UTM
UNIVERSITI TEKNOLOGI MALAYSIA

FACULTY OF COMPUTING
UTM Johor Bahru

SECJ 2203: Software Engineering

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PROJECT PROPOSAL

UTM Ethics Approval Management System (EAMS)

Faculty of Computing

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1. Introduction

We are **Hyperrush** company which has been assigned the task of developing a new, automated system for UTM's Research Ethics department under the Deputy Vice-Chancellor. The goal is to improve and streamline the existing application process, which currently relies heavily on manual tasks. The primary objective for the new system is to automate the application processes to make it easy to use for both staff and applicants, integrating multiple functions into a single platform. Key features include the addition of a payment gateway, the ability to submit only completed application forms, a messaging system for applicant-staff communication, and the ability for applicants to track their application status.

After reviewing UTM Research Ethics' current website, it was noted that the majority of applications are processed manually. Applicants are required to download an application form, fill it out, and re-upload it. Additionally, the payment process lacks a payment gateway, requiring applicants to manually upload payment receipts. In meetings with staff, it was also revealed that incomplete or incorrect applications are often submitted, creating additional work for the staff to manage and rectify.

The new system proposed is **UTM Ethics Approval Management System (EAMS)** which will be a web-based platform that automates the application process. It will include a third-party payment gateway, ensuring applicants can complete payments within the system. The system will check for incomplete fields, preventing submission until all required information is provided. It will also feature a chatbot to assist applicants 24/7, with the option to contact staff if further assistance is needed. Applicants will have access to a page displaying the evaluation progress of their application, along with any issues that need addressing. Upon completion, applications will be saved to the department's database, where staff can review and evaluate them. If an issue is found, the system will automatically notify the applicant to log in and resolve it.

UTM EAMS offers numerous benefits for both staff and applicants, making the application process more efficient and user-friendly. Key advantages include reduced staff workload, as application management is automated, as well as secure access restricted to authorized staff only. Additionally, the system ensures that applications are complete and accurate before submission, improving data integrity and reducing processing time.

The proposed **UTM EAMS** has been benchmarked against similar systems at other institutions, including the **Oregon State University Institutional Review Board (IRB)**, **the University of Malaya's Animal Care and Use Committees (IACUC)**, and the **NHS Health Research Authority's Research Ethics Committee (REC)** in Europe.

1. **Oregon State University Institutional review boards(IRB):** reviews the research on the human subjects to ensure ethical conduct. [1]
2. **The University of Malaya Animal care and use committees (IACUC):** ensure human treatment for animals. [2]
3. **NHS health research authority Research ethics committee (REC):** used mainly in Europe, basically reviews both research on humans and animals but focuses more on the ethical conducts. [3]

These systems provide the same main functions for reviewing and approving research. However, our proposed system provides a way to communicate with the applicants and allow the applicant to see the evaluation progress.

2. Existing Systems

2.1 The Oregon State University IRB:

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.

This system has a problem, which is that the pre-submission process is manual. You must download some forms and fill it before submitting. One of its features is that the applicants can request a virtual session if they want some help regarding the submission process.

2.2 The University of Malaya IACUC:

UNIVERSITY OF MALAYA ANIMAL CARE AND USE POLICY (UM ACUP) provides the framework within which animals may be used at the University of Malaya (UM) for teaching and research in a manner that conforms with all government laws and regulations, provides for approved research and teaching activities, and safeguards the health and welfare of staff and students involved in scholarly activities using animals or animal parts

derived from animals. As evidence to the full commitment of UM to the judicious and humane use of animals in research and teaching, the UNIVERSITY OF MALAYA INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) was established.

One of its features is that it provides guidance for applicants in different languages.

2.3 NHS health research authority REC:

The Health Research Authority and the Devolved Administrations provide a Research Ethics Service so that research proposals relating to their areas of responsibility can be reviewed by a Research Ethics Committee (REC). Research Ethics Committees protect the rights, safety, dignity and wellbeing of research participants. Managing the Research Ethics Committees in England is one of the Health Research Authority's core functions.

