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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/.

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”.

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.

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.*

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 Cave Hill 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. Section 13.5 Consent Form
   i. All Campuses - upload a ‘simple’ consent form that may be incorporated in the data collection instrument or
f. Any other supporting documents can be attached at 13.6. E.g. Principal Investigator’s authorization, permission letters from other institutes etc.

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. Complete Consent Forms - See Section E for instructions on completing these optional forms, if applicable to your research.
21. Click “Submit Application” button.
22. 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
   • 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.
• If the PI is a student, please enter programme information.
• Upload CITI completion reports for the PI – if applicable

*Note: Based on disciplinary norms students may be listed as the Principal Investigator*

* B. Principal Investigator
  * Principal Investigator
  A A A
  * Email of P.I.
  Chelsea.Seetahal@sta.uwi.edu
  * Affiliation of P.I.
  Affiliation
  * Address
  Address
  * Qualifications of P.I.
  A B C
  * Phone Number of P.I.
  XYZ
  * 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
  Email of C.I.
  Chelsea.Seetahal@sta.uwi.edu
  Affiliation of C.I.
  Affiliation
  Programme Title
  Prog
  CITI training or equivalent certificate for C.I. one
  View File Choose File No file chosen
  Qualifications of C.I.
  ABC
  Phone Number of C.I.
  xyz
  Programme Level
  MA/MSc

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.

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.

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

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

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

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 and Consent Forms

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.

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.

I. Requesting Extensions of Approval

Approvals are valid for 1 year. Researchers need to request extension of approval if the research continues past 1 year

53. Email your request for extension with justification and quoting application reference number.

J. Requesting Modification of Approval

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.

54. Email your request for modification with details of the modification, justification for and impact of changes and quoting application reference number.

N.B. Automation of this requests J and K above are being finalized. The Manual will be updated when these features become available.
K. Helpful Tips

How to share a copy of the Application Form (Forms A, B and C) 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
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.

Copy and paste

- Use keyboard shortcuts CTRL + C to copy and CTRL + V to paste text into relevant sections of the applications
L. Guidelines for answering the questions in the Research Proposal Form

Title
Title of planned research project or research activity

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)
Provide the context for your research - why are you doing this study, justification, importance of the research.

[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)
- If deceptive methods are being used, these must be justified. The process of revealing the deception to the participants must also be detailed. (reword)
- If the Research includes intervention(s)data this must also be described in detail.
  - In the case of medical research this may include: Such as 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
  - In the case of Educational or Social Sciences Research, this may be a new teaching technique, [committee members to expand on this]

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
M. 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 IRB Human Subject Review Form been addressed?
- Completed Online Training with CITI Course
- 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)
- All required inked signatures have been obtained
- If other agencies or institutions require PI approval, attach originals of letters of cooperation or approval from those organizations.