



**STANDARD OPERATING PROCEDURE**  
**Do not Photocopy**

**Document Information Classification: Unrestricted**

<b>Title:</b>	<b>TRE Project Application Review</b>
<b>Effective Date:</b>	<b>22 Jul 2019</b>
<b>Reference Number:</b>	<b>SOP-03-09</b>
<b>Version Number:</b>	<b>2.0</b>
<b>Owner:</b>	<b>Information Security Manager,</b>
<b>Review Date:</b>	<b>22 Jul 2021</b>

## Table of Contents

<b>1. Purpose .....</b>	<b>3</b>
<b>2. Scope .....</b>	<b>3</b>
<b>3. Responsibilities.....</b>	<b>3</b>
<b>4. Procedure.....</b>	<b>3</b>
4.1. Before submitting the TRE Project Application Form .....	3
4.2. Distribution and Review of Completed Application Forms.....	4
4.2.1. TRE Project Board .....	4
4.3. Following the first TRE Project Board Recommendation.....	4
4.4. Arrangements for TRE Project Board Meetings.....	4
<b>5. Cross-referenced ISMS Documents .....</b>	<b>5</b>
<b>6. Appendices.....</b>	<b>5</b>

## 1. Purpose

This document provides guidance for the initiation of a Trustworthy Research Environment (TRE) project application and the process for the review of the application.

## 2. Scope

New TRE Projects that have not been reviewed by the TRE Project Board are in the scope of this procedure.

## 3. Responsibilities

TRE Operations staff are responsible for:

- Communicating with representatives of intended projects and monitoring shared mail boxes.
- Adding and updating the TRE Project details on JIRA
- Circulating TRE Project Application Forms to TRE Project Board members

TRE Project Board members are responsible for:

- Reviewing materials circulated by TRE Operations in preparation for Project Board meetings
- Attending these meetings and providing detail for TRE Operations to be able to justify Board decisions to the Project Principal Investigator (PI).

Project Principal Investigators are responsible for:

- Completing and signing a TRE Project Application Form for their project
- Ensuring all necessary documentation is provided for the TRE Project Board to understand and discuss the proposed project.

## 4. Procedure

### 4.1. Before submitting the TRE Project Application Form

PIs planning to apply to use the TRE for a project must direct their application request to TRE Operations.

TRE Operations will, where necessary:

- Liaise with the PI to describe the application process
- Provide FORM-002 TRE Project Application Form
- Liaise with PIs or other project representatives, e.g. PhD student or project manager, about project requirements;
- Provide supporting documentation for grant applications,
- Provide advice on how the TRE operates and on how to complete FORM-002 TRE Project Application Form.
- Add the TRE project to JIRA (SOP-03-06)

A TRE Project Application Form is complete when it has details in all relevant sections, supporting documents are attached, there is a signature from the PI, and it has been submitted as per the instructions in the Application Form.

On receipt of the form, TRE Operations will update the project workflow status on the JIRA project record to 'Application Form Received'.

## **4.2. Distribution and Review of Completed Application Forms**

TRE Operations will circulate completed TRE Project Application Forms to TRE Project Board members, prior to review at the next TRE Project Board Meeting.

On distribution of the form, TRE Operations will update the project workflow status on the JIRA project record to 'Application Review in progress'.

Following a review of the application, the TRE Project Board should unanimously reach one of the following recommendations:

1. Project rejected
2. Project accepted
3. Project needs to be re-submitted with:
  - a. Amendments to the application form to clarify certain points, e.g. technical requirements, or
  - b. Certain criteria being met, e.g. ethical approval, data sharing agreements signed.

### **4.2.1. TRE Project Board**

The TRE Project Board comprises all members of TRE Staff, the University's Research Domain Director for Digital Health and the Director of the Centre for Health Informatics. Additionally, the Board will invite specialists in the field of health informatics to attend meetings as non-voting members.

## **4.3. Following the first TRE Project Board Recommendation**

TRE Operations will update the project workflow status on the JIRA record and communicate the recommendation and relevant details to the PI who can follow these steps:

- 1) For rejected projects the recommendation can be appealed and/or application form revised for review at a future TRE Project Board meeting (project status 'Application Rejected').
- 2) For accepted projects TRE Operations must follow SOP-03-08 TRE Change Control (project status 'Application Approved').
- 3) For applications to be re-submitted the PI must ensure the requested amendments or criteria are met before submitting updated documentation to TRE Operations for consideration at the next TRE Project Board Meeting (project status 'Awaiting Application').

## **4.4. Arrangements for TRE Project Board Meetings**

- The Board is quorate when at least three members are present, including at least one from TRE Operations. With fewer members any agenda items requiring a decision will roll over to the next scheduled meeting
- Either the TRE Operations Manager or the TRE Information Governance Manager will chair the meetings, depending on who is available
- The Board will normally review updates sent by email each month. Additionally, the Board will meet in person every 3 months, but if an urgent matter arises, this could be more frequent

## 5. Cross-referenced ISMS Documents

Number	Type	Title
FORM-002	ISMS\Forms	TRE Project Application Form
SOP-03-06	ISMS\SOP\TRE Operations - SOP	Managing TRE Project Records
SOP-03-08	ISMS\SOP\TRE Operations - SOP	TRE Change Control

## 6. Appendices

None