One of its features is that the application process is automated and integrated in their system.

Table 1: Comparison of existing systems

Features	Oregon State University IRB	The University of Malaya IACUC	REC	Proposed UTM EAMS
Virtual session request	Yes	No	No	Yes
Provide guidance in different languages	No	Yes	No	No
Integrated application system	No	No	Yes	Yes
Automated application verification	No	No	No	Yes
Integrated payment gateway	No	No	No	Yes
Application tracking for applicants	No	No	No	Yes
Real-time communication with applicants	No	No	No	Yes
Chatbot for instant support	No	No	No	Yes
Role-based access control	No	No	No	Yes

3. Proposed System

To address the challenges currently faced by UTM REC, we propose **UTM Ethics Approval Management System (EAMS)** equipped with advanced features to replace existing manual workflows. By implementing this system, we aim to streamline the entire UTM REC process, enhancing its efficiency, effectiveness, quality, and usability. Below are the proposed modules to improve UTM REC's work processes:

No	Modules	Description
1.	Registration and Access Control Module	- Allows existing users to sign in with their UTM email and password. - Allows new users to sign up in the system by using their UTM credentials. - Collects essential applicant information to pre-fill forms for future applications, streamlining the process. - Require verification through UTM email link to confirm identity before granting full access. - Automatically assigns access roles based on the user's identity (applicant or staff) to control what they can view or edit in the system. - Allows users to upload necessary identification documents, ensuring applicants meet UTM REC's eligibility requirements. - Requires applicants to review and agree to UTM REC's terms, policies, and ethical guidelines during registration, ensuring users understand their responsibilities regarding research ethics.
2.	Application Submission and Document Management Module	- Provides an online form submission portal, allowing applicants to fill in required fields directly on the website. - Automates document verification, alerting applicants to any errors or incomplete fields before submission. - Automatically categorizes the application based on the research type (clinical, non-clinical, animal research). - Routes categorized applications to the appropriate

		subcommittee for review. - Offers guidelines, sample forms, and FAQs to support applicants in meeting ethical approval requirements. - Assists applicants in understanding the submission process and ensuring their applications meet all necessary standards.
3.	Integrated Payment Gateway for Application Fees Module	- Enables applicants to securely pay the required application fee through third-party payment gateways, including e-wallets, online banking, and debit cards. - Verifies payment status in real time and automatically updates the applicant's record. - Provides applicants with an instant payment receipt. - Maintains a logged payment history accessible to both applicants and administrative staff.
4.	Application Tracking and Communication Module	- Offers a dashboard for applicants to track the status of their applications. - Displays estimated processing times, real-time updates, and a summary of completed and pending steps on the applicant’s dashboard. - Sends automated email notifications at each stage of the application process. - Updates applicants with acknowledgements, review status and final results automatically.
5.	Review and Scheduling Module	- Detects high-risk research applications that require additional review. - Provides automated scheduling for applicants needing a pitching session for high-risk research. - Notifies applicants through email to select an available timeslot for the review session. - Automatically updates the selected timeslot on the dashboards of both the applicant and administrative staff.

6.	Live Chat Support and Chatbot Integration Module	- Offers a chatbot to address common questions from applicants. - Routes complex inquiries to the appropriate staff member. - Provides instant support for the applicants and freeing up staff for more complex tasks.

3.1 Users' Role

3.1.1 Applicant (student or UTM staff)

In this system, existing users can simply log in using their UTM email and password. New users, however, must sign up using UTM credentials, such as their UTM email, matric number, or staff number, to ensure that only authorized UTM members have access. Upon registration, users receive a verification link via their UTM email to confirm their identity before being granted full access. They are also required to upload identification documents to confirm their eligibility for UTM REC. During registration, new users must review and agree to UTM REC's terms, policies, and ethical guidelines to acknowledge their responsibilities regarding research ethics. After successful registration, users are automatically assigned an access role, granting them specific view and edit permissions.

