FACULTY OF HEALTH SCIENCES
RESEARCH ETHICS COMMITTEE

RESEARCH ETHICS APPLICATION FORM (REC 2.0): SHORT USER GUIDE

1. Purpose of the Application Form

Use of an application form for the ethics review process is new – previously only a research proposal was submitted for review. Following the National Health Research Ethics Council (NHREC) audit in September 2022, the Council specified in their audit report that an application form must be used as part of the review process. Reasons cited for this were that (i) this is standard practice at other research ethics committees and is considered a minimum standard for ethics review, (ii) that an application form can assist researchers in understanding (through the structure of the form) what information is required of them and (iii) that an application form can expedite the review process by making key information easily accessible to reviewers. This does not mean that reviewers will not refer to the research proposal during the review process. Rather, it means that the application form and research proposal when read together will typically streamline the review process by making key information relevant to ethics review easy to find, structured and more coherent.

2. General Approach to Completing the Application Form

Information required in the application form should be extracted from the research proposal and entered in the relevant fields in the application form (if copying and pasting into the application makes sense this is fine but avoid copying information into the application form that does not directly address what is required in the form). If information is required in the application form but is not present in the research proposal, it should be added to the research proposal in addition to being entered into the application form (this is an example of a benefit of the application form in potentially improving the quality of research proposals with regard to ethics-related information). Please make sure that text information entered into the application form is (i) adequate to address what is being requested and that it is (ii) aligned with information in the research proposal (i.e., there should not be contradictory information between the application form and research proposal).

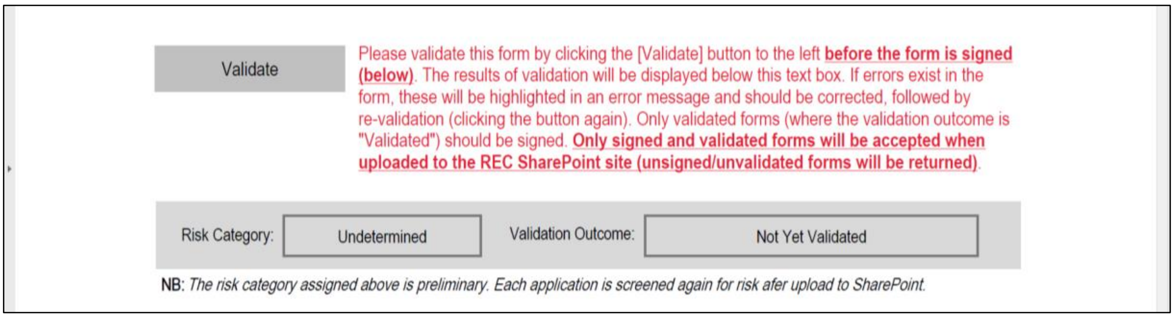
3. Required Parts/Fields of the Application Form

Depending on the nature or type of research, there are several required parts of the application form that must be populated. Some of these are basic information and some of these are parts of the application form that are conditional on the completion of other parts (e.g., a [yes/no] option may require entry of further information if the response is [yes]). Top level required fields - i.e. fields that will typically always require a response - in the application form are identified with a red asterisk (*). Other fields that are conditional (i.e. dependent on responses to other parts of the application form) are not identified in this way, however instructions in the form will clearly indicate these – please check the instructions carefully. In addition, validation of the application form (see below) will identify all conditionally required fields if these are not completed.

4. Validating the Application Form and Determining the Risk Category

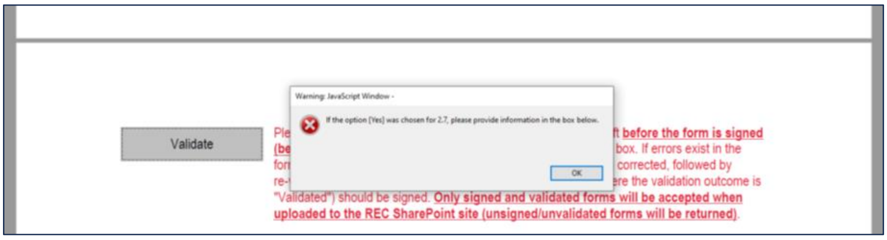
a) Validation

Because the structure of the application form is fairly complicated with many conditional fields, it is important that the form is checked for completeness prior to upload. This is done through validation, by clicking on the [Validate] button found on the last page of the application form (see below).



