.05)	20/15	0% (0)	4.75 (0.62)
Change UDI Status	12	100% (0)	6/4	15 (0.95)	15/10	0% (0)	4.75 (0.62)
Access UDI, device description, identifiers, and attributes	12	100% (0)	1/1	5 (0.42)	5/5	0% (0)	4.75 (0.62)
§ 170.315 (b)(2) Clinical Information Reconciliation and Incorporation							
Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient’s record	12	75% (0.45)	28/25	48 (4.53)	48/40	25% (0.45)	4.08 (0.66)
Generate a new CCDA with reconciled data	12	100% (0)	12/10	30 (4.86)	30/20	0% (0)	4.08 (0.66)
§ 170.315 (a)(9) Clinical Decision Support							

<p>Reference resource for each of the required elements</p> <ul style="list-style-type: none"> - Problem list - Medication list - Medication Allergy List - At least one Demographic - Laboratory Test - Vital Signs - And a combination of at least 2 of the elements listed above 	12	91.66% (0.28)	11/4	52 (27.9)	52/30	8.33% (0.28)	4.5 (0.52)
<p>Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements</p>	12	100% (0)	10/9	55 (10.80)	55/25	0% (0)	5 (0)
<p>View the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics</p>	12	100% (0)	11/4	52 (27.9)	52/30	0% (0)	4.5 (0.52)
<p>Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary</p>	12	100% (0)	28/25	48 (4.53)	48/40	0% (0)	4.08 (0.66)

Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date	12	100% (0)	11/4	52 (27.9)	52/30	0% (0)	4.5 (0.52)
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Table 1: Summary of Performance and Rating

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: **91.04**

In addition to the performance data, the following qualitative observations were made:

- Major findings
 - o Test environment was slow otherwise participants agreed to have shown much better performance
 - o No major errors or deviations found by any of the participants.
- Areas for improvement
 - o No feedbacks were given by participants for areas for improvement and they raised their support for existing flow without any change.

INTRODUCTION

The EHRUT(s) tested for this study was **DigiDMS EHR 19.0**. DigiDMS EHR is designed to present medical information to healthcare providers in Ambulatory care and multispecialty. The EHRUT consists of Ambulatory workflow for mainly three areas of ambulatory clinic: Front Desk, Clinical and Billing. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, such as Number of Participants per task, Task Success, Path Deviation. Task Time Mean (SD) and Task Time Deviations, Errors and Task Ratings were captured and created. System Usability scale matrix was captured and SUS ratings were calculated.

METHOD

PARTICIPANTS

A total of 12 participants were tested on the **DigiDMS EHR 19.0**. Participants in the test were different specialty healthcare providers such as internal medicine, pediatric, cardiologist,

hematology and oncology and pain management. Participants were selected by DigiDMS and each participant volunteered for test event participation. None of the participants were provided compensation for their time. Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received.

For the test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants;

Recruited participants had a mix of backgrounds and demographic characteristics conforming to participant screener. The following is a table of participants by characteristics, including demographics, professional experience, computing experience and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual’s data cannot be tied back to individual identities.

Part. ID	Gender	Age	Education	Occupation Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needs
SEDUSER01	F	60-69	Doctorate degree	Physician	30	10	10	NO
SEDUSER02	M	50-59	Doctorate degree	Physician	17	17	17	NO
SEDUSER03	F	40-49	Doctorate degree	Physician	09	09	09	NO
SEDUSER04	M	60-69	Doctorate degree	Physician	29	15	15	NO
SEDUSER05	F	50-59	High school graduate, diploma or the equivalent	Practice Manager	15	20	02	NO
SEDUSER06	M	60-69	Doctorate degree	Physician	40	30	05	NO
SEDUSER07	F	60-69	Doctorate degree	Practice Assistant Manager	13	20	05	NO
SEDUSER08	M	50-59	Doctorate degree	Physician	24	24	10	NO
SEDUSER09	F	40-49	Doctorate degree	Physician	36	20	10	NO
SEDUSER10	M	60-69	Doctorate degree	Physician	23	20	06	NO

SEDUSER11	M	50-59	Master's degree	Practice Manager	09	09	10	NO
SEDUSER12	M	60-69	Master's degree	Medical Assistant	09	09	02	YES

Table 2: Participants Details

Total 12 participants were recruited and all participants were able to show up and participated in the usability test.