On the homepage, applicants can access the application form through an online submission portal, allowing them to directly fill in required fields. The system will automatically alert applicants to any incomplete or incorrect fields during the form-filling process. Once completed, the submitted application is categorized by research type (clinical, non-clinical, or animal research) and routed to the appropriate subcommittee for review. While filling out the form, applicants can also access guidelines, sample forms, and FAQs to help them meet ethical approval requirements.

Applicants can securely pay the required application fees through third-party payment gateways, such as e-wallets, online banking, and debit cards. Once payment is successfully verified, applicants receive an instant receipt via email, and their payment history is updated in their profile.

A dedicated dashboard allows applicants to track their application status, including estimated processing times, real-time updates, and a summary of completed and pending steps. Applicants receive email notifications at each stage of the application process, and the dashboard automatically updates with acknowledgments, review statuses, and final results.

If a high-risk research application is flagged for additional review, the applicant is notified via email to select an available timeslot for a pitching session with staff. After a timeslot is selected, applicants receive reminders, and the scheduled session appears on both the applicant's and staff's dashboards.

The system also provides live chat support for applicants who encounter issues that cannot be resolved through guidelines or FAQs. Additionally, a chatbot is available to handle less complex inquiries, improving efficiency and helping applicants resolve common issues quickly.

3.1.2 Staff UTM REC

For registration, new staff members follow a similar process as applicants but must select the "staff" option to differentiate their role within the system. In this system, staff no longer need to send emails manually, as all communications are automated, freeing up their time for more complex tasks.

The system also eliminates the need for staff to visit the treasurer's department to verify application fee transactions from applicants. Staff can verify transactions directly within the system using third-party payment gateways, and once applicants complete their payments, transaction logs are automatically available to staff.

Any updates in the application process are reflected on applicants' dashboards, providing them with clear visibility and acknowledgment of their application status. However, staff are still responsible for detecting high-risk research applications and facilitating additional reviews when necessary. For high-risk cases, staff coordinate a pitching session with applicants.

Additionally, staff provide live chat support for applicants who use this feature, ensuring effective communication with emergency conditions.

4. Software Process Model

The process of software development is generally broken down into three phases.

A. For the first phase:

Requirements gathering and planning phase, which will follow the waterfall methodology where as defining the scope and analyzing the existing processes, and identifying stakeholders and gathering their requirements. Then followed up by the development of the system architecture, Then the phase is concluded by the creation of the system design.

Why waterfall methodology?

Structured Phases: It follows a very structured and sequential approach, with very lucid defined phases (e.g., requirements analysis, system design, implementation, and testing).

Predictability: It provides a clear predictable path, as each and every phase is completed before moving to the next, making it appropriate for projects with clearly defined requirements.

Documentation: Focused on good documentation which ensures that the project requirements and specifications are known before the development begins.

Why not agile methodology?

Less Predictability: Due to the adaptability of the methodology nature.

Higher Requirement for Skilled Teams: It requires a team that can work efficiently with the changes and adapt with the feedbacks quickly.

Documentation Challenges: Lacking details which makes future upgrades and maintenance very challenging.

B. For the second phase:

The agile methodology is to be taken, which will be in the development phase which focuses on the rapid iterations and feedback gathering activities, leading to various sprints based on the stakeholders' requirements and should follow up with them after completion with each single sprint and modify it based on their feedback. Then the integration and maintenance part which is based on gathering the stakeholders feedback, after the completion of each sprint leading to further integration implementation, gathering the overall feedback for maintaining the continuity of the development.

Why agile methodology?

Flexibility and Adaptability: Highly flexible approach, with iterative cycles that permit the development team to adapt to changes and new requirements quickly.

Customer Involvement: Continuous customers' feedback at the end of every iteration ensures that the final software product matches with customer needs and expectations.

Early and Frequent Delivery: It ensures delivering functional components every given time interval, so that the customers can give their feedback and gain value sooner.

Why not waterfall methodology?

Inflexibility: When the project is underway it is very hard to make changes and go back to the previous phases.

Limited Customer Involvement: The customer will see the product at the finalization of the software, which may lead to great customer dissatisfaction.