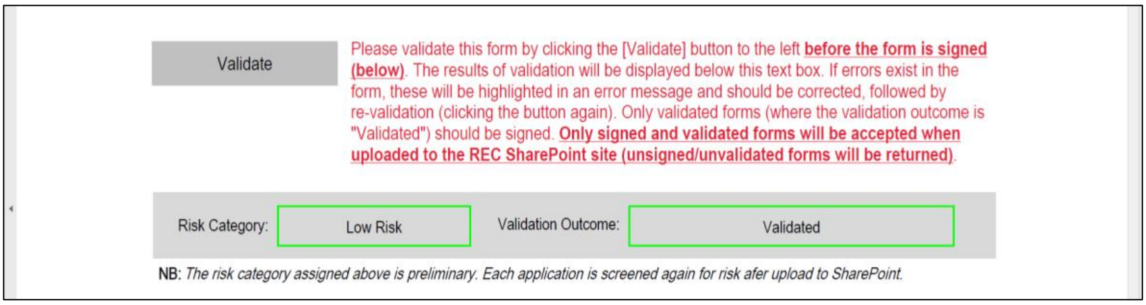
Important points regarding validation:

- The application form should be completed before validation is attempted (except for signing, which is discussed below). If validation is attempted without the entire form being completed, many required fields will be identified each generating an error message.
- If any error messages occur (an example is shown below), please take note of them (they will refer to an item [field] number on the form) then go back and add the missing information. After this is done, you will need to validate the application form again by clicking the [Validate] button.



- If for some reason it is necessary to change anything (other than signing) in the application form after successful validation, the validation outcome will be reset back to [Not Yet Validated]. This will mean that it is necessary to validate the application form again by clicking the [Validate] button.
- Only validated application forms will be accepted once uploaded to SharePoint.

A successfully validated application form will display a message as shown below (ignore the risk category, this is discussed below):

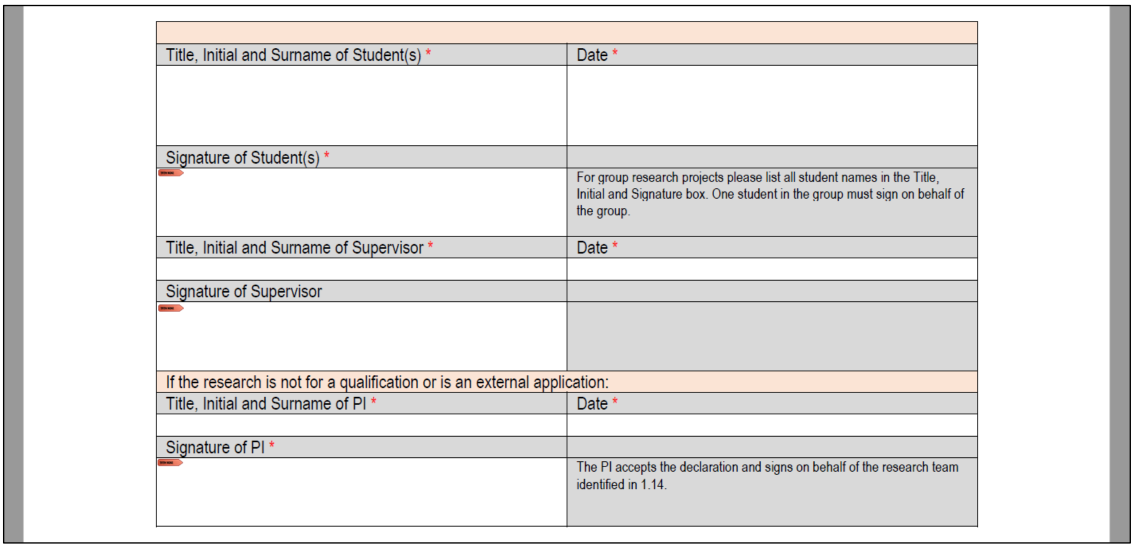


b) Risk Categorisation

Ethics review takes into consideration differences in risk for each application. There are two risk categories: low risk and > low risk (see the REC Standard Operating Procedures for more information). Determination of risk is based on specific criteria all of which are contained in the application form. As part of the validation process, a risk category is determined algorithmically and displayed alongside the validation outcome (see above for an example). The risk category displayed on the application form is read-only (i.e. it cannot be manually changed). The risk category determined as part of the validation process is preliminary and is assessed again after upload to SharePoint.

