URECA – the Research Ethics and Data Protection Online Review Platform used by the University of Malta

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Cover Page Footnote

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Abstract

Nowadays, research ethics and data protection are given very high importance, and research organizations, including universities, need to safeguard their level of professionalism and integrity by providing the necessary guidelines. Moreover, they need to ensure that these guidelines are being adhered to by their affiliated researchers, including students. This is needed for protection of the research subjects, researchers, and the organization (university) itself. However, care must be taken so that the research ethics review process is streamlined as much as possible to minimize bureaucracy, as such guidelines would then be viewed as a research barrier. This study describes URECA, the online review platform developed in-house by the University of Malta to streamline its research ethics review process, thus simplifying matters for the researchers/students, reviewers, and auditing committees. This platform is utilized by researchers and students to submit information regarding their research and related data collection, by supervisors to endorse their students' research, by Faculty Research Ethics Committee members to review research proposals as required, and by the University Research Ethics Committee to manage and audit the overall process.

Keywords: Research ethics, data protection, data collection, review procedures, research code of practice

Introduction

Teaching and the pursuit of research are two of the most fundamental roles of a university. However, research must be conducted in an ethical manner by maintaining high standards of integrity and professionalism to avoid harm to research subjects, researchers, and the organization (university) itself. In the last 10 years, we have witnessed incidents, such as the Cambridge Analytica Scandal (Gilbert & Ma, 2019) that have aptly demonstrated the adverse effects of disregard of research ethics and misuse of data.

In view of this, organizations and universities are obliged to provide guidelines and codes of practice that help researchers ascertain that their research adheres to the necessary ethical and data protection standards (University of Malta, 2019a; UK Research Integrity Office, 2021). Additionally, they should also publish review procedures and provide the supporting organizational structure that help researchers to comply with their codes of practice (UK Research Integrity Office, 2021, University of Malta, 2019b).

Although the codes of practices adopted by different organizations are not expected to significantly vary, the review procedures have been found to differ considerably. For instance, while the University College London (UCL) considers dissertation supervisors to be the principal investigators (and thus the "main" researcher), the University of Malta (UM) considers the students to be as such (University College London (UCL), 2022; University of Malta, 2019b). However, assigning the student as the principal investigator does not eliminate all responsibilities from the supervisor. The corresponding supervisors need to endorse all research ethics proposals submitted by students within the UM (University of Malta, 2019b). Although this requirement is understandable, its implementation involves some complexities since all proposals made by a student need to be accompanied by supervisor endorsement.

Nevertheless, it is standard practice in universities to provide ethics review committees or "Institutional Review Boards" to review research proposals from the research ethics and data protection perspective and provide guidance accordingly. However, such committees need to strive to be as efficient as possible and provide the necessary help; otherwise, researchers may perceive them to be obstacles to research and try to circumvent them in certain cases (Brown et al., 2020). The administrative effort required by the researcher to provide the necessary information to such boards must be kept to a minimum, and the necessary feedback should be provided to the researcher in a timely manner.

In an effort to increase its efficiency and effectiveness in relation to research ethics and data projection, UM updated its review procedures in 2017. Before that, researchers needed to assess if their own research requires an ethical review (and only then can they submit the necessary form and documentation). Currently, all researchers are asked to fill in a self-assessment form, which contains a questionnaire (consisting of 22 Yes/No questions) whose outcome determines if the proposed research has any ethical issues and thus requires review. If this is the case, the researcher is requested to fill in further relevant details as necessary. Forms whose self-assessment does not highlight any issues are archived without any further review, and the researcher is allowed to proceed with their research and data collection as described in the form. Meanwhile, forms whose self-assessment results indicate potential issues are reviewed by the corresponding Faculty Research Ethics Committee (FREC). In such cases, the researcher must wait for the clearance from FREC before proceeding with the data collection.

Until a few months ago, such forms were submitted on Google Forms and were also required to be submitted via email to the relevant FREC (University of Malta, 2019b). Supervisors were expected to provide their endorsement by replying accordingly to the emails

with the submissions in which students were supposed to copy them. The limitations of Google Forms and the reliance on emails indicated that the process was not as straightforward as desired, resulting in a number of issues such as forms with missing information, forms without required supervisor endorsements, and forms that were not received by the corresponding FREC at all.

In view of these issues, in 2020, UM started the development of URECA–an online platform that streamlines the research ethics review procedures and simplifies the process for all the stakeholders involved, including the researchers, supervisors (where applicable), members of the review committees (FRECs), and the University Research Ethics Committee (UREC) that manages the entire process. URECA was launched on October 1, 2021, and its reception has been overwhelmingly positive since it simplifies the process and minimizes the issues encountered to date. This study describes the structure and operation of the URECA system and demonstrates how similar systems enhance the capability of universities and other organizations to improve their research ethics review process.

In the remainder of this paper, we first review the related literature, whereby we discuss the role of the ethics review committees in different organizations and the varying ethics review procedures in place. Subsequently, we provide a description of the URECA platform and its different components, followed by an evaluation of URECA. Finally, one can find the conclusions and a description of some future work being carried out.

Literature Review

Role of Ethics Review Committees

In a study carried out among researchers, Geuillemin et al. showed that the majority of researchers understand the role of ethics review committees in protecting research subjects, researchers, and the research organization itself. However, certain perceptions exist that such committees tend to overprotect the research subject (thus shielding the research organization) at the expense of the research being carried out (Guillemin et al., 2012). Clear communication can be a solution to alleviate these perceptions. In fact, Brown et al. highlight the importance of transparency between committees and researchers to help ascertain adherence to the relevant codes of practice (Brown et al., 2020).

Inefficiencies in the review process, e.g., administrative delays, requiring an excessive number of forms, and inordinate review for research with minimal risk, contribute to "research waste" (Glasziou et al., 2021). This waste can result in considerable financial cost and time lost by the researchers, apart from increasing friction between researchers and review committees. Glasziou et al. (2021) suggest a number of approaches that can help reduce inefficiencies as follows:

- Reducing the review time and the range of studies that need to be reviewed
- Reusing parts of the previously approved applications
- Standardizing requirements for different types of research
- Streamlining ethics review processes that can adapt itself according to a project's risk level

Overview of Existing Review Procedures

It is our impression that the review procedures of most universities require researchers to first identify the risk level of research proposals and then fill in a form corresponding to the risk level. UCL, one of the top universities in the United Kingdom, also follows this procedure (University College London, 2022). The risk level of a research proposal can be determined based on a checklist similar to that published by the UK Research Integrity Office (UK Research Integrity Office, 2021).

We have not encountered a software platform that handles research ethics submission for academia in a streamlined fashion. Research ethics forms at UCL are submitted as PDF forms (University College London, 2022). Although one may argue that reviewers will need to view the filled out forms to perform their review, such forms make it hard to extract and correct, where necessary, the data contained within.

e-EC and TREAD are publicly available platforms that attempt to streamline research ethics review procedures. e-EC can be used by multiple organizations and can provide their review forms as PDF and applicants can submit such forms, which are then harvested and can be reviewed by relevant committees. This platform also allows the forms to be stored in a database that can be searched in the future (CDSA India, 2022). Meanwhile, TREAD is a publicly available repository of research applications. Its scope is that existing/previous researchers can show how they adhered to ethical practices, thus providing guidance for other researchers who plan on carrying out similar research (The Global Health Network, 2022). TREAD is useful in the sense that it helps researchers formulate research plans that satisfy general research codes of practice; however, it does not seem to provide any review functionality.

Bowser and Tsai (2015) describe a similar system that is more closely related to what is required for academia. This system involves a framework that allows researchers to submit their proposals. Researchers also need to provide responses to a number of questions, allowing the proposal to be flagged according to the risk involved. Reviewers can then evaluate the individual proposals and send their reviews to the chair who coordinates the review process. According to the study, this system is not yet fully implemented.

The URECA System

The section discussing related literature highlighted the importance of streamlined and efficient ethics review processes and analyzed a few of the available solutions. Nevertheless, the solutions discussed do not provide a complete implementation of the ethics review procedures in place at UM (described in the Introduction). None of these systems allow for the supervisor to endorse a student's ethics application and follow its approval process. Moreover, UM is required to conduct a yearly audit of the submitted applications. Therefore, data must be available for aggregation and searching as required for auditing purposes.

The developed system, that is, URECA, aims to provide a complete solution that renders the process simple and streamlined for all the users and stakeholders involved. This system has two interfaces:

- Back end–accessed only by administrators
- Front end–accessed by
    ◦ Students/researchers submitting ethics form/s and checking their status
    ◦ Supervisors to endorse or reject the students' research ethics and data protection (REDP) review forms

◦ The FREC members to view the forms submitted to their respective FREC

◦ The FREC secretary to accept or reject REDP forms pending FREC review

In the subsequent subsections, we first describe the underlying system architecture,

followed by a description of the system front end, and end with a description of the back end.

System Architecture

URECA is a web-based system that can be accessed by users via their web browsers

without requiring them to install any additional software. Its interfaces were developed to be

mobile-friendly and responsive to devices with different screen sizes. Therefore, it can be

accessed using any device connected to the Internet, ranging from normal PCs to mobile phones

and devices.

The system is hosted on a Linux virtual machine (running Ubuntu Linux OS) and has

been developed using open source technologies; thus, it does not require any software licensing

costs. The virtual machine specifications are quite basic, given that the system does not require

heavy resources to run. The interfaces are developed using HTML, CSS, and JavaScript, and

server-side scripts are implemented in Python. The system's data are harvested within a

MongoDB database (*MongoDB*, n.d.), and all data are encrypted for security purposes. All

communication between the users' browsers and the server is carried out over HTTPS, that is, all

the data transferred is encrypted as well.

The system authentication works using Google's single sign-on (SSO) for email accounts

with the um.edu.mt domain, that is, users are redirected to UM's login page for authentication

and then redirected back to the URECA system after successful authentication. UM uses Google

Workspace for its emails, and Google's SSO provides a secure way to ensure that the system is

available to all (and only) UM users and all user accounts are valid accounts. This also provides

additional security as URECA does not handle passwords for its users (apart from the few

external users), and users need to go through the two-factor authentication (2FA) mandated by

logins to their um.edu.mt account.

Given that UM occasionally provides REDP reviews for external (non-UM) users such as

industry partners, URECA needed to allow for authentication by such users who do not have a

um.edu.mt account. Hence, functionality was implemented to allow for the authentication of

such external users. External user accounts are set up from the back end, whereby login

credentials are sent directly via email to the users (without them being accessible to the back-end

user). External users then access a special login form that accepts their username and password.

In addition, they need to provide a unique code sent via email upon submission of a valid

username and password as a two-factor authentication.

System Front End

URECA's front-end interface is accessible to all users with an um.edu.mt account and to

approved external users and allows all users to submit REDP forms, and review previously

submitted forms. Supervisors are provided with extra functionality for them to be able to review

and endorse forms that their students have submitted. FREC secretaries and members can

perform their FREC-related tasks to review forms submitted for reviews and enter audit

information via the front end as well. Figure 1 shows the front-end landing page, which displays

the menu that contains all this functionality to different users.

Notably, this functionality is not visible to all users. Users who are not supervisors and/or

members of any FREC will only have the menu sections named "Researcher Actions" and

"Account" visible. The system detects supervisors as users whose email has been listed in the

supervisor in at least one of the REDP forms submitted by researchers. Thus, the supervisors can access the menu section named "Supervisor Actions." However, FREC members are set from the back end. Upon login, the system checks if the user's email is listed as an FREC member; if this is the case, the "F/REC Action" Menu section is made accessible.

Figure 1

URECA Front End interface

Researcher Functionality: REDP Form Submission

All students and staff (researchers) with a UM account can access the front end to submit REDP forms. The applicants need to submit certain basic details about their research proposal and then answer a series of self-assessment questions. Each form contains the following parts:

1. Applicant and project details: Users enter information about themselves, and the project being undertaken and other ancillary information, such as the faculty affiliation and supervisor details (where applicable).

2. Self-assessment and relevant details: This contains 22 self-assessment questions. By default, the answer to each question is set as "No or Not Applicable." Researchers need to set any answer to "Yes or Unsure" if the corresponding issue applies to their research. The latter case indicates that the research proposal presents potential issues regarding research ethics or data protection, and the user is then asked further questions to elaborate on these issues. These elaboration questions are automatically shown by the system and are made compulsory for the user to answer when shown. This also indicates that the REDP form will require a review from FREC prior to data collection. Figure 2 shows a snapshot from the REDP form displaying some of the self-assessment questions.

3. Submission: Users are expected to upload files as attachments to their proposal (e.g., information letters, consent forms, and data management plan), provide necessary declarations of correctness, and provide further information related to their submission (e.g., data collection start date).

Figure 2

Part of the Research Ethics and Data Protection (REDP) Form

The self-assessment questions are divided into five categories to cater for the different

types of research projects that can be undertaken by a university.

- Human participants: Applicable for projects that involve primary data collection from human participants or their tissues/samples

- Unpublished secondary data: Applicable for projects that make use of secondary data that are not publicly available

- Animals: Applicable for projects that involve primary data collection from animals or their tissues/samples

- General considerations: General questions that are applicable for all projects (e.g., whether there is any risk to the researchers and environment and whether the research project makes use of commercially sensitive data)

- Other potential risks: Asking about other risks, such as those arising from conflicts of interest, harvesting of social media data, and need for special permits/licenses.

The form has a number of validations to ensure that the necessary information is provided, thus minimizing the probability of any missing information or data. For instance, certain information (e.g., project details) is always compulsory, and if an elaboration on a certain aspect is needed, this additional information must be entered to allow the submission.

Forms can be saved as a draft for future completion. Once the forms are submitted, the applicants can keep track of a form's review status through its audit trail. Once a form has been submitted, it becomes read-only to prohibit any further changes. However, it is always possible for a researcher to withdraw any previously submitted form. In such cases, any endorsements or reviews on the form will be rendered invalid, and the researcher will have to perform any necessary amendments and resubmit, thus restarting the reviewing process.

Supervisor Functionality: Endorsement of the Submitted REDP Forms

The forms submitted by students need to be endorsed by their supervisors. Therefore, once a form is submitted by a student, the corresponding supervisor is notified via email regarding the submission. A supervisor can review forms submitted by their students and can endorse these forms or return them to the student for further correction. Each action can be accompanied by a message and will be recorded in the form's audit trail. Notably, the supervisor cannot alter the REDP form apart from endorsing or returning it to the student. The original applicant is always notified via email regarding any change in the form's status.

Given the importance of endorsement by the supervisors, URECA takes care to send automatic periodic reminders to supervisors who have pending forms waiting for their endorsements for the last few days. All email alerts sent to the supervisors contain a link to UREC, which will directly open the form in question to provide ease of access to the supervisor.

F/REC Functionality: Review/Acknowledgment of the Submitted REDP Forms

Once a supervisor approves an REDP form, it is made accessible to the corresponding FREC. Such forms are then categorized into "submitted in records" (forms that have passed self-assessment and do not require any further review) or "pending review" (forms whose self-assessment has indicated potential issues that require FREC review). According to UM's research ethics review procedures, the FREC must determine if a form requires review or not.

FREC members can review any form (including its attachments) that is under "pending review," and the FREC secretary can approve or send it back to the researcher, each time notifying the researcher via email and updating the form's audit trail. The FREC secretary can set FREC forms that do not require any review as "Acknowledged" to acknowledge their receipt

to the researcher. Only the FREC secretary has access to modify a form's status (approve it or send it back to the researcher in case of forms submitted for review or acknowledge it in case of forms not requiring review). However, FREC members have read-only access to all forms submitted to FREC.

The accessible repository of forms submitted to FREC (each one with its own audit trail of status updates and associated comments) allows all FREC members to search through previous forms for audit purposes or to help in coming up with a decision concerning a new form pending review. Figure 3 shows the audit trail of a sample REDP application.

Apart from allowing members to review forms, the Front-End F/REC section provides the capabilities for FRECs to provide audit information to UREC. UREC carries out a yearly audit, where, among other things, it audits a sample of REDP forms that were submitted for records to assess whether the researchers made the correct decision that the corresponding research did not require FREC review and approval. Therefore, this section includes the audit evaluation form, whereby FREC members can provide such audit reviews. This audit evaluation form aims to simplify the FREC member's role by pre-populating certain fields as soon as the original REDP form ID is provided, thus minimizing the input required.

Figure 3

Audit Trail of a Sample REDP Form (Sensitive Content has been Grayed Out)
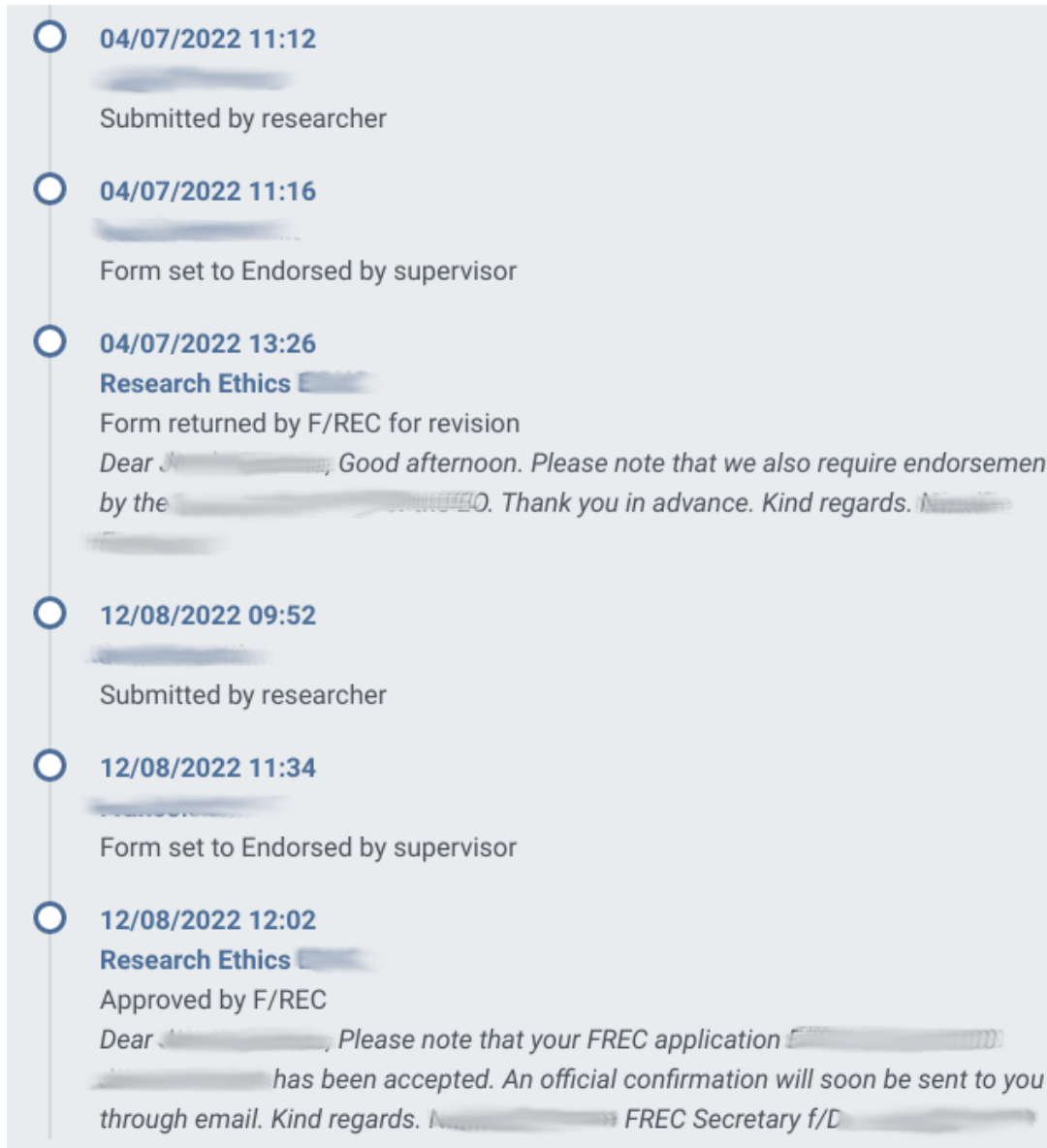
System Back End

While the URECA front end is utilized by a multitude of users, its back end is only

accessible by a few select users who administer the system. The overall aim in URECA's

development was to easily configure the system without requiring changes to its code.

The main back-end functionalities include the following:

- User management: This allows the updating of the list of back-end users and their access rights.

- Faculty/institute/center management: This allows the updating of the list of faculties/institutes/centers and for each one providing the list of FREC secretaries and members.

- External applicant management: This allows the creation and activation/deactivation of external user accounts and the reissuing of external users' credentials if needed.

