

UWIScholar

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# RESEARCH APPLICATION MANAGEMENT MODULE

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Applicant Manual for Research Ethics Module V3.0

DECEMBER 1, 2021

THE UNIVERSITY OF THE WEST INDIES

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## How to use this Manual

### **This manual is divided into three parts.**

- **Part 1** – provides a guide for users logging into the application portal and completing the online application forms. Part one also gives information on how to track the applications, revise and resubmit applications and retrieve final decision letters and request extensions or modification of approvals.
- **Part 2** - contains guidelines on answering the questions on the forms and uploading relevant documents
- **Part 3** - contains sample forms to assist the user with gathering the relevant information for completing the online forms ahead of time.

It is recommended that applicants review all parts of these instructions before attempting to complete the online forms and before posting queries as these may be addressed in the different parts of the manual.

### **Queries:**

- If you have queries related to *UWIScholar* e.g. registering for or logging into the account or error messages when submitting the forms, please send an email to [uwischolar@sta.uwi.edu](mailto:uwischolar@sta.uwi.edu)
- If you have any queries related to completing the forms, questions about guidelines and rules please contact
  - CaveHill Campus - [ResearchEthics@cavehill.uwi.edu](mailto:ResearchEthics@cavehill.uwi.edu)
  - Mona Campus - [mcrec@uwimona.edu.jm](mailto:mcrec@uwimona.edu.jm)
  - Open Campus - [ethics@dec.uwi.edu](mailto:ethics@dec.uwi.edu)
  - St. Augustine Campus - [campusethics@sta.uwi.edu](mailto:campusethics@sta.uwi.edu)

**Please Note:** This manual may be updated from time to time and you are advised to refer to the most recent version which will be posted on the Research Ethics website. Additionally, as features of the online system are updated, these will also be reflected in the Manual. Finally, as your queries come into us, we may update sections of the manual for ease of reference and reading to ensure instructions and guidelines are clear and understandable for all.

### **Tips for Completing the Online Application Form**

- If you wish to save your progress and return to finish the application at a later time, insert some text in the sections with an asterisk and click the Save button. You will then be directed to the main application page.
- Some sections have word limits, pay attention to these when filling out the form
- If you get any error messages when saving the forms, after you fix the errors, **ensure the uploaded files are still attached before you click the save button.**
- Before submitting the application, check back to ensure uploaded files are still attached.
- **Only pdf files can be uploaded to the application system.**
- Copy and paste: Use keyboard shortcuts CTRL + C to copy and CTRL + V to paste text into relevant sections of the applications

How to **share a copy** of the Forms with other members of your team:

This can be done either before or after submission of the application.

1. Please review the information on this webpage to learn how to “Print to PDF” from your Browser <https://pdf.wondershare.com/pdf-knowledge/print-to-pdf-firefox-chrome-ie-safari.html>
2. **Before Submission** - Click on “Research Proposal”/**After Submission** - Click on “View Application”. Forms A and B appear as tabs at the top of your screen. Select the relevant form.
3. Follow instructions to “Print to PDF” provided above
4. Repeat for Investigators Information and Consent Forms as required
5. You can now circulate your PDF forms to your Supervisor, Students or other Researchers for them to view the completed Application Forms.

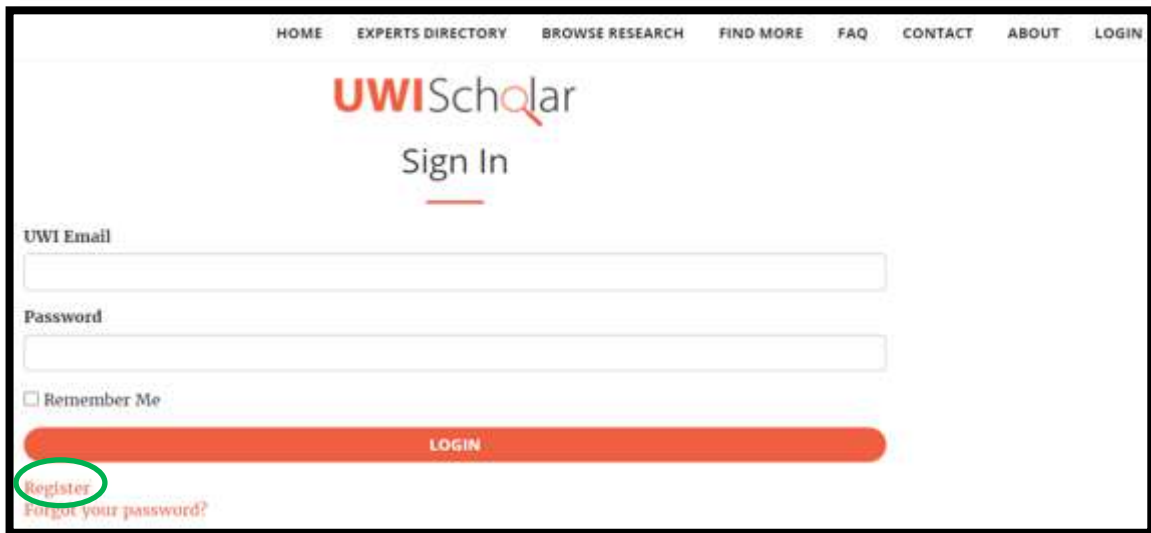
## Part 1 – Online Application Guidelines

### A. Registering for a *UWIScholar* Account

1. All applicants must create a *UWIScholar* profile by visiting <https://UWIScholar.sta.uwi.edu/>.



2. Click on “Login” at the top right corner.



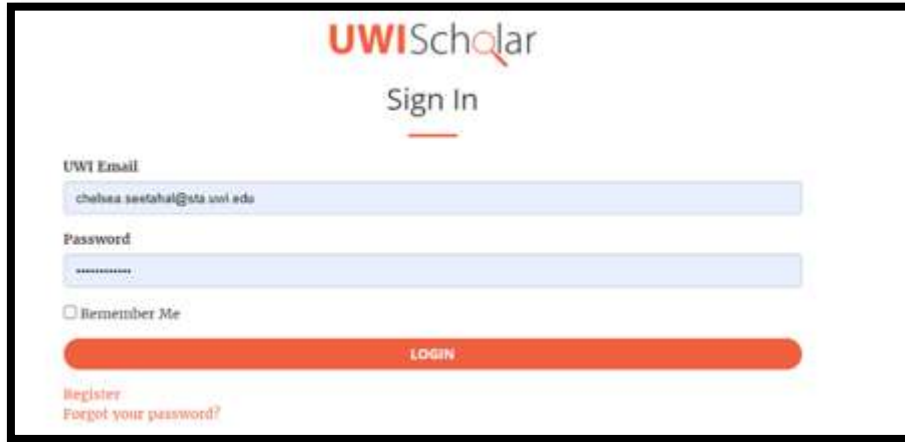
1. You will be directed to the page below.
2. Click on “Register” to create an account.
3. Enter UWI email address and password of your choice and other relevant details.

#### **N. B. Please use your UWI (Staff/Student) email address to register.**

4. When you receive the confirmation email that your account has been created, you may proceed to login to the *UWIScholar* Account

## B. Log into *UWIScholar* & Research Ethics Module

5. Login to your *UWIScholar* profile by entering your UWI email address and the preselected password at <https://UWIScholar.sta.uwi.edu/>.

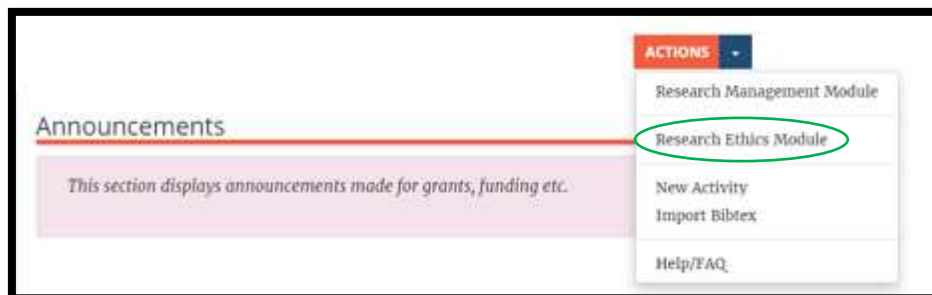


The screenshot shows the 'UWIScholar Sign In' page. At the top, the 'UWIScholar' logo is displayed. Below it, the text 'Sign In' is centered. There are two input fields: 'UWI Email' with the value 'chelsea.seefah@sta.uwi.edu' and 'Password' with masked characters. A 'Remember Me' checkbox is present and unchecked. A prominent red 'LOGIN' button is located below the fields. At the bottom left, there are links for 'Register' and 'Forgot your password?'.

6. Select "My Profile" at the top, right of the screen.

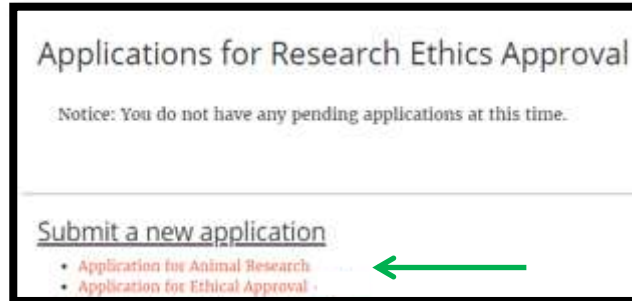


7. Click on the dropdown arrow next to "Actions" and select "Research Ethics Module".



### C. Completing the *Research Proposal* Form and uploading supporting documents

8. For a new application submission, scroll to the end of the page under “Submit a new application” and select “Application for Ethical Approval” or the “Application for Animal Research” form as applicable.



9. You will now be directed to the “**Research Proposal**” page to complete this first form.  
10. Complete all sections in the form. Sections with asterisks (\*) indicate that a response is mandatory and the form will not be saved if there is no response in these sections. If a section is not applicable to your research, fill in that section with “N/A”.

*N.B. Some sections contain help messages. To view these help messages, click on the help button (question mark icon) at the end of the section and the help message will be displayed in red text.*

11. Upload your data collection instruments under Section 5.5.
12. Insert the name of the file you wish to upload in the "Description" section e.g. Questionnaire, Interview Questions etc.
13. Click "Choose File" and select the relevant file for upload.
14. To add more than two (2) data collection instruments, click "Add Row" and repeat steps above.

**5.5 Data Collection Instruments**

Please upload the data collection instruments that will be used. These can include:

- Measurements
- Questionnaires
- Focus group questions/topics
- Interview questions/topics

Enter a description for the instrument and upload the file

* Description	* File (doc; docx; pdf)
Questionnaire 1	Choose File Doc1.docx
Questionnaire 2	Choose File Doc1.docx

Add Row

15. Section 7.1 uses a drop down menu to identify the most appropriate response based on the type of research to be conducted. Click on the help button for more information on each option.

**N.B. Section 7.4 and 7.5 may be relevant to Exemption and Waiver applications.**

**7. Risk/Benefit**

\* 7.1 Indicate what is the level of risk associated with this research ?

No more than minimal risk

\* 7.2 Please describe risk, discomfort (physical/psychological), inconvenience, side effects, and financial costs to participants (include measures to mitigate these risks/discomforts)

\* 7.3 Indicate direct benefits to participants (not applicable for Waiver Applications)

7.4 Impacts of the study on human groups that are not participants in the study (positive/negative, where applicable)

7.5 Impacts of the study on the environment (positive/negative, where applicable)

8. Compensation for participants: including payments or payments in kind

16. Section 13 “Document Upload” allows you to upload all relevant supporting documents for your application.
  - a. Research proposal – mandatory for clinical trials only
  - b. SPIRIT/WHO Guidelines – mandatory for clinical trials (**only at CaveHill Campus**)
  - c. Recruitment Materials – as required for research activity
  - d. Letters to institutions for permissions to access research site e.g. Letters to Regional Health Authorities, Government Ministries, School Principals, Government Organizations , Private Companies etc. requesting
    - i. access to secondary/institutional data or
    - ii. permission to survey staff/personnel in their care/jurisdiction.

**N.B. permission to survey staff or students of the UWI or access institutional data must be requested from the Campus Registrar and may only be granted after confirmation of ethics approval, exemption or waiver.**

- e. Consent Form (s)
- f. Any other supporting documents can be attached at 13.6. E.g. Principal Investigator’s authorization, permission letters from other institutes etc.