5. Signing the Application Form

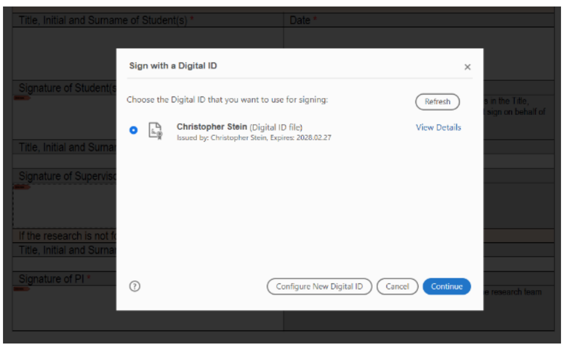
Each application form must be signed electronically. This is done using the signature panel at the end of the form (see below). Not all sections need to be completed and signed. If the research is for a qualification both the student (or, if the research is done by a group, one student representing the group) and supervisor must sign. If the research in not for a qualification or external then only the principal investigator (PI) must sign.

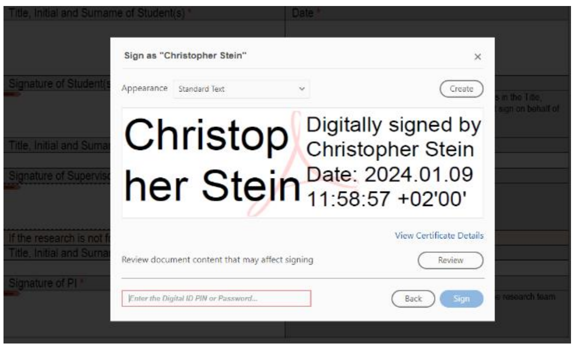


Title, Initial and Surname of Student(s) *	Date *
Signature of Student(s) *	
	For group research projects please list all student names in the Title, Initial and Signature box. One student in the group must sign on behalf of the group.
Title, Initial and Surname of Supervisor *	Date *
Signature of Supervisor	
If the research is not for a qualification or is an external application:	
Title, Initial and Surname of PI *	Date *
Signature of PI *	
	The PI accepts the declaration and signs on behalf of the research team identified in 1.14.

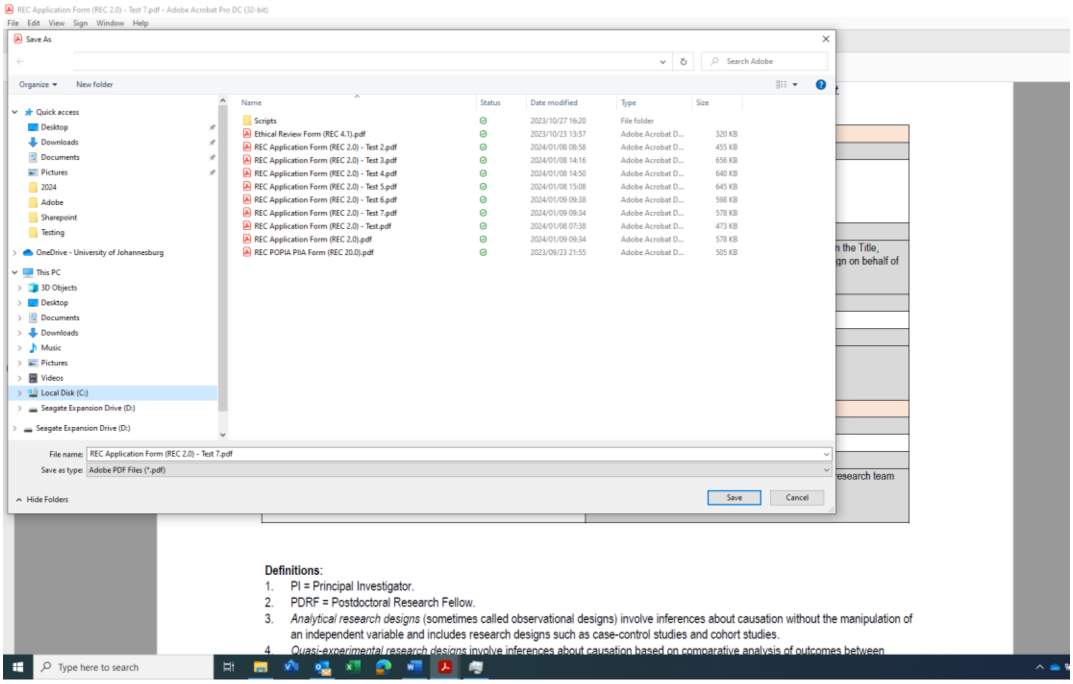
To sign the application form, the following steps must be followed:

1. Click on the small orange tab in the top left corner of the signature field.
2. This will open a dialogue box similar to that shown below, left. Clicking on the [Continue] button will open show the saved digital signature which can be used after the signature password has been entered at the bottom of the dialogue box (see below, right). If there are no saved signatures, you can set one up easily by clicking on [Configure New Digital ID] at the bottom of the picture to the left below.