Participants were scheduled for 60-minute sessions with average 5-10 minutes in between each session for debrief by the administrator and data loggers, and to reset systems to proper test condition. A spreadsheet was used to keep track of the participant schedule, and included each participant's demographic characteristics. Event was also debriefed in the beginning for 15 minutes.

STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, participants interacted with only DigiDMS EHR. Each participant used the system from different location but on same hosted solution, and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

Additional information about the various measures can be found in the Usability Metrics section.

TASKS

A total of 10 tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Patient Demographics (170.315 (a)(5))
 - a. Record new patient's with preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity
 - b. Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity,
 - c. Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity

2. Problem List (170.315 (a)(6))
 - a. Record a problem to the problem list
 - b. Change a problem on the problem list
 - c. Display the active problem list
 - d. Display the historical problem list

3. Allergy List (170.315 (a)(8))
 - a. Record a medication allergy
 - b. Change a medication allergy
 - c. Display the active medication allergy list
 - d. Display the historical medication allergy list

4. Medication List (170.315 (a)(7))
 - Record a medication to the medication list
 - Change a medication on the medication list
 - Display the active medication list
 - Display the historical medication list

5. Electronic Prescribing
 - a. Create new prescription
 - b. Change prescription (dosage or duration)
 - c. Cancel prescription
 - d. Refill prescription
 - e. Receive fill status notification
 - f. Request and receive medication history information

6. CPOE Medication (170.315 (a)(1))
 - a. Record medication via CPOE
 - b. Change medication via CPOE
 - c. Display changed CPOE medication order

7. Drug-drug, Drug-allergy Interaction Checks for CPOE (170.315 (a)(4))
 - a. Using CPOE, trigger a drug-drug interaction by entering a new medication order
 - b. Using CPOE, trigger a drug-allergy interaction by entering a new medication order
 - c. Adjust the severity level of a displayed drug-drug interaction

8. CPOE Lab Order (170.315 (a)(2))
 - a. Record Lab order via CPOE
 - b. Change Lab order via CPOE
 - c. Display changed CPOE Lab order

9. CPOE Diagnostic Imaging Order (170.315 (a)(3))
 - a. Record Imaging order via CPOE
 - b. Change Imaging order via CPOE
 - c. Display changed CPOE Imaging order

10. Implantable Device List (170.315 (a)(14))
 - a. Record UDI
 - b. Change UDI Status
 - c. Access UDI, device description, identifiers, and attributes.

11. Clinical Information Reconciliation (170.315 (b)(2))
 - a. Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient's record
 - b. Generate a new CCDA with reconciled data

12. Clinical Decision support Instructions
 - a. Reference resource for each of the required elements
 - i. Problem list
 - ii. Medication list
 - iii. Medication Allergy List
 - iv. At least one Demographic
 - v. Laboratory Test
 - vi. Vital Signs
 - vii. And a combination of at least 2 of the elements listed above
 - b. Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements
 - c. View the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics
 - d. Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary

- e. Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date

Tasks were selected as recommended by study objectives defined by NIST

PROCEDURES

Upon arrival, participants were greeted; their identity were verified and matched with a name on the participant schedule. Participants were then assigned a participant ID. Each participant reviewed and signed an informed consent and release form. A representative from the test team witnessed the participant's signature.

To ensure that the test ran smoothly, three staff members participated in this test, the usability administrator and the logger. The usability testing staff conducting the test was experienced usability practitioners with 5 to 30 years of experience, Medical, Post Graduate and Graduate backgrounds.

The administrator moderated the session including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Participants were instructed to perform the tasks;

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task.

Following the session, the administrator gave the participant the post-test questionnaire (e.g., The System Usability Scale), compensated them for their time and thanked each individual for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet. Participants were thanked for their time.

TEST LOCATION

The test facility included a waiting area and a quiet testing room with a table, computer for the participant, and recording computer for the administrator. Many other participants did join using online meeting tool 'WebEx'. All observers and the data logger worked from a separate location. Data logger assured all screen recording is happening by checking each terminal used by remote as well as local participants/ To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

The **DigiDMS EHR 19.0** would be typically be used in a healthcare office or facility. In this instance, the testing was conducted in healthcare service facility as well as Healthcare clinics. For testing, "Remote Desktop Connection" software was used in order to connect with hosting server with windows server 2012 R2 operating system in order to provide same environment to all participants. The participants used mouse and keyboard when interacting with the **DigiDMS EHR 19.0**.

