INSTRUCTIONS: Version 2

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1. TITLE
RPlus

2. EXTERNAL IRB REVIEW HISTORY*
N.A

3. PRIOR APPROVALS:
N.A.

CONFLICT OF INTEREST (COI):
N.A.

BIOHAZARDOUS AGENTS:
N.A.

RADIATION:
N.A.

4. BACKGROUND*

Both the tools are used to prototype and we want to see and evaluate the user experience in using both the tools "Mock PLus" and "Azure RP". The functionality provided by both the tools is same. In our team we haven't use both tools and we want to study how the users with no experience would be able to use the tool in both efficiency and at the difficulty level.

5. OBJECTIVES*

Our main goal is to compare both the tools while prototyping.we want to examine

1. Efficiency - Prototyping in one tool is quicker than another tool.
2. Difficulty level -prototyping in either of tools is hard/difficult than other tool.

Learners having no prior experience in later life require to use prototyping tools. If so, the transition to such tools is difficult because they are beginners,Learning different tools for same task can provide a basis to determine the duration of task completion.

H1:Prototyping in one tool is quicker than another tool.

Learning different tools for same task can provide a basis to determine the level of difficulty in either one, both or none.

H2:prototyping in either of tools is hard/difficult than other tool.

6. Study Outcomes*

By the end of the study we are expecting to find out -
one tool is better than another to use for the beginners
Overall User experience in using both the tools .

Are beginners able to user the tool and what is the difficulty level?
Which tool is easier for prototyping ?

7. Inclusion and Exclusion Criteria*

Inclusion criteria:

- Adults able to consent.
- Classmate and English Speaking subjects.
- Users with no or minimum experience in using the prototyping tools.

Exclusion criteria:

- Adults unable to consent (adults lacking capacity)
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Non-English speaking subjects

8. Vulnerable Populations*

- Our subjects will be withdrawn from the research if they appear to be unduly distressed.
- Results of the research would not affect the subjects as the subjects are not identified with their names and cannot link the results with the subjects.

9. Setting

- Before the study begins we greet the users and make them feel comfortable.
- we would orally explain
  why we are here?
  what are the goals?
- Instructions on facilities/snacks/water/contact information
- After we collect the Consent forms, the study would begin
- Sites or locations where your research team will identify and recruit potential subjects, perform research procedures, and conduct data entry and analysis: Classroom. and Computer Lab on 4thFloor

- User-Study will be in the classroom setting or the conference rooms.

10. RESOURCES AVAILABLE

Describe study personnel.

- Do not list people by name.
- Shruti and Snehitha would work collect and analyse the data.
- The only qualification required is that the human subject shouldn't know either of the prototypes or have less knowledge.
- On each subject 25-30 minutes would be devoted. Once this is done, we would like to analyse the data in a weeks time..

The human subjects will be provided with a consent form to understand the protocol. During the process of them reading we would verbally explain the protocol. Also, a sheet with the information about whom to contact and the information about the research procedures will be passed onto the desk where they are working on the prototype.

11. STUDY TIMELINES*

- The duration of an individual subject's participation in the study: 25-30 min
- The duration anticipated to enroll all study subjects: 40 min - 1 hour.
- The estimated date for the investigators to complete this study (complete primary analyses) : Mid May.