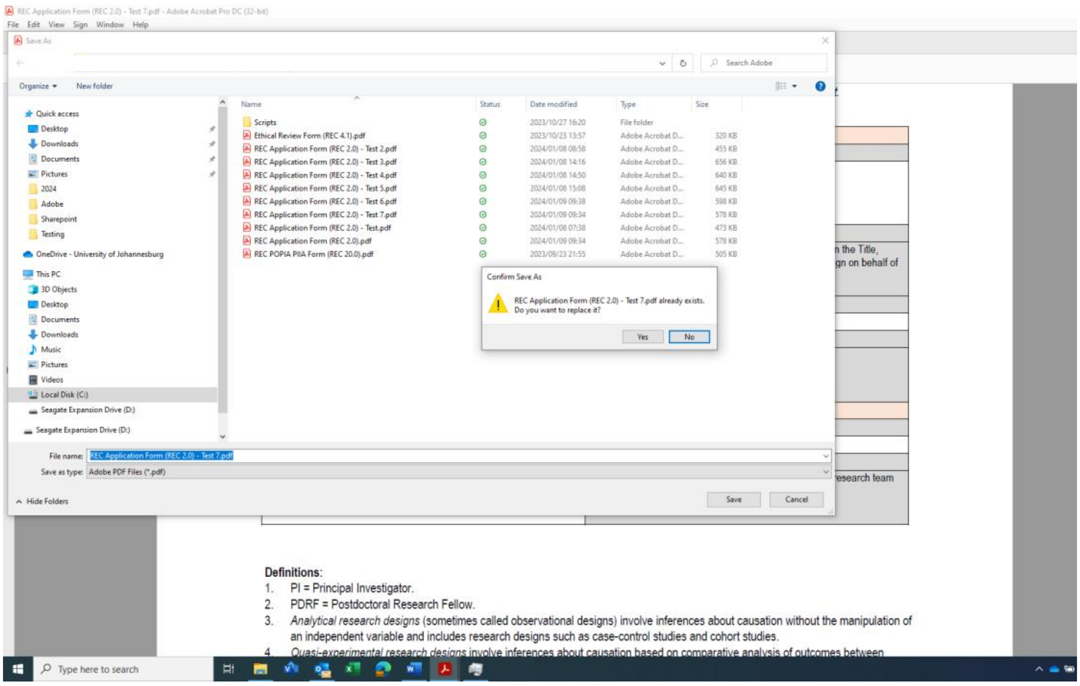




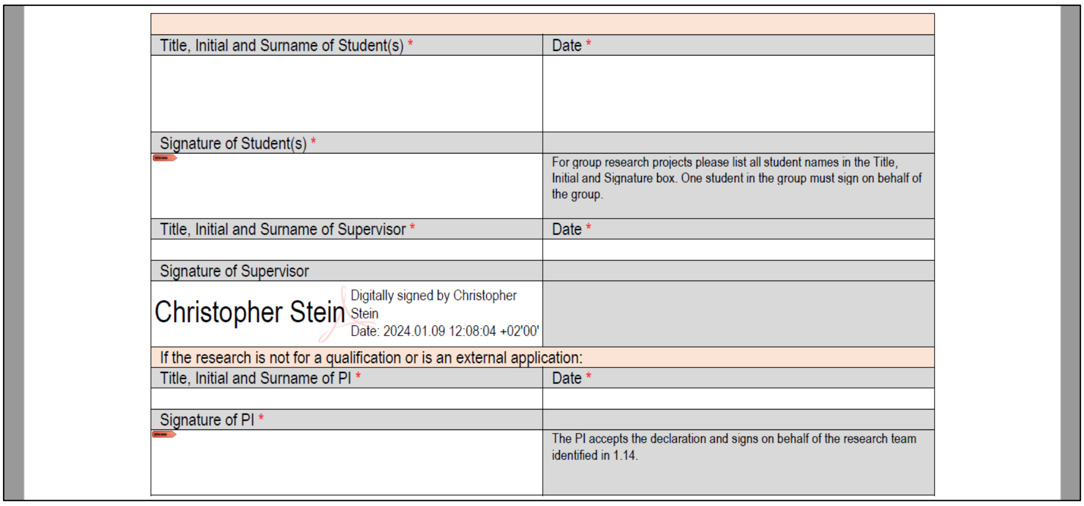
3. Once the signature password has been provided, clicking on the enabled [Sign] button will open a save file dialogue box as shown below.