13. Document Upload

13.1 Research Proposal (required for clinical trials) Choose File No file chosen

13.2 SPIRIT/WHO guidelines checklist for clinical trials Choose File No file chosen

13.3 Recruitment Materials Choose File No file chosen

13.4 Letters to institutions for permission to access research sites and approvals as required Choose File No file chosen

13.5 Consent Forms Choose File No file chosen

13.6 Other Documents

Description	File
<input type="text"/>	<span>Choose File</span> No file chosen

BACK SAVE

17. Once the sections are filled out and all supporting documents are uploaded click “Save” button at the end of the form.
18. You will be redirected to the “Research Ethics Module” page where your application will be displayed under “Incomplete Applications”. At this point, you will be able to identify your application by the displayed title under “Title of the Research Project”

**N.B The user will be able to edit the information on their research proposal form prior to submission by clicking on “Research Proposal”.**

19. Complete “Investigator’s Information” Form - see Section D for instructions on completing this mandatory form.
20. Click “Submit Application” button.
21. A reference number will be generated upon submission – See Section G on tracking the application.



## D. Completing the Investigators' Information Form

25. After saving the Research Proposal Form, the Investigators Information Form will be available for completion under the relevant project title, in the "Incomplete Applications" Section.
26. Click on "Investigators information" form to enter contact information for all named researchers on the project.
27. The Form is mandatory and is made up of 3 sections:
  - Section A – Research Type
    - This section allows the user to identify the type of research – staff, student or external researcher.
    - For student research, the student and supervisor names and programme information will be collected in this section

The screenshot shows the 'UWIScholar Investigator's Information' form. At the top, there is a privacy statement: 'The name, email addresses, and telephone numbers entered in this research application will be used exclusively for the review of the application and will not be made available to any other party.' Below this is section 'A. Research Type'. It features a dropdown menu for 'Research Type' with the selected option 'This research in partial fulfillment of a UWI degree programme'. There are input fields for 'Name of Student' and 'Name and Affiliation of Supervisor'. A note below the supervisor field states: 'Please ensure that your supervisor reviewed and approved the contents of the application. A supporting email from your supervisor with the reference number must be sent to the ethics committee's email address or a supporting cover letter should be uploaded with the application.' Below the supervisor field is an 'Add Row' link. At the bottom, there are dropdown menus for 'Department' (selected: Agricultural Economics and Extension), 'Faculty' (selected: Faculty of Engineering), and 'Programme' (selected: BA/BSc).

- Section B – Principal Investigator(PI) Information
  - This section allows the user to fill in the relevant contact information for the Principal investigator including the address information for the final approval letters.
  - Upload CITI completion reports for the PI – if applicable

**B. Principal Investigator**

\* Principal Investigator: A A A

\* Qualifications of P.I.: A B C

\* Email of P.I.: Chelsea.Seetahal@sta.uwi.edu

\* Phone Number of P.I.: XYZ

\* Affiliation of P.I. ⓘ: Affiliation

\* Address ⓘ: Address

Programme: Prog

Programme Level: MA/MSc

\* CITI training or equivalent certificate for P.I.

View File Choose File No file chosen

- Section C – Co Investigator(Co-I) Information
  - This section allows the user to fill in the relevant contact information for the Co- investigators on the project. Up to 10 Co-investigators can be added in Section C
  - If the Co-I is a student, please enter programme information.
  - Upload CITI completion reports for the Co-I

**C. Co-Investigators**

Co-Investigator: ABC

Qualifications of C.I.: ABC

Email of C.I.: Chelsea.Seetahal@sta.uwi.edu

Phone Number of C.I.: xyz

Affiliation of C.I.: Affiliation

Programme Title: Prog

Programme Level: MA/MSc

CITI training or equivalent certificate for C.I. one

View File Choose File No file chosen

28. Complete Sections A, B and C – indicating “N/A” where relevant
29. Click “Save” at the end of the page and you will be redirected to the “Research Ethics Module” page.

## E. Submitting the Completed Application

30. When all relevant forms are complete click on “Submit Application” under “Incomplete Applications” to submit your application for review to the Ethics Committee.

Incomplete Applications:

**INSTRUCTIONS:**

- These applications have multiple forms to be completed before submitting.
- Click on the form name to fill it.

Application for Ethical Approval - STA:

#	Date Submitted	Title of the Research Project	Reference Number
1	2020-08-25 15:06:05	ABC	CREC-SA.0507/

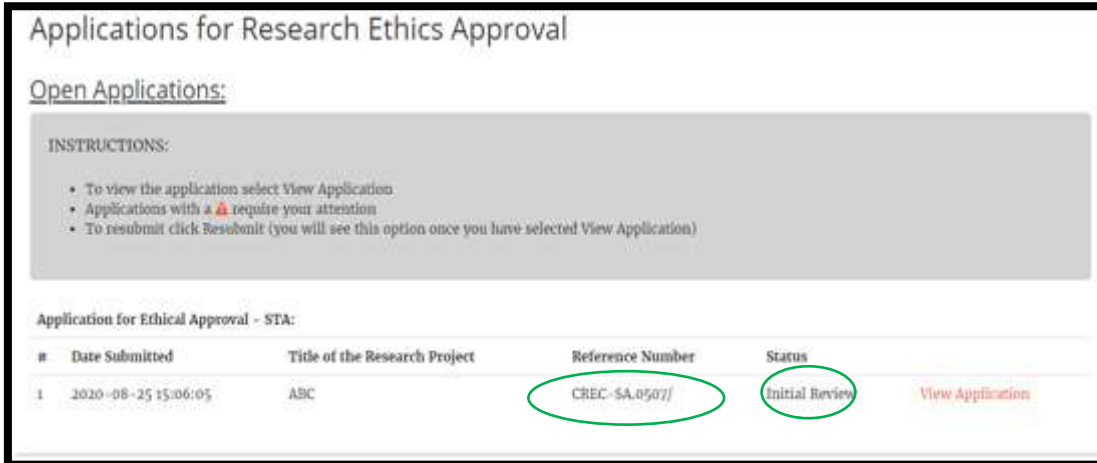
Research Proposal  
Investigator's Information  
Consent Form  
Consent Form 1  
Consent Form 2  
Consent Form 3  
Consent Form 4  
Parent/Guardian Consent Form  
Parent/Guardian Consent Form 1  
Parent/Guardian Consent Form 2  
Parent/Guardian Consent Form 3  
Parent/Guardian Consent Form 4

**SUBMIT APPLICATION**

31. Once the application has been submitted it will be moved to the “Open Applications” section on the Research Ethics Module page. You can view, but not edit the submitted application by clicking on “View Application”
32. See Section G on tracking the status of the application.