12. NUMBER OF SUBJECTS*

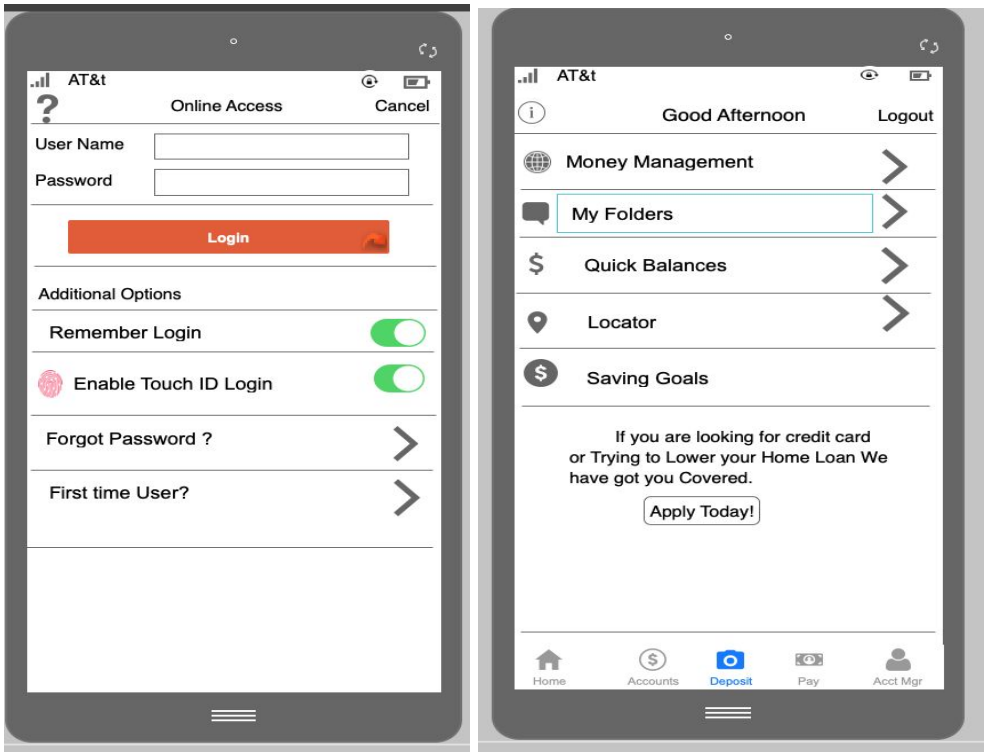
- The total number of subjects will be approximately 5-7.

13. PROCEDURES INVOLVED*

- **Tasks:**
- Two tasks are given to the users in our study. One task is used to identify the difficulty level in Axure Rp vs MockPlus.
- For task 2 we identify the quickness in the prototyping tools by comparing the finished time in both of the applications.
- After greeting the users and taking the consent from the users out study would begin.
- Laptops with pre-installation of both the apps are provided to the users to perform study.
- Task videos are shown to the users before study.
- As we are of team two we divide the participants and add the notes from the participants by observation for both of the tasks.
- For one task as we are measuring time we would add the timer while users are performing the task.
- We also provide the post-survey to the users and use this information in our data collection.

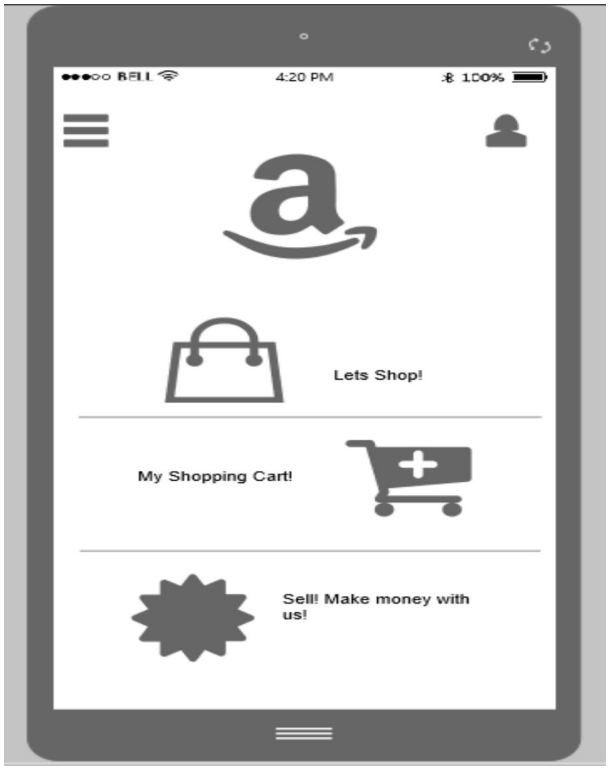
- Screen Recording is done to view the user mouse clicks while performing the survey.
- From our study data is both qualitative and quantitative.
- Qualitative data is converted onto a scale to view in the quantitative form.
- we maintain a data collection sheet and would verify if we have collected all the data.

Task1: Micky is a graduate student who is studying HCI in the current semester. In his project work he want to use a tool to Prototype his design. He never used prototyping tool and he wants to pick up to the speed. He is also busy with his research work and want to finish up his Project work.