The EHRUT used Remote Desktop Connection tool and configured to match full screen resolution of participant's computer, Color settings were selected as 32 bit (Highest Quality). The application was set up by the DigiDMS according to the documentation describing the system set-up and preparation. The application itself was running on a windows platform, operating system: windows server 2012 R2, using a test database on LAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings and participate with configured settings.

TEST FORMS AND TOOLS

During the usability test, various documents and instruments were used, including:

1. Informed Consent
2. Non-Disclosure Agreement
3. Instructions for Participants
4. Post-test Questionnaire
5. System Usability Scale Questionnaire

The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. The test session were electronically transmitted to a data logger where the data logger observed the test session.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to the each participant

Thank you for participating in this study. Your input is very important. Our session today will last about 60 minutes. During that time you will use an instance of an electronic health record. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.

Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary you are able to withdraw at any time during the testing.

Following the procedural instructions, participants were shown the EHR and as their first task, were given time 10 minutes to explore the system and make comments. Once this task was complete, the administrator gave the following instructions:

For each task, I will read the description and instruction to you and I will raise poll which will end as per time associated with task. After task completion, I will raise another poll which will collect data and feedback of each participant. I would like to request that you not talk aloud or verbalize while you are doing the tasks.

Participants were then given 10 tasks to complete.

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to assess:

1. Effectiveness of **DigiDMS EHR 19.0** by measuring participant success rates and errors
2. Efficiency of **DigiDMS EHR 19.0** by measuring the average task time and path deviations
3. Satisfaction with **DigiDMS EHR 19.0** by measuring ease of use ratings

DATA SCORING

The following table details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p>	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.</p> <p>Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator’s Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.25] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [x] seconds then allotted task time performance was [x * 1.25] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.</p>
<p>Effectiveness: Task Failures</p>	<p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an “Failures.” No task times were taken for errors.</p> <p>The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors.</p> <p>This should also be expressed as the mean number of failed tasks per participant.</p> <p>On a qualitative level, an enumeration of errors and error types should be collected.</p>

<p>Efficiency: Task Deviations</p>	<p>The participant’s path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks</p>
<p>Efficiency: Task Time</p>	<p>Each task was timed from when the administrator said “Begin” until the participant said, “Done.” If he or she failed to say “Done,” the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.</p>
<p>Satisfaction: Task Rating</p>	<p>Participant’s subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate “Overall, this task was:” on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. 12 Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants’ confidence in and likeability of the [EHRUT] overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, “I think I would like to use this system frequently,” “I thought the system was easy to use,” and “I would imagine that most people would learn to use this system very quickly.” See full System Usability Score questionnaire in Appendix 5.13</p>

Table 3: Details of how data were scored

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Participants who failed to follow session and task instructions had their data excluded from the analyses.

Task\ Measure	N	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5 = Very Easy Likert Scale
	#	Mean (SD)%	Deviations (Observed/Optimal)	Mean (SD)	Deviations (Observed/Optimal)	Mean (SD)%	Mean (SD)
§ 170.315 (a)(5) Demographics							
Record new patient's with preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	11	90.90% (0.30)	14/10	60 (22.60)	60/30	9.09% (0.30)	4.75 (0.45)
Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity,	11	100% (0)	3/3	40 (10.80)	40/20	0% (0)	4.75 (0.45)
Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	11	100% (0)	2/2	20 (7.65)	20/10	0% (0)	4.75 (0.45)
§ 170.315 (a)(6) Problem List							
Record a problem to the problem list	12	91.66% (0.28)	10/9	55 (10.80)	55/25	8.3% (0.28)	5 (0)
Change a problem on the problem list	12	100% (0)	4/3	20 (4.05)	20/8	0% (0)	5 (0)
Display the active problem list	12	100% (0)	1/1	8 (1.15)	8/6	0% (0)	5 (0)
Display the historical problem list	12	100% (0)	1/1	8 (1.49)	8/6	0% (0)	5 (0)
§ 170.315 (a)(8) Medication Allergy List							
Record a medication allergy	11	100% (0)	9/9	30 (5.07)	30/25	0% (0)	4.83 (0.38)
Change a medication allergy	11	100% (0)	3/3	8 (1.6)	8/8	0% (0)	4.83 (0.38)

Display the active medication allergy list	11	100% (0)	1/1	6 (1)	6/6	0% (0)	4.83 (0.38)
Display the historical medication allergy list	11	100% (0)	1/1	6 (0.75)	6/6	0% (0)	4.83 (0.38)
§ 170.315 (a)(7) Medication List							
Record a medication to the medication list	12	83.33 % (0.38)	20/18	60 (11.67)	60/40	16.6% (0.38)	4 (0.85)
Change a medication on the medication list	12	100% (0)	6/6	20 (5.29)	20/10	0% (0)	4 (0.85)
Display the active medication list	12	100% (0)	2/1	11 (3.21)	11/5	0% (0)	4 (0.85)
Display the historical medication list	12	100% (0)	1/1	10 (2.6)	10/5	0% (0)	4 (0.85)
§ 170.315 (b)(3) Electronic Prescribing							
Create new prescription	12	75% (0.45)	40/30	100 (7.9)	100/90	25% (0.45)	4 (0.73)
Change prescription (dosage or duration)	12	100% (0)	10/10	60 (11.67)	60/20	0% (0)	4 (0.73)
Cancel prescription	12	100% (0)	5/5	12 (1.27)	12/10	0% (0)	4 (0.73)
Refill prescription	12	100% (0)	6/6	10 (2.6)	10/10	0% (0)	4 (0.73)
Receive fill status notification	12	100% (0)	3/3	10 (2.6)	10/10	0% (0)	4 (0.73)
Request and receive medication history information	12	100% (0)	5/4	15 (0.95)	15/10	0% (0)	4 (0.73)
§ 170.315 (a)(1) CPOE – medications							
Record medication via CPOE	12	75% (0.45)	40/30	100 (7.9)	100/90	25% (0.45)	4 (0.73)
Change medication via CPOE	12	100% (0)	10/10	60 (11.67)	60/20	0% (0)	4 (0.73)
Display changed CPOE medication order	12	100% (0)	9/7	14 (2.33)	14/10	0% (0)	4 (0.73)
§ 170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE							
Using CPOE, trigger a drug-drug interaction by entering a new medication order	12	100% (0)	40/30	100 (7.9)	100/90	0% (0)	4 (0.73)
Using CPOE, trigger a drug-allergy interaction by entering a new medication order	12	100% (0)	40/30	100 (7.9)	100/90	0% (0)	4 (0.73)

Adjust the severity level of a displayed drug-drug interaction	12	100% (0)	6/6	14 (2.33)	14/10	0% (0)	4 (0.73)
§ 170.315 (a)(2) CPOE – laboratory							
Record Lab order via CPOE	12	100% (0)	10/10	40 (9.81)	40/35	0% (0)	4.25 (0.45)
Change Lab order via CPOE	12	100% (0)	2/2	15 (2.66)	15/10	0% (0)	4.25 (0.45)
Display changed CPOE Lab order	12	100% (0)	1/1	6 (0.51)	6/5	0% (0)	4.25 (0.45)
§ 170.315 (a)(3) CPOE – diagnostic imaging							
Record Imaging order via CPOE	12	100% (0)	10/8	40 (5.40)	40/35	0% (0)	4.75 (0.45)
Change Imaging order via CPOE	12	100% (0)	4/4	10 (2.6)	10/10	0% (0)	4.75 (0.45)
Display changed CPOE Imaging order	12	100% (0)	1/1	8 (1.15)	8/5	0% (0)	4.75 (0.45)
§ 170.315 (a)(14) Implantable Device List							
Record UDI	12	100% (0)	10/7	20 (4.05)	20/15	0% (0)	4.75 (0.62)
Change UDI Status	12	100% (0)	6/4	15 (0.95)	15/10	0% (0)	4.75 (0.62)
Access UDI, device description, identifiers, and attributes	12	100% (0)	1/1	5 (0.42)	5/5	0% (0)	4.75 (0.62)
§ 170.315 (b)(2) Clinical Information Reconciliation and Incorporation							
Incorporate a CCDA and conduct reconciliation of the medications, medication allergies, and problems in the CCDA with the information currently in the patient’s record	12	75% (0.45)	28/25	48 (4.53)	48/40	25% (0.45)	4.08 (0.66)
Generate a new CCDA with reconciled data	12	100% (0)	12/10	30 (4.86)	30/20	0% (0)	4.08 (0.66)
§ 170.315 (a)(9) Clinical Decision Support							