Risk of Obsolescence: Due to the dynamic business environment the requirements of the software might be in need for changes either minor or major.

C. For the third phase:

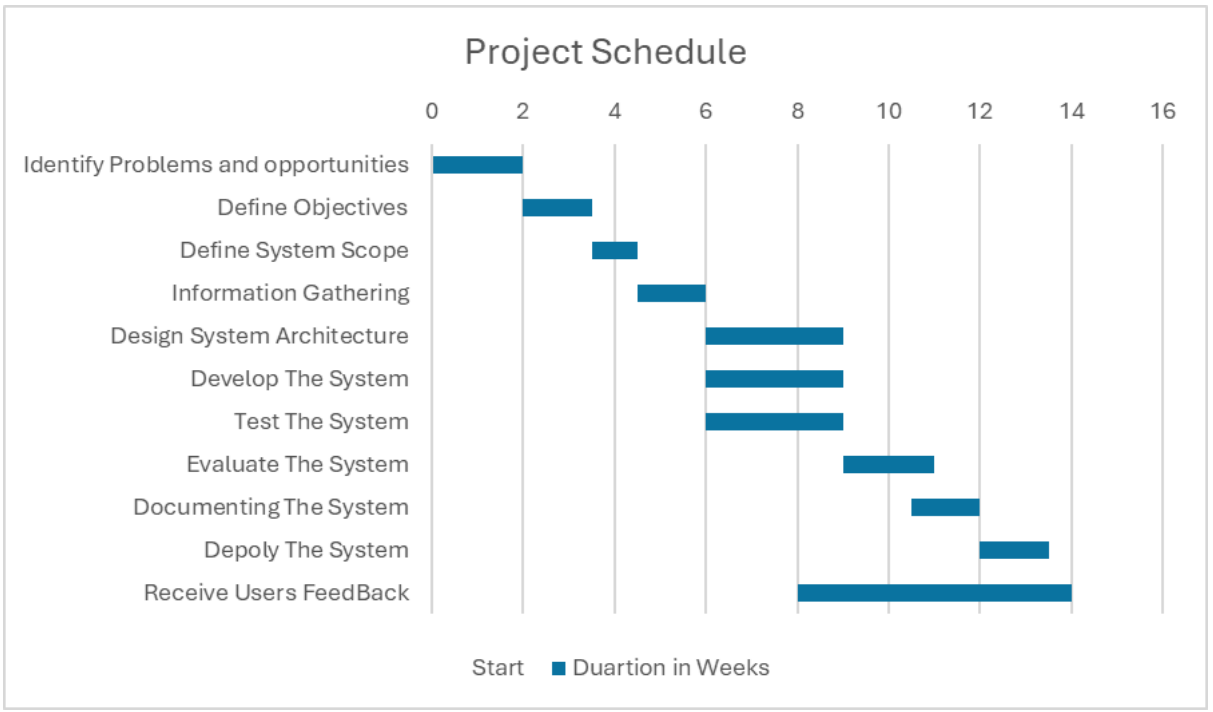
It will be focused on the deployment and maintenance where it will be focusing on the hybrid methodology, taking a combination of their overall benefits.

What are the benefits of having a hybrid system in this phase?

- Structured approach while maintaining flexibility.
- Predictability due to high customer involvement.
- Well documentation for future maintenance and upgrades.

5. Project Schedule

Following the SPM module we mentioned above, we will start the process of identifying the problems, objectives, system scope and information gathering using the waterfall model in a sequential approach until week 6. As for the development, testing and evaluating of the system we will use the agile development model to reach major sprints in the system process and keep the progress effective. The agile method will end by week 9. For the last 5 weeks it will be a mixture of both methods to gather the required feedback while making a constructed progress for the deployment and documenting to achieve the highest accomplishment possible. All of the system building should take no more than 14 weeks as stated by the gantt chart below.