Difficulty level parameter is collected in Task 1.
User comments, questions,post survey questions,screen recording data is taken here.

Task2: Sara is a bachelor student and she is working on a web design project in one of her courses. She want to design the prototype before implementing with the code. She is looking for a tool where she can try out and see which tool fits her best.



Time efficiency parameter is taken in to consideration while users are performing the task. Screen recording time parameter and user comments is taken into consideration.

14. RECRUITMENT METHODS*

- The potential subject ranges from 20-25. We would require 1/5th of the candidate to be suitable subjects.The potential subjects will be recruited from the class.
- Users with minimum or no experience are considered as our potential subjects.
- Before the study we ask our participants if they have time and then we proceed with the study.
- Since the subjects will be the recruited from the Evaluation of HCI class, identifiers with respect to what their background is noted. They will be de-linked with their identity after the analysis.
- Recruitment will begin after the first half of the HCI class during the allocated time. The participants are the students and as long as they are willing to participate they will be our potential subjects.

15. CONSENT PROCESS*

- Subjects are given the consent forms ahead of the Study via email.They need to fill out the form and bring it to the study.All the staff members in the research(if in case we include another staff in our research) will be aware of this process as we share the information beforehand with them.

- We provide the consent forms a week or 2 weeks before the study so that the users have sufficient time to consider for the study.
- Currently there is no ongoing consent.
- Non-English speakers are not considered as subjects in this study.

16. Process to Document Consent in Writing

- All the staff members in the research will be aware of this process as we share the information beforehand with them via email.

17. Withdrawal of Subjects Without Their Consent*

N.A.

18. Sharing of Research Results with Subjects*

- The research results will be shared with the subjects towards the end of the semester. The hypothesis will be stated and so will be the results.

19. Risks to Subjects*

N.A.

20. Potential Direct Benefits to Subjects*

N.A.

21. Data and Specimen Analysis and Management*

N.A

22. Provisions to Monitor the Data to Ensure the Safety of Subjects*

The risk is very minimal in the study so this is not required.

23. Data and Specimen Banking*-

N.A.

24. Confidentiality

- The data which is collected will be of age and the gender of the subject and screen recording.Data is not stored with subject's identifiable information.Different identifiers are used in naming the subjects.
- we are only storing the research data which could not be backtracked to subjects.

- User Consent forms forms are stored on our shared google drive with encryption.

25. Provisions to Protect the Privacy Interests of Subjects

- Research is done in the classroom setting .Sensitive information is not collected from the users

26. Compensation for Research-Related Injury
N.A

27. Economic Burden to Subjects
N.A

28. Community-Based Participatory Research*
N.A

29. Multi-Site Research*
N.A

30. Research Conducted in a Foreign Country
N.A

31. Drugs or Devices
N.A

IRB Checklist

This checklist is provided for your convenience and is not a requirement for review.

Y	Investigator Study Plan (ISP)
Y	Consent form(s)
Y	Assent forms(s)
Y	Fact sheet(s)
Y	Surveys, measures, instruments, etc.
Y	Data collection sheets, case report forms, etc.
Y	Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.
N	Written approvals from ancillary reviews (COI, IBC, RSC,)
N	Adverse event log
N	Approval order for Humanitarian Use Device
N	Certificates of translation or translator attestationsFact sheet(s)
N	Compensation logAssent forms(s)
Y	Data safety monitoring plan
Y	Data use agreements, memoranda of understanding, Multi-site communication plan
N	DMC or DSMB charter
N	Documentation of data/specimen anonymity (i.e., provider will never break the code)Study staff training plan
N	HIPAA authorization
N	HIPAA waiver
	IND or IDE documentation
N	Instructions for use or approved FDA labeling for devices
N	Investigator brochure or package insert for drugs
N	Measures to assess capacity to consent
N	Multi-site communication plan
N	Patient information sheet for Humanitarian Use Device
N	Product labeling for Humanitarian Use Device
N	Screening logConsent form(s)
N	SOPs or Manuals of OperationsAuthorization to contact form
N	Sponsor justification or FDA documentation for non-significant risk device study
N	Study staff training planHIPAA authorization