<p>Reference resource for each of the required elements</p> <ul style="list-style-type: none"> - Problem list - Medication list - Medication Allergy List - At least one Demographic - Laboratory Test - Vital Signs - And a combination of at least 2 of the elements listed above 	12	91.66% (0.28)	11/4	52 (27.9)	52/30	8.33% (0.28)	4.5 (0.52)
<p>Trigger the CDS interventions/resources added using the applicable data elements from each of the required elements</p>	12	100% (0)	10/9	55 (10.80)	55/25	0% (0)	5 (0)
<p>View the intervention/resource information using the Infobutton standard for data elements in the problem list, medication list, and demographics</p>	12	100% (0)	11/4	52 (27.9)	52/30	0% (0)	4.5 (0.52)
<p>Trigger the CDS interventions/resources based on data elements in the problem list, medication list, and medication allergy list by incorporating patient information from a transition of care/referral summary</p>	12	100% (0)	28/25	48 (4.53)	48/40	0% (0)	4.08 (0.66)

Access the following attributes for one of the triggered CDS interventions/resources: bibliographic citation, developer, funding source, release/revision date	12	100% (0)	11/4	52 (27.9)	52/30	0% (0)	4.5 (0.52)
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Table 4:Data Analysis & Reporting

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: **91.04**. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

DISCUSSION OF THE FINDINGS

EFFECTIVENESS

DigiDMS EHR 19.0 proved to be very effective based on overall success reported on all 10 tasks. Effective calculation is **91.66%**

EFFICIENCY

Based on observations of the task time and deviation data, most of the participants were able to complete task ahead of time. Few participants could not finish task and as suggested by them, they could not do it because it was hard to read instructions on screen and then work on software. It could have been easier if printed instructions given. Few deviations reported because of interpreting instructions wrongly and try to achieve it with software.

Efficiency calculation: Average path deviation recorded as **1.32**. Average Time deviations recorded as **1.50**

SATISFACTION

Based on the task ratings, most of the users found the tasks to be easy to very easy. The SUS score was calculated to be **91.04**

MAJOR FINDINGS

- Test environment was slow otherwise participants agreed to have shown much better performance
- Few Participants also indicated if they had paper instructions then they could have performed better.
- No major errors or deviations found by any of the participants.

AREAS FOR IMPROVEMENT

No feedbacks were given by participants for areas for improvement and they raised their support for existing flow without any change.

APPENDICES

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

1. Sample recruiting screener.
2. Participant demographics.
3. Non-Disclosure Agreement (NDA) and Informed Consent Form.
4. Moderator's Guide
5. System Usability Scale Questionnaire

Appendix 1: SAMPLE RECRUITING SCREENER

The purpose of a screener to ensure that the participants selected represent the target user population as closely as possible. (Portions of this sample screener are taken from www.usability.gov/templates/index.html#Usability and adapted for use.)

Recruiting Script for Recruiting Firm

Hello, my name is _____, calling from *DigiDMS Inc.*. We are recruiting individuals to participate in a usability study for an electronic health record. We would like to ask you a few questions to see if you qualify and if would like to participate. This should only take a few minutes of your time. This is strictly for research purposes. If you are interested and qualify for the study, you will be paid to participate. Can I ask you a few questions?

1. Are you male or female? [Recruit a mix of participants]
2. Have you participated in a focus group or usability test in the past 12 months? [If yes, Terminate]
3. Do you, or does anyone in your home, work in marketing research, usability research, web design [...etc.]? [If yes, Terminate]
4. Do you, or does anyone in your home, have a commercial or research interest in an electronic health record software or consulting company? [If yes, Terminate]
5. Which of the following best describes your age? [23 to 39; 40 to 59; 60 - to 74; 75 and older] [Recruit Mix]
6. Which of the following best describes your race or ethnic group? [e.g., Caucasian, Asian, Black/African-American, Latino/a or Hispanic, etc.]
7. Do you require any assistive technologies to use a computer? [if so, please describe]

Professional Demographics

8. What is your current position and title? (Must be healthcare provider)
 - a. RN: Specialty _____
 - b. Physician: Specialty _____
 - c. Resident: Specialty _____