6. References

[1] Oregon State University. (2012, May 25). *What is the Institutional Review Board (IRB)? | Division of Research and Innovation | Oregon State University*. Research.oregonstate.edu. https://research.oregonstate.edu/ori/irb/what-institutional-review-board-irb

[2] *Animal Care and Use - UMResearch*. (2023, July 2). UM Research. https://umresearch.um.edu.my/animal-care-and-use/

[3] NHS Health Research Authority. (2023). *Research Ethics Service and Research Ethics Committees*. Health Research Authority; NHS Health Research Authority. https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/

[4] Xie, J., Lin, R., & Keller, C. (2014). *Understanding the adoption of third-party online payment An empirical study of user acceptance of Alipay in China ACKNOWLEDGEMENTS*. https://www.diva-portal.org/smash/get/diva2:733072/FULLTEXT01.pdf

[5] *Challenges in the Implementation of Risk Evaluation Mitigation Strategies (REMS): A Survey of Industry Views - ProQuest*. (2018). Proquest.com. https://www.proquest.com/docview/2402076776/fulltextPDF/F4FEE1DA0F144F98PQ/1?accountid=41678&sourcetype=Dissertations%20&%20Theses

[6] Kachuck, N. J. (2011). Registries, research, and regrets: is the FDA's post-marketing REMS process not adequately protecting patients? *Therapeutic Advances in Neurological Disorders*, *4*(6), 339–347. https://doi.org/10.1177/1756285611424461

Appendices

1. Use of Generative AI tool: ChatGPT

1.1 Screenshot

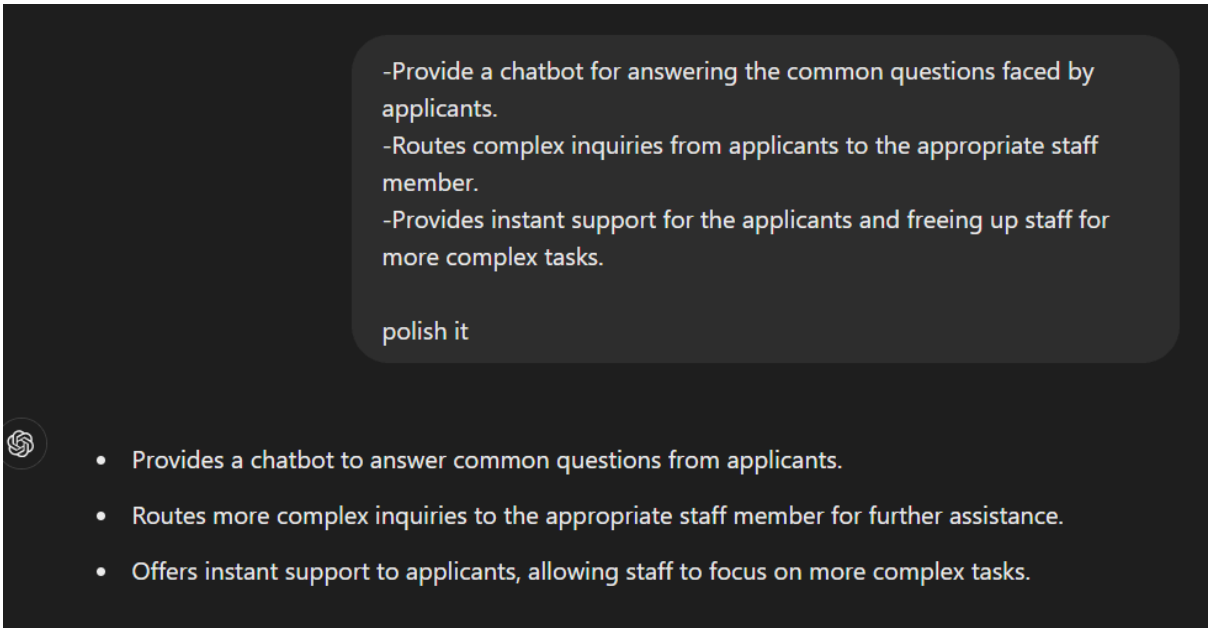


Figure 1.1.1: Screenshot ChaGPT polish the sentences used

1.1 URL

https://chatgpt.com/share/672b33dd-a8f8-8007-9b74-b3332c600614