

NWRHA RESEARCH ETHICS COMMITTEE

APPLICATION TO CONDUCT RESEARCH IN THE NWRHA



Print the completed application and accompanying documents and authorise page 1. Ten (10) copies (one original and 9 double-sided photocopies) of the package are to be mailed to the Secretary of the NWRHA Ethics Committee, Health Policy, Research & Planning, NWRHA Head Office, # 39 Dundonald Street, Port of Spain or hand-delivered to Health Policy, Research & Planning, 2nd Floor Medical Library, Port-of-Spain General Hospital, Charlotte Street, POS. For guidelines e-mail health.services@nwrha.gov.tt. Only complete protocols will be reviewed. The NWRHA Ethics Secretariat will inform the Principal Investigator responsible for the project if the documentation is incomplete. **This application will not be processed unless ALL fields are completed and signed.** Approval from the NWRHA Research Ethics Committee must be granted prior to research commencement.

DATE OF APPLICATION	
PROTOCOL TITLE	
PRINCIPAL INVESTIGATOR (SEE APPENDIX 1)	
CO-INVESTIGATOR (S)	
STUDY COORDINATOR (S)	
DATA ANALYSIS COLLABORATOR (S)	
RESEARCH SITE (S)	
PROPOSED START DATE	
DURATION OF RESEARCH STUDY	

SIGNATURES:

PRINCIPAL INVESTIGATOR

Principal Investