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

Abstract. Research ethics and data protection are being given a very high importance, and universities need to provide the necessary guidelines. Moreover, they need to ensure that these guidelines are adhered to by their researchers for the protection of the research subjects, the researchers, and the university itself. On the other hand, care must be taken so that the research ethics review process is kept as streamlined as possible. In this paper, we describe URECA - the online review platform that was developed by the University of Malta to streamline its research ethics review process, thus simplifying matters for the researchers/students, the reviewers and also the auditing committees.

1 Introduction

The two most fundamental roles of a university are teaching and the pursuit of research. However, research must be conducted in an ethical manner maintaining high standards of integrity and professionalism. In view of this, organisations and universities are obliged to provide guidelines and codes of practice that help researchers ascertain that their research adheres to the necessary ethical standards[1, 2]. Additionally, review procedures and supporting organisational structures should be provided to help researchers accordingly[2, 3].

Whilst the codes of practices adopted by the different organisation are not expected to vary significantly, review procedures have been found to differ. For instance, whilst the University College London (UCL) considers a dissertation supervisor to be the principal investigator (PI), the University of Malta (UM) considers the student to be as such [3, 4]. However, placing the student as the PI does not abolish the supervisor's responsibility. All research ethics proposals submitted by students need to be endorsed by the corresponding supervisors [3].

Nevertheless, it is standard practice in universities to provide ethics review committees or "Institutional Review Boards" to review research proposals. Such committees need to strive to be efficient and provide the necessary help as otherwise researchers may perceive them to be as obstacles to research, and in certain cases may try to circumvent them [5].

In an effort to increase its efficiency and effectiveness, in 2017 UM updated its ethics review procedures. Whereas prior to then, researchers needed to assess if their research requires ethical review (and only then submit the necessary form and documentation), all researchers are now asked to fill in a self-assessment form. This form helps to determine if the research proposed has ethical issues and thus requires review. If this transpires to be 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, whilst the other forms are reviewed by the corresponding Faculty Research Ethics Committee (FREC). Initially, these

forms were submitted on Google Forms[1], and submitted via email to the relevant FREC[3]. The limitations of Google Forms, and the reliance on emails resulted in a number of forms lacking information, missing supervisor endorsements, or not received by the 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 – i.e. the researchers, the supervisors (where applicable) and the members of the review committees. This paper describes the structure and operation of the URECA system, and demonstrates how similar systems enhance the capability of universities and other organisations to enhance their research ethics review process.

2 Literature Review

In a study carried out amongst researchers, Geuillemin et al. show that the majority of researchers understand the role of ethics review committees to protect research subjects, the researchers, and the research organisation itself. However, perceptions exist that such committees tend to over-protect the research subject and the research organisation at the expense of the research being carried out [6]. Clear communication can be a solution to allievate such perceptions. In fact, Brown et al highlight the importance of transparency between such committees and researchers to help ascertain adherance to the relevant codes of practice [5].

Inefficiencies in the review process – for instance administrative delays, requiring an excessive number of forms, and inordinate review for research with minimal risk – contribute to "research waste" [7]. Such waste can result in considerable financial cost and lost time, apart from increasing friction between researchers and review committees.

It is our impression that the review procedures of most universities require researchers to to first identify the risk level of research proposals, and then fill in a form corresponding to this risk level. This is the procedure that is followed at UCL – one of the top universities in the United Kingdom [4]. The risk level for a research proposal can be determined on the basis of a checklist similar to that published by the UK Research Integrity Office [2].

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 [4]. Whilst one may argue that reviewers will need to view filled out forms to perform their review, such forms make it hard to extract, and correct where necessary, the data contained within.

Publicly available platforms that attempt to allievate research ethics review are e-EC and TREAD. e-EC is a platform that can be used by multiple organisations. Organisations can provide their review forms as PDF, and applicants submit such forms which are then harvested, and can be reviewed by the relevant committees. This platform also allows the forms to be stored in a database that can be searched in the future [8]. On the other hand, 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 a guidance for other researchers planning similar research [9].

A similar system that is more closely related to what is required for academia is described by Bowser et al [10]. It allows researchers to submit their proposals, and then provide responses to a number of questions thus 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 paper, this system is not yet fully implemented.

[1] https://docs.google.com/forms/u/0/, last accessed March 2022

3 The URECA System

The previous section highlighted the importance of streamlined and efficient ethics review processes, and analysed a few of the available solutions. Nevertheless, the solutions discussed do not provide a complete implementation of the ethics review procedures in place at the UM (described in Section 1). 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 carry out a yearly audit of the submitted applications. Therefore, data must be available for aggregation and searching as required for auditing purposes.

The system has 2 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 their students' REDP forms,
  - Faculty Research Ethics Committee (FREC) members to view the forms submitted to their respective FREC, and
  - FREC secretary to accept or reject REDP forms pending FREC review.

The system authentication works using Google's Single Sign On for accounts on the um.edu.mt domain. This means that the system is available to all (and only) valid UM users. There is a functionality that allows external (non-UM) users. However, each such account must be set up from the back end.

All students and staff (researchers) with a UM account can access the front end to submit ethics forms. Applicants needs to submit some basic details about their research proposal, and then answer a series of self-assessment questions. Certain answers may prompt the user to enter further details as required (e.g. if the student states that primary data collection from humans is going to be performed, he/she is asked about salient participant characteristics, the recruitment process, etc.). The form has a number of validations to ensure that the necessary information is entered. Moreover, the form allows applicants to attach documents such as information letters, consent forms, data management plan, etc. Forms can be saved as draft for future completion, and once submitted, the applicants can keep track of a form's review status through its audit trail.

Forms submitted by students need to be endorsed by supervisors. Therefore, once a form is submitted by a student, the corresponding supervisor is alerted via email about this submission. A supervisor can review forms submitted by his/her students, and can accept these forms, or return them to the student for further correction. Each such action can be accompanied by a message, and will be recorded in the form's audit trail. The original applicant is always alerted via email about any change in the form's status.

Once a supervisor approves a form, it is made accessible to the corresponding FREC. Such forms are then categorised into "*submitted in records*" (forms that do not require review), or "*pending review*". FREC members can review any form that is pending review, and the FREC secretary can approve it or send it back to the researcher – each time alerting the researcher via email, and updating the form's audit trail. The provided audit trail ensures transparency for all the users involved. Moreover, given that the forms are always kept harvested within the system, the effort required by FRECs for archival and record keeping has been reduced dramatically.

Front-end users can only access specific forms (e.g. FREC members can not access forms from other faculties, and a researcher can only access the forms submitted by him/herself). However, an FREC member can search through previous forms (that were submitted to

his/her FREC) – this provides help to FREC members when determining whether a specific form should be approved on the basis of previous judgements.

On the other hand, back-end users can access the entire repository of forms (in read-only). Search facilities, and export functionalities help simplify auditing procedures. Back end access is only limited to very few specific users to manage the system. Through the back-end functionalities, FREC details (including the members and the secretaries) can be updated as needed, and also user accounts for specific external users can be created.

4 Conclusion

The URECA system has been launched on 1st October 2021 and used as the sole method of ethics review by the UM since then. In its first 6 months, there have been over 1500 submitted review forms across 46 different faculties and institutes. The feedback provided by users has been overwhelmingly positive – it has been in fact labelled as a "massive" improvement on the previous system as it simplifies the effort for all the users involved.

Given that URECA has been developed in-house, it is a live system that is being continuously enhanced to reflect the evolving users' needs. The simplification and streamlining of the research ethics review procedures helps the University of Malta maintain a high standard of professionality and integrity amongst its researchers.

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