## F. Tracking Application Status

33. Once your application is submitted it will appear in the “Open Applications” section.
34. The “Reference Number” is the unique number that identifies your application which will be generated once the application is submitted. Please use this reference in all correspondence related to the application.
35. To track the progress of the review please refer to the “Status” section of the application .



The screenshot displays the 'Applications for Research Ethics Approval' interface. Under the 'Open Applications' section, there are instructions: 'To view the application select View Application', 'Applications with a red triangle require your attention', and 'To resubmit click Resubmit (you will see this option once you have selected View Application)'. Below this is a table titled 'Application for Ethical Approval - STA:' with columns for '#', 'Date Submitted', 'Title of the Research Project', 'Reference Number', and 'Status'. A single application is listed with the reference number 'CREC-SA.05077' and status 'Initial Review', both of which are circled in green. A 'View Application' link is visible to the right of the application row.

#	Date Submitted	Title of the Research Project	Reference Number	Status
1	2020-08-25 15:06:05	ABC	CREC-SA.05077	Initial Review

36. The Stages of Review are as follows:
  - Secretary Initial Review
  - Categorization
  - Full Committee Review/Expedited Committee Review/ Exempted Review/Waiver Review
37. After reviews are completed, the application may be returned to you for revision (see Section G) or approval letters will be generated (See Section H)

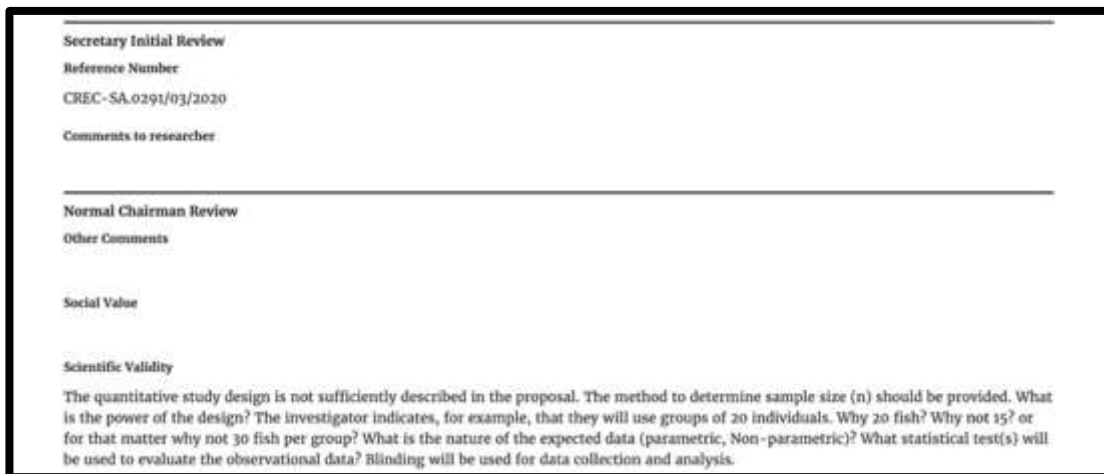
## G. Revising and Resubmitting Applications

38. If your application requires some revision, you will receive an email notification.
39. Log into *UWIScholar* “Research Ethics Module” page
40. The application that requires revision will be identified by the orange triangle to the left of the screen.
41. Click on the “View Application” button



#	Date Submitted	Title of Research	Reference Number	Status
1 ▲	2020-03-04 15:16:30	Neophobia and the assessment of predation risk in aquatic ecosystems.	CREC-SA.0291/03/2020	<a href="#">View Application</a>

42. Scroll down until you see the comments section of the application



Secretary Initial Review

Reference Number  
CREC-SA.0291/03/2020

Comments to researcher

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Normal Chairman Review

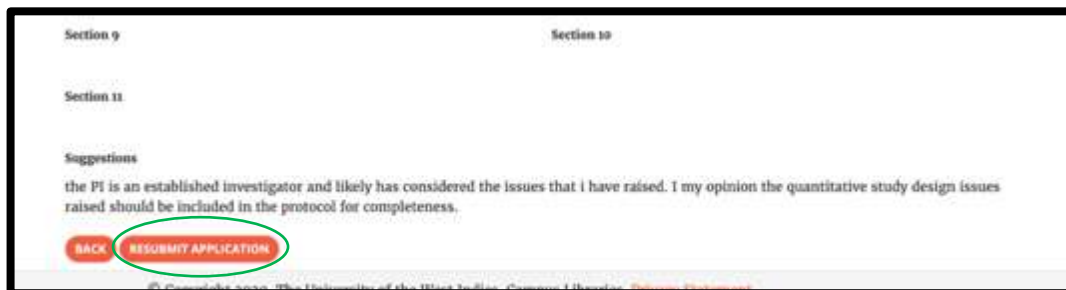
Other Comments

Social Value

Scientific Validity

The quantitative study design is not sufficiently described in the proposal. The method to determine sample size (n) should be provided. What is the power of the design? The investigator indicates, for example, that they will use groups of 20 individuals. Why 20 fish? Why not 15? or for that matter why not 30 fish per group? What is the nature of the expected data (parametric, Non-parametric)? What statistical test(s) will be used to evaluate the observational data? Blinding will be used for data collection and analysis.

43. Click on the resubmit application button to make the application editable.



Section 9

Section 10

Section 11

Suggestions

the PI is an established investigator and likely has considered the issues that i have raised. I my opinion the quantitative study design issues raised should be included in the protocol for completeness.

[BACK](#) [RESUBMIT APPLICATION](#)

44. Follow steps in Section C to edit and resubmit the application.
45. Ensure you click the ‘submit’ button to resubmit the application.

## H. Retrieving Approval Letters

46. When the application is approved you will receive an email notification
47. Log into *UWIScholar* “Research Ethics Module” page
48. The approved application will appear under the “Completed Applications Section”
49. Click on the “View Application” button.

**Open Applications:**

**INSTRUCTIONS:**

- To view the application select View Application
- Applications with a require your attention
- To resubmit click Resubmit (you will see this option once you have selected View Application)

Application for Animal Research:

#	Date Submitted	Title of Research	Reference Number	Status
1	2020-03-04 15:16:30	Neophobia and the assessment of predation risk in aquatic ecosystems.	CREC-SA.0291/03/2020	<a href="#">View Application</a>

**Completed Applications:**

Application for Animal Research:

#	Date Submitted	Title of Research	Reference Number	Status
<input type="checkbox"/> 1	2020-03-03 11:10:23	Mixed Species Shoaling and Information Flow in Trinidadian Poecilia sp.	CREC-SA.0277/03/2020	<a href="#">View Application</a>
<input type="checkbox"/> 2	2020-03-03 13:44:23	Interactions between behaviour and ecology in Trinidadian guppies	CREC-SA.0276/03/2020	<a href="#">View Application</a>
<input type="checkbox"/> 3	2020-03-03 13:17:23	Social foraging in low and high predation surges	CREC-SA.0275/03/2020	<a href="#">View Application</a>

50. Scroll to the end of the application’s page
51. Click on the “Approval Letter” and “Consent Forms” (if relevant) to download pdf versions of the documents.
52. Click on the “Back” button to exit the application.

**Files**

File Name	File (pdf or word)
cover letter	<a href="#">View File</a>
proposal?	<a href="#">View File</a>
consent form	<a href="#">View File</a>
update with online survey	<a href="#">View File</a>

[Approval Letter](#)

[BACK](#)

## I. Requesting Extensions and or Modification of Approval

- Request for Extension - For Full and Expedited applications approvals are valid for 1 year. Researchers need to request extension of approval if the research continues past 1 year – **Complete Part A and C**
- Request for Modification(s) - After receiving ethics approval, modification to research protocols may be required. This can impact selection of research sites, categories and numbers of participants, data collections instruments, consent forms etc. **Complete Part A, B and C of the form.**
- Requests for Modifications & Extensions may be submitted on the same form. **Complete Part A, B and C of the form.**

53. Log into UWI Scholar and navigate to Research Ethics Application page.

54. Under each Completed and approved application is a link to an Extension/Modification request form.

55. Click on application form

### Completed Applications:

#### Application for Ethical Approval - STA:

#	Date Submitted	Title of the Research Project	Reference Number	
<input type="checkbox"/> 1	2020-12-08 10:49:57	AN EXPLORATORY STUDY OF MATHEMATICS ANXIETY IN TRINIDAD PRESERVICE TEACHERS	CREC- SA.0564/11/2020	<a href="#">View Application</a>

[Research Ethics Extension/Modification Application - STA](#)

56. The application form lists some of the relevant information from the previously approved forms

## UWIScholar Research Ethics Application

#### Reference Number

CREC-SA.0564/11/2020

#### Title of the Research Project

AN EXPLORATORY STUDY OF MATHEMATICS ANXIETY IN TRINIDAD PRESERVICE TEACHERS

#### Research Start Date

2020-10-30

#### Research End Date

2021-07-31

Investigators

57. Indicate if the application is for an Extension, Modification or both
- Complete Part A for Extensions only; Complete Part A and B for Modifications

PART A - Type of Change

Extension  Modification  Extension & Modification

**Justification for Extension/Modifications**



58. When Completing Part B please fill in the sections that are relevant and put in “N/A” where not applicable.

PART B - Modifications to Protocols

- In the Sections below, please indicate if any changes were made to the protocols. If the Section is not applicable/no changes made, please insert N/A

**1. Summary of Modifications**



59. Upload Supporting documents in Part C and click the “Submit Application” Button

PART C - Document Upload  
(as applicable)

<b>13.1 Research Proposal (required for clinical trials)</b> <input type="button" value="Choose File"/> No file chosen	<b>13.2 SPIRIT/WHO guidelines checklist for clinical trials</b> <input type="button" value="Choose File"/> No file chosen
<b>13.3 Recruitment Materials</b> <input type="button" value="Choose File"/> No file chosen <a href="#">Add Row</a>	<b>13.4 Letters to institutions for permission to access research sites and approvals as required</b> <input type="button" value="Choose File"/> No file chosen <a href="#">Add Row</a>



## Part 2 – Guidelines for Researchers to complete forms

### A. Guidelines for answering the questions on the *Research Proposal Form*

Applicants can read these guidelines in conjunction with the [Mona Toolkit](#), in particular pages 16-20 and 24-26.

#### **Title**

Title of planned research project or research activity - Title of the study should be succinct while clearly and accurately reflecting the aim of the study

#### **Expected Start Date for data collection**

Indicate planned start date for the data collection activities in the research project. This must be a date after Research Ethics approval is granted.

#### **End Date Expected End Date for data collection**

Indicate planned end date for your data collection activities, these dates should coincide with the descriptions given in section 5 below.

#### **1. Lay Summary**

This section gives the Reviewers on the Research Ethics Committee and overview of your application and planned research activities. Summarize the Aims, Methodology, Location, Data Storage/Access, Time Frame. Include Confidentiality Statement or Declaration for the study, as applicable.

#### **2. Background and Rationale for the study (300 words)/ Literature Review (Mona Campus)**

Provide the context for your research - why are you doing this study, justification, importance of the research. For Mona Campus a Literature Review is required in this section.

*[Note: the research project being a requirement for your degree is not a rationale or justification. Please focus on the actual research and its benefits]*

#### **3. Aims, Objectives and Research Questions (300 words)**

List aims, objectives and research questions (study population)

#### **4. Hypotheses (If Applicable)**

State the hypotheses of the project/study (usually inferential quantitative research projects only)

#### **5. Methodological Design**

##### **5.1 Overall Study Design (including Theoretical Framework, where applicable)**

This section should include the following with details:

- Methodology – Quantitative /Qualitative/mixed methods /experimental etc,
- Research Design – phenomenological, case study, ethnography, clinical trial, cross sectional, interventional etc.
- Method of data collection – secondary, interviews, surveys etc
- Theoretical Framework – if applicable, usually within the Social Sciences and Education disciplines

##### **5.2 Location and Time Frame of the study**

- List research sites where data collection will take place e.g country, institution, organization
- Include Justification for the use of these sites
- Indicate time frame for each phase/location

##### **5.3 Justification for Participants or Subjects (not applicable for Waiver applications)**

###### **5.3.1.1 Inclusion Criteria**

- Define study population and List Characteristics of participants you wish to include in your study

- List categories and type of participants/research subjects that you will recruit in the target population

#### 5.3.1.2 Exclusion Criteria is required

- List the categories stated in 5.3.1.1, the subset of participants that will be excluded, if applicable
- List all other categories of study population that may be excluded

#### 5.3.2 Special/Vulnerable Populations and Justification

- List any special/valuable groups included in the study.
  - These include any category of persons who can be considered vulnerable or disadvantaged in the context of the conduct of your research. Such as: minors, persons who are institutionalized including prisoners, persons with diminished mental capacity, disabled persons in dependent relationships, migrants, refugees, pregnant women etc.
- State justification for use of these participants.
- Justification for use of UWI staff or students must be indicated in this section.

#### 5.3.3 Research Related Justification for Sample Size is required

- State sample size.
- How is sample size determined? Include method or formula.

#### 5.3.4 Recruitment of Subjects

- Describe, in detail the process for getting persons to participate in your research project/activity, including types of media to be used, requests for permission to conduct the research within institutions.
- The methods for recruitment must not be coercive in substance or in relation to any special/vulnerable groups involved.

#### 5.4 Research Intervention *to be retitled Data Collection/Research Intervention Procedures*

- Describe in detail the methods and process for collecting your data indicate the following steps, as applicable - Screening of participants, informed consent etc(full process for Informed Consent to be described in Section 9 below)
- Explain the process of debriefing to participants, if there is deception.
- If the Research includes intervention(s) data this must also be described in detail.
  - In the case of medical research this may include: Materials and Procedures to be administered to participants or subjects (e.g. drugs, diet, educational intervention, social interventions), Treatments or beneficial procedures that may be withheld from participants, Samples to be taken from participants or subjects, including methods of processing.
  - For research involving Infectious Diseases, it is important to indicate if the research is part of Routine Care or Investigational. If the research is considered routine care, then the individual will benefit from adequate treatment. However, if it is investigational, the researcher needs to consider how the participant would be informed if (s)he has an infectious diseases that may need to be treated; in other words, how blinding will be removed to allowed the participant to be adequately treated.
  - In the case of Educational or Social Sciences Research, this may be a new teaching technique, baseline assessments or pre-test treatment assessments, randomised controlled trials for psychological/psychosocial interventions, follow-up assessments or post-test treatment assessments

Important Note: The reader must be able to clearly distinguish the methods or activities that are routine and those that are part of your data collection activities, where applicable.

#### 5.5 Data Collection Instruments [FILE UPLOAD SECTION]

Upload the data collection instruments that will be used. These can include:

- Measurements / Data table
- Questionnaires
- Focus group questions/topics
- Interview questions/topics

## 5.6 Methods of Data Analysis

State methods of analyzing data including if a service or a specialized analyst will be used.

## 6. Confidentiality

### 6.1 Methods for storing and securing study/biological data

- Hard copy Data should be stored in secure location.
- Electronic data must be password protected or stored in a secure location to preserve both confidentiality and integrity of the data.
- Biological data must be stored in secure locations and details on the handling by third parties must be stated to ensure the data/samples are not misused.
- Data must be stored for a minimum of 5 years.

### 6.2 Methods for protecting participants' confidentiality (not applicable for Waiver Application)

- Describe how participants confidentiality will be protected,
- Indicate whether identifiers (DOB, home addresses, telephone numbers etc) will be collected and what methods will be used to separate these identifiers from the stored study data

## 7. Risk/Benefit (provide more details on risk and types of risk)

### 7.1 Indicate what is the level of risk associated with this research is required

**Minimal Risk** to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected. Examples of minimal risk are:

- Study poses no more risk than expected in daily life (e.g., blood draw, physical exam, routine psychological testing).
- Non-interventional studies (e.g., observational studies of behaviour or nutrition).
- Survey/Questionnaire studies of a non-sensitive nature.
- Electrophysiological studies in healthy subjects or clinical populations (surface recordings such as EEG, ERP, MEG)
- Genomic studies
- Non-invasive imaging (e.g., MRI and fMRI) in healthy subjects or clinical populations to investigate basic mechanisms of brain function.
- Research involving the collection or meta-analysis of existing data, documents, records, pathological specimens, or diagnostic specimens to understand basic bio-behavioural processes.

**Greater than Minimal Risk** to subjects means that the probability and magnitude of harm or discomfort anticipated in the research risks are more than minimal risk, but not significantly greater. Studies that fall under this category will range in their probability of a moderate-severity event occurring as a result of study participation (and the level of safety monitoring will depend on that probability) but there are adequate surveillance and protections in place to identify adverse events promptly and to minimize harm. Examples of greater than minimal risk are:

- Some imaging studies (e.g. PET scan)
- Studies using transcranial magnetic stimulation
- Post-approval studies of FDA-approved drugs or devices

**Significantly Greater than Minimal Risk** to subjects means that there is a probability of an event that is serious, prolonged and/or permanent occurring as a result of study participation or there is significant uncertainty about the nature or likelihood of adverse events. Trials with Significantly Greater than Minimal Risk require adequate protections for foreseeable adverse events. Examples of significantly greater than minimal risk are:

- Interventions to prevent or treat serious conditions (e.g., conditions associated with early death, significant self-harm, or danger to others)
- Involves an intervention or invasive procedure with substantial risk or high potential for serious adverse events (e.g., an investigational agent with high liability for toxicity)
- Clinical trials to support the testing of investigational implantable devices
- Some clinical trials involving vulnerable populations (e.g., children, pregnant women, prisoners etc.)
- Some studies of new chemical entities or drugs for which there is limited or no available safety data in humans

**7.2 Please describe risk, discomfort (physical/psychological), inconvenience, side effects, and financial costs to participants (include measures to mitigate these risks/discomforts)**

If risk is minimal, there must still be a description of the minimal risk or a statement from the researcher that indicates they understand the risk element and why this study has minimal risk.

**7.3 Indicate direct benefits to participants (not applicable for Waiver Applications)**

There may be no direct benefit to the participants, this should be stated along with reasons for involving these persons when there is no direct benefit to them.