- d. Administrative Staff _____
- e. Other [Terminate] _____

- 9. How long have you held this position?
- 10. Describe your work location (or affiliation) and environment? (Recruit according to the intended users of the application) [e.g., private practice, health system, government clinic, etc.]
- 11. Which of the following describes your highest level of education? [e.g., high school graduate/GED, some college, college graduate (RN, BSN), postgraduate (MD/PhD), other (explain)]

Computer Expertise

- 12. Besides reading email, what professional activities do you do on the computer? [e.g., access EHR, research; reading news; shopping/banking; digital pictures; programming/word processing, etc.] [If no computer use at all, Terminate]
- 13. About how many hours per week do you spend on the computer? [Recruit according to the demographics of the intended users, e.g., 0 to 10, 11 to 25, 26+ hours per week]
- 14. What computer platform do you usually use? [e.g., Mac, Windows, etc.]
- 15. What Internet browser(s) do you usually use? [e.g., Firefox, IE, AOL, etc.]
- 16. In the last month, how often have you used an electronic health record?
- 17. How many years have you used an electronic health record?
- 18. How many EHRs do you use or are you familiar with?
- 19. How does your work environment patient records? [Recruit according to the demographics of the intended users]
 - a. On paper
 - b. Some paper, some electronic
 - c. All electronic

Contact Information

If the person matches your qualifications, ask
Those are all the questions I have for you. Your background matches the people we're looking for. [If you are paying participants or offering some form of compensation, mention] For your participation, you will be paid [amount].

Would you be able to participate on [date, time]? [If so collect contact information]

May I get your contact information?

- Name of participant:
- Address:
- City, State, Zip:
- Daytime phone number:
- Evening phone number:

- Alternate [cell] phone number:
- Email address:

Before your session starts, we will ask you to sign a release form allowing us to videotape your session. The videotape will only be used internally for further study if needed. Will you consent to be videotaped?

This study will take place at [location]. I will confirm your appointment a couple of days before your session and provide you with directions to our office. What time is the best time to reach you?

Appendix 2: PARTICIPANT DEMOGRAPHICS

The report should contain a breakdown of the key participant demographics. A representative list is shown below.

Following is a high-level overview of the participants in this study.

Gender

Men	[X]
Women	[X]
Total (participants)	[X]

Occupation/Role

RN/BSN	[X]
Physician	[X]
Admin Staff	[X]
Total (participants)	[X]

Years of Experience

Years' experience	[X]
Facility Use of EHR All paper	[X]
Some paper, some electronic	[X]
All electronic	[X]
Total (participants)	[X]

As an appendix to the report, the full participant breakdown (de-identified) should be included.

Appendix 3: NON-DISCLOSURE AGREEMENT AND INFORMED CONSENT FORM

Non- Disclosure Agreement

THIS AGREEMENT is entered into as of _____, 2018, between _____ (“the Participant”) and the testing organization Test Company located at Address.

The Participant acknowledges his or her voluntary participation in today’s usability study may bring the Participant into possession of Confidential Information. The term "Confidential Information" means all technical and commercial information of a proprietary or confidential nature which is disclosed by Test Company, or otherwise acquired by the Participant, in the course of today’s study.

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulae, data, know-how, products, designs, drawings, computer aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, or forecasts.

Any information the Participant acquires relating to this product during this study is confidential and proprietary to Test Company and is being disclosed solely for the purposes of the Participant’s participation in today’s usability study. By signing this form, the Participant acknowledges that s/he will receive monetary compensation for feedback and will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant’s printed name: _____

Signature: _____ **Date:** _____

Informed Consent

Test Company would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 60 minutes. At the conclusion of the test, you will be compensated for your time.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Test Company I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Test Company.

I understand and consent to the use and release of the videotape by Test Company. I understand that the information and videotape is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the videotape and understand the videotape may be copied and used by Test Company without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared with outside of Test Company and Test Company's client. I understand and agree that data confidentiality is assured, because only de-identified data – i.e., identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

YES, I have read the above statement and agree to be a participant.

NO, I choose not to participate in this study.

Signature: _____ **Date:** _____

Appendix 4: EXAMPLE MODERATOR'S GUIDE

EHRUT Usability Test

Moderator's Guide

Administrator _____

Data Logger _____

Date _____ Time _____

Participant # _____

Location _____

Prior to testing

- Confirm schedule with Participants
- Ensure EHRUT lab environment is running properly
- Ensure lab and data recording equipment is running properly

Prior to each participant:

- Reset application
- Start session recordings with tool

Prior to each task:

- Reset application to starting point for next task

After each participant:

- End session recordings with tool

After all testing

- Back up all video and data files

Orientation (X minutes)

Thank you for participating in this study. Our session today will last XX minutes. During that time you will take a look at an electronic health record system.

I will ask you to complete a few tasks using this system and answer some questions. We are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors or deviations. Do not do anything more than asked. If you get lost or have difficulty I cannot answer help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

I did not have any involvement in its creation, so please be honest with your opinions.

The product you will be using today is describe the state of the application, i.e., production version, early prototype, etc. Some of the data may not make sense as it is placeholder data.

We are recording the audio and screenshots of our session today. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

Preliminary Questions (X minutes)

What is your job title / appointment?

How long have you been working in this role?

What are some of your main responsibilities?

Tell me about your experience with electronic health records.

Task 1: First Impressions (XXX Seconds)

This is the application you will be working with. Have you heard of it? ____ Yes ____ No If so, tell me what you know about it.

- Show test participant the EHRUT.
-
- Please don't click on anything just yet. What do you notice? What are you able to do here? Please be specific.

Notes / Comments:

Task 2: Patient Summary Screen (XXX Seconds)

Take the participant to the starting point for the task.

Before going into the exam room and you want to review *Patient's* chief complaint, history, and vitals. Find this information.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path: Screen A → Screen B → Drop Down B₁ → "OK" Button → Screen X...

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 3: Find Lab Results (XXX Seconds)

Take the participant to the starting point for the task.

On her last visit, you sent Patient to get a colonoscopy. Locate these results and review the notes from the specialist.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path: Screen A → Screen B → Drop Down B₁ → “OK” Button → Screen X...

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: “Very Easy” (1) to “Very Difficult” (5)

Administrator / Notetaker Comments:

Task 4: Prescribe medication (XXX Seconds)

Take the participant to the starting point for the task. Ensure that this patient has a drug-drug and a drug-food allergy to the drug chosen. This will put force the participant to find other drugs and use other elements of the application.

After examining Patient, you have decided to put this patient on a statin – drug name. Check for any interactions and place an order for this medication.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path: Screen A → Screen B → Drop Down B₁ → “OK” Button → Screen X...

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: “Very Easy” (1) to “Very Difficult” (5)

Administrator / Notetaker Comments:

Final Questions (X Minutes)

What was your overall impression of this system?

What aspects of the system did you like most?

What aspects of the system did you like least?

Were there any features that you were surprised to see?

What features did you expect to encounter but did not see? That is, is there anything that is missing in this application?

Compare this system to other systems you have used.

Would you recommend this system to your colleagues?

Administer the SUS

Appendix 5: SYSTEM USABILITY SCALE QUESTIONNAIRE

In 1996, Brooke published a “low-cost usability scale that can be used for global assessments of systems usability” known as the System Usability Scale or SUS. Lewis and Sauro (2009) and others have elaborated on the SUS over the years. Computation of the SUS score can be found in Brooke’s paper, in at <http://www.usabilitynet.org/trump/documents/Suschapt.doc> or in Tullis and Albert (2008).

	Strongly disagree						Strongly agree			
1. I think that I would like to use this system frequently		1		2		3		4		5
2. I found the system unnecessarily complex		1		2		3		4		5
1. I found the system unnecessarily complex		1		2		3		4		5
3. I found the system unnecessarily complex		1		2		3		4		5
4. I found the system unnecessarily complex		1		2		3		4		5
5. I found the system unnecessarily complex		1		2		3		4		5
6. I found the system unnecessarily complex		1		2		3		4		5
7. I found the system unnecessarily complex		1		2		3		4		5
8. I found the system unnecessarily complex		1		2		3		4		5

9. I found the system unnecessarily complex

1	2	3	4	5

10. I found the system unnecessarily complex

1	2	3	4	5

Appendix 6: INCENTIVE RECEIPT AND ACKNOWLEDGMENT FORM

Acknowledgement of Receipt

I hereby acknowledge receipt of \$_____ for my participation in a research study run by Test Company.

Printed Name: _____

Address: _____

Signature: _____ Date: _____

Usability Researcher: _____

Signature of Usability Researcher: _____

Date: _____

Witness: _____

Witness Signature: _____

Date: _____