4. The reason why this dialogue is shown is that digitally signing a document should be done just before saving it – saving the document then preserves it in its current form with the signature. You should click [Save] to save the signed file. If you are saving the file with the same file name in the same folder you will see a message like the one below (i.e. that the file exists, asking you if you want to replace it). By default, you should click [Yes] and overwrite the file – it is perfectly safe to do so.



5. Once you have followed the steps above you will see the digital signature inserted into the application form as shown below. Note that if you choose to overwrite the existing file as suggested above you do not need to re-open the newly saved file – it will stay open and you will see the signature as shown below.

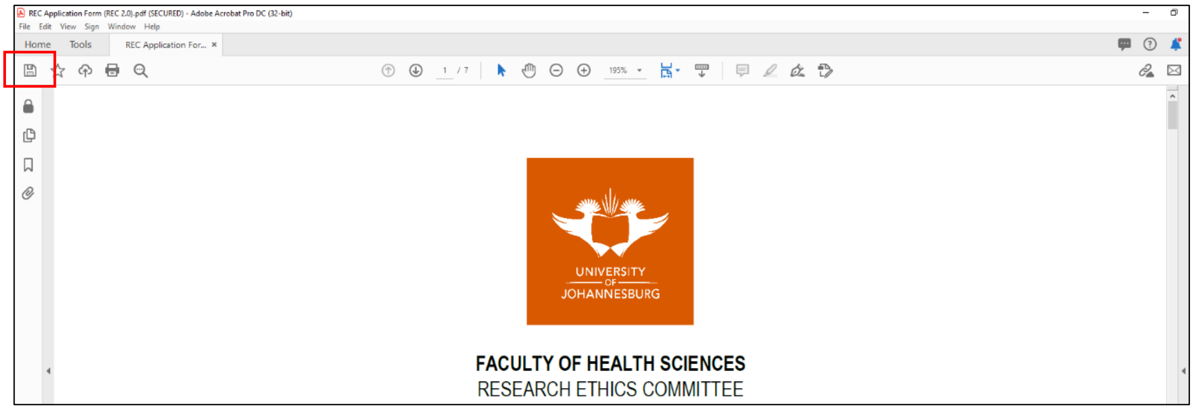


Title, Initial and Surname of Student(s) *	Date *
Signature of Student(s) *	
	For group research projects please list all student names in the Title, Initial and Signature box. One student in the group must sign on behalf of the group.
Title, Initial and Surname of Supervisor *	Date *
Signature of Supervisor	
Christopher Stein Digitally signed by Christopher Stein Date: 2024.01.09 12:08:04 +02'00'	
If the research is not for a qualification or is an external application:	
Title, Initial and Surname of PI *	Date *
Signature of PI *	
	The PI accepts the declaration and signs on behalf of the research team identified in 1.14.

6. Please note that the picture above is just an example to show the inserted digital signature. When you fill in a real application form you will need to also complete the other fields as required (for student, supervisor or PI name and the date).
7. For signing of application forms <u>please do **not** use Fill & Sign</u> – this will not produce an authentic digital signature.
8. Lastly if you sign, save and close an application form and then re-open it you will probably see a message like the one displayed in the blue bar at the top of the picture below. The message says that the document has changed (i.e. has been updated) since it was signed and saved. This occurs because there is programming code embedded in the document that runs when it is opened, updating the document. <u>Please ignore the message below – it is of no relevance and does not require any response from you</u>.

9. Saving the Application Form

It is possible to save the application form at any stage. If you cannot complete the form at one time, you can save a partially completed form and come back to it later to complete it. To save the application form, click on the disk icon at the top left of the document window (see below, outlined in red). However, it is important to remember that you need to validate and sign the form (not just save it) before uploading it to SharePoint (validation is explained above).



10. Upload of the Application Form to SharePoint

Once the application form has been completed, validated, signed and saved it should be uploaded to SharePoint together with a <u>separate</u> PDF copy of the research proposal (the research proposal file should also contain any annexures required such as an information letter and consent form etc.). As part of the upload process, some information must be entered into the upload form on SharePoint as shown below (next page), shaded in blue. This information is required for NHREC annual reporting purposes. All of this information can be obtained from various fields in the completed application form. Please ensure that the risk level entered into the SharePoint from is the same as the risk category displayed on the application form after it has been validated. An application form is only required for the first version of an application (i.e. the very first submission for ethics review) – after this, if revisions are required only the revised research proposal and relevant revisions form (REC 7.0 if it was a 02a or REC 6.0 if it was a 02b or 03) need to be attached in subsequent uploads.