**7.4 Impacts of the study on human groups/social environment that are not participants in the study (positive/negative, where applicable)**

There must be benefits listed here.

**7.5 Impacts of the study on the environment (positive/negative, where applicable)**

This may not be applicable for all research applications

**8. Compensation for participants: including payments or payments in kind**

This information is important to determine whether the compensation may be used to coerce participants to agree to be involved in the research.

**9. Informed Consent (written/verbal)**

**9.1 Describe process for informed consent. Indicate if waiver of written consent is requested with justification or waiver of consent all together with justification. is required**

Please indicate

1. If Written Informed Consent will be collected. You must describe the process of interacting with the participants to get the written consent, in detail.
2. If a Waiver of Written Consent is being requested. You must describe details of the process to get verbal consent from participants.
3. If Waiver of Consent is being requested all together and a justification for the same.

**10. Funding**

**10.1 State sources of Funding. Indicate any potential for conflict of interests between researcher and funder.**

**10.2.1 What is the budget for the study (enter details below)**

**10.2.2. Or upload a file containing the budget details**

Full disclosure of any potential conflicts of interest is required. Failure to indicate these details may lead to Research Misconduct accusations.

**11. Expected outcomes and impact of the study**

**11.1 How the results will be disseminated?**

Will the research results be disseminated via academic publications? Will there be presentation to scholarly communities or communities that were research or can be impacted by the results? Where will the project and its results be stored for later review by other interested parties?

**11.2 How the results will be acted upon for both the participants and the community?**

Do you plan to use the results to make an intervention for the participants or the community? Please describe.

**11.3 Limitations**

Indicate any known limitations including suggestions for future research studies to be carried out.

**12. References**

Please list at least between 3 – 12 academic references for your research

### **13. Document Upload Section**

#### **13.1 Research Proposal**

Required for clinical trials only

#### **13.2 SPIRIT/WHO guidelines checklist for clinical trials**

Required for clinical trials only

#### **13.3 Recruitment Materials**

Flyers, posters, letters, information booklets, newspaper or electronic media ads, links to videos to be used to recruit your participants.

#### **13.4 Letters to institutions for permission to access research sites and approvals as required**

Draft Letters to Ministries, CEOs etc describing the research, why persons under their jurisdiction are being asked to participate and what participation involves.

In some cases permission from these external institutions may be required prior to research ethics review. This may include research that can create reputational risk for the organization etc.

#### **13.5 Consent Forms**

Draft Consent forms for each different group/category of participant included in the research project. These consent forms must be approved by the Research Ethics Committee prior to data collection.

#### **13.6 Other Documents**

Include any other documents in support of your application.

## B. Application Self Checklist

### Application Content Checklist

- Does the application state the purpose of the study?
- Does the application describe the subject population?
- Does the application state the tasks the subjects need to complete?
- Are the subjects placed at risk?
- Has the researcher made provisions for minimal risk?
- Does the scientific merit of the study merit placing subjects at risk?
- Are there provisions for the care of subjects in the event of an accident or complications related to the procedures?
- Does the proposal identify how confidentiality will be preserved?
- Are there provisions to obtain approval from appropriate authorities (e.g., parents, school officials, company officials, etc.) related to the study?
- Do informed consent forms meet the criteria? If not, is justification provided?
- Has the investigator described the procedures used to obtain informed consent or justified why it will not be used?



### Application Technical Completeness Check List

- Have all questions on the *Research Proposal* form been addressed?
- Completed Online Training with CITI Course? (if required by your campus)
- Attach copies of written consent, permission, and/or assent forms, or oral consent script
- Attach copies of study materials and instruments (e.g., questionnaires, data forms)
- Attach copies of recruitment materials (e.g., scripts, advertisements)
- If other agencies or institutions require PI approval, attach originals of letters of cooperation or approval from those organizations.

## Part 3 - Application Forms

### A. Research Ethics Application

#### Form 1 - Research Proposal Form

**Research Proposal**  
**Title of the Research Project**  
  
**Research Start Date**   **Research End Date**  

---

**1. Abstract/ Lay Summary**  
Summarise the Aims, Methodology, Location, Data Storage/Access, Time Frame, and Confidentiality Statement or Declaration for the study  
  
**2. Background and Rationale for the study**  
  
**3. Aims and Objectives**  
  
**4. Research Objectives/ Research Questions/ Hypotheses** (if Applicable)  
  
**5. Methodological Design**  
**5.1 Overall Study Design (Theoretical Framework)**  
  
**5.2 Location and Time Frame of the study**

**5.3 Justification for Participants or Subjects**

**5.3.1.1 Inclusion Criteria**

**5.3.1.2 Exclusion Criteria**

**5.3.2 Special/Vulnerable Populations**

**5.3.3 Research Related Justification for Sample Size**

**5.3.4 Recruitment of Subjects**

**5.4 Research Procedures/Protocols - Data Collection/Research Intervention Procedures**

**5.5 Data Collection Instruments**

Please upload the data collection instruments that will be used. These can include:

- Measurements
- Questionnaires
- Focus group questions/topics
- Interview questions/topics

Enter a description for the instrument and upload the file

**Description**

**File (pdf)**

No file chosen

[Add Row](#)

**5.6 Methods of Data Analysis**

**6. Confidentiality**

**6.1 Methods for storing and securing study/biological data**

**6.2 Methods for protecting participants' confidentiality (not applicable for Waiver Application)**



## 7. Risk/Benefit

7.1 Indicate what is the level of risk associated with this research

No more than minimal risk

7.2 Please describe risk, discomfort (physical/psychological), inconvenience, side effects, and financial costs to participants (include measures to mitigate these risks/discomforts)

7.3 Indicate direct benefits to participants (not applicable for Waiver Applications)

7.4 Impacts of the study on human groups that are not participants in the study (positive/negative, where applicable)

7.5 Impacts of the study on the environment (positive/negative, where applicable)

## 8. Compensation, rewards or other incentives for participants

## 9. Informed Consent

9.1 Describe process for informed consent. Indicate if waiver of written consent is requested with justification or waiver of consent all together with justification.

## 10. Funding

10.1 State sources of Funding. Indicate any potential for conflict of interests between researcher and funder.

10.2.1 What is the budget for the study (enter details below)?

10.2.2 Or upload a file containing the budget details

Choose File No file chosen

## 11. Expected outcomes and impact of the study

### 11.1 How the results will be disseminated?

### 11.2 How the results will be acted upon for both the participants and the community?

### 11.3 Limitations

## 12. References

## 13. Document Upload

### 13.1 Research Proposal (required for clinical trials)

No file chosen

### 13.2 SPIRIT/WHO guidelines checklist for clinical trials

No file chosen

### 13.3 Recruitment Materials

No file chosen

[Add Row](#)

### 13.4 Letters to institutions for permission to access research sites and approvals as required

No file chosen

[Add Row](#)

### 13.5 Consent Forms

No file chosen

[Add Row](#)

### 13.6 Other Documents

**Description**

**File (pdf)**

No file chosen

[Add Row](#)

Form 2 - Investigators Information Form

**Investigator's Information**

**Privacy statement**

The name, email addresses, and telephone numbers entered in this research application will be used exclusively for the review of the application and will not be made available to any other party.

---

**A. Research Type**

**Research Type**

This research in partial fulfillment of a UWI degree programme

**Name of Student**

**Name and Affiliation of Supervisor**

Please ensure that your supervisor reviewed and approved the contents of the application. A supporting email from your supervisor with the reference number must be sent to the ethics committee's email address or a supporting cover letter should be uploaded with the application.

[Add Row](#)

**Department**

**Faculty**

**Programme**

BA/BSc

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**B. Principal Investigator**

**Principal Investigator**

**Qualifications of P.I.**

**Email of P.I.**

**Phone Number of P.I.**

**Affiliation of P.I.**

**Address for Official Letters**

**Programme**

**Programme Level**

BA/BSc

**CITI training or equivalent certificate for P.I.**

No file chosen

## B. Research Ethics Extension/Modification Application Form

<b>Reference Number</b> <input type="text"/>	
<b>Title of the Research Project</b> <input type="text"/>	
<b>Research Start Date</b> <input type="text" value="dd/mm/yyyy"/>	<b>Research End Date</b> <input type="text" value="dd/mm/yyyy"/>
<hr/>	
<b>Investigators</b>	
<b>Principal Investigator</b> <input type="text"/>	
<b>Department</b> <input type="text"/>	<b>Faculty</b> <input type="text"/>
<b>Co-Investigators</b>	
<b>Co-Investigator One</b> <input type="text"/>	<b>Co-Investigator Two</b> <input type="text"/>
<b>Co-Investigator Three</b> <input type="text"/>	<b>Co-Investigator Four</b> <input type="text"/>
<b>Co-Investigator Five</b> <input type="text"/>	<b>Co-Investigator Six</b> <input type="text"/>
<b>Co-Investigator Seven</b> <input type="text"/>	<b>Co-Investigator Eight</b> <input type="text"/>
<b>Co-Investigator Nine</b> <input type="text"/>	<b>Co-Investigator Ten</b> <input type="text"/>
<b>PART A - Type of Change</b>	
<input checked="" type="radio"/> Extension <input type="radio"/> Modification <input type="radio"/> Extension & Modification	
<b>Justification for Extension/Modifications</b> <input type="text"/>	
<b>Change in Researchers/Investigators(if Applicable)</b> <input type="text"/>	

---

## PART B - Modifications to Protocols

- In the Sections below, please indicate if any changes were made to the protocols. If the Section is not applicable/no changes made, please insert N/A

### 1. Summary of Modifications

### 2. Background and Rationale for the study

### 3. Aims and Objectives

### 4. Research Objectives/ Research Questions/ Hypotheses

## 5. Methodological Design

### 5.1 Overall Study Design (Theoretical Framework)

### 5.2 Location and Time Frame of the study

### 5.3 Justification for Participants or Subjects

#### 5.3.1.1 Inclusion Criteria

#### 5.3.1.2 Exclusion Criteria

### 5.3.2 Special/Vulnerable Populations

### 5.3.3 Research Related Justification for Sample Size

### 5.3.4 Recruitment of Subjects

### 5.4 Research Procedures/Protocols - Data Collection/Research Intervention Procedures

### 5.5 Data Collection Instruments

Please upload the data collection instruments that will be used. These can include:

- Measurements
- Questionnaires
- Focus group questions/topics
- Interview questions/topics

Enter a description for the instrument and upload the file

Description	File (PDF)
<input type="text"/>	<input type="button" value="Choose File"/> No file chosen
<a href="#">Add Row</a>	

### 5.6 Methods of Data Analysis

## 6. Confidentiality

### 6.1 Methods for storing and securing study/biological data

### 6.2 Methods for protecting participants' confidentiality (not applicable for Waiver Application)

## 7. Risk/Benefit

### 7.1 Indicate what is the level of risk associated with this research

### 7.2 Please describe risk, discomfort (physical/psychological), inconvenience, side effects, and financial costs to participants (include measures to mitigate these risks/discomforts)

### 7.3 Indicate direct benefits to participants (not applicable for Waiver Applications)

### 7.4 Impacts of the study on human groups that are not participants in the study (positive/negative, where applicable)

### 7.5 Impacts of the study on the environment (positive/negative, where applicable)

**8. Compensation, rewards or other incentives for participants**

**9. Informed Consent**

9.1 Describe any changes to process for informed consent, or process for new groups added to study. Indicate if waiver of written consent is requested with justification or waiver of consent all together with justification.

**10. Funding**

10.1 State any changes to sources of Funding. Indicate any potential for conflict of interests between researcher and funder.

10.2.1 What there any changes to the budget for the study (enter details below)?

**11. Expected Impact/Outcomes**

11.1 How the results will be disseminated?

11.2 How the results will be acted upon for both the participants and the community?

11.3 Limitations

**PART C - Document Upload**

(as applicable)

**13.1 Research Proposal (required for clinical trials)**

 No file chosen

**13.2 SPIRIT/WHO guidelines checklist for clinical trials**

 No file chosen

**13.3 Recruitment Materials**

 No file chosen

[Add Row](#)

**13.4 Letters to institutions for permission to access research sites and approvals as required**

 No file chosen

[Add Row](#)

**13.5 Consent Forms**

 No file chosen

[Add Row](#)

**13.6 Other Documents**

Description	File (PDF)
<input type="text"/>	<input type="button" value="Choose File"/> No file chosen

**END OF INSTRUCTIONS**