- View submitted forms: This provides access to the full archive of submitted REDP forms across all faculties. The access provided here is fully read-only since the status of the REDP forms should only be updated from the front end. This functionality also allows back-end users to select and export a number of REDP forms as CSV.

- View self-assessment audit evaluation forms: This allows the viewing and exporting of the audit forms submitted by FREC members for samples of forms submitted for records (as described in Section 3.2.3).

- Management of audit evaluation forms for forms that required FREC review: As part of the yearly audit carried out by UREC, a sample of forms that underwent review and approved by the relevant FREC needs to be reanalyzed by an auditor appointed by UREC to determine whether the decision reached by FREC was correct. This functionality provides a purposely built form that can be filled in for each review. Within this section, the previously filled audit forms can be viewed and updated as well and can be exported as CSV.

Evaluation

The URECA system was launched on October 1, 2021, and has been used as the sole method of ethics and data protection review by UM since then. In the 10 and a half months between then and the day of writing, there have been over 2200 submitted review forms across 46 different faculties, institutes, centers, and schools within UM. The feedback verbally provided by various users has been overwhelmingly positive, and it has been in fact labeled as a "massive" improvement from the previous system as it simplifies the effort for all the users involved (i.e., researchers, supervisors, and FREC members).

The main improvement for researchers is simplifying the submission of REDP forms and allowing them to keep track of the previously submitted forms and their audit trail. Thus, at any point in time, a researcher can check upon the current status of any previously submitted form, and REDP submissions only need to be performed through the portal. The supervisors are kept duly informed of (and reminded about) any pending endorsement. Moreover, they can check the forms submitted by their students.

In the previous systems, FREC members faced a number of challenges when carrying out their duties. These included the receipt of REDP forms with missing information, lack of supervisor endorsements, and receipt of information in a piecemeal fashion (as often, when students were notified via email of some missing document/information, students used to reply without updating the original form and just provide the missing information or documents). The validations performed by URECA reduce the likelihood of researchers submitting forms with missing information, and supervisor endorsement is enforced to a certain extent as REDP forms reach FRECs only after supervisor endorsement has been provided. Furthermore, in case of

incorrect or missing information, the REDP form is returned back to the researcher, and after necessary corrections, the form is resubmitted in its entirety.

Another major challenge faced by FRECs in the previous systems was the archival of received forms. FRECs were expected to archive forms in a logical manner. This process relied on FREC secretaries to properly archive forms, and issues arose especially when there were changes in FREC secretaries. URECA has greatly diminished this responsibility as it harvests the REDP forms within the database itself and provides only the necessary access to each user. For instance, FREC members cannot access forms from other faculties, and a researcher can only access the forms that they submitted, while admin users can have access to an entire archive of REDP forms.

An evaluation that provides proper quantification of the improvement rendered by URECA in the application of the research ethics and data protection review procedures employed by the UM can be performed in the coming months after completion of the current yearly audit on REDP forms. Each audit is carried out on REDP forms from the past academic year, and the data collection for each audit is terminated after September (after the end of the academic year). By comparing the results of the audit for the academic year 2021–2022 (once available) with those of the previous year, one can have a clear image of how URECA helped improve REDP matters at the UM.

Conclusions and Future Work

This study describes the URECA system and how it helps the UM to apply its REDP reviews procedures. URECA solves a number of issues that were encountered by the UM using

the previous systems and has been hailed as a reliable software solution that helps simplify and streamline such procedures.

Given that URECA has been developed in-house, it is a live system in the sense that it is being continuously enhanced to reflect the needs of the evolving users. In fact, over the past academic year during which it was in operation, a number of enhancements have been implemented to help the users further. Currently, a major enhancement is underway to cater to the review of REDP applications concerning special categories of personal data (SPCD). An REDP application that is received by an FREC concerning collections or processing of SPCD data must be referred to a university-wide committee, namely, the UREC-DP committee. To date, such reviews are performed outside of URECA and rely on email communication between UREC-DP members and the referring the FREC. By implementing the enhancement, the referral and review of such applications will be handled through URECA itself.

The UM intends to keep utilizing and enhancing its URECA platform to further simplify and streamline its REDP review procedures while also ensuring that all research carried out within it adheres to its research code of practice. This helps the UM maintain a high standard of professionalism and integrity among its researchers while minimizing the administrative overload on these researchers in the application of its review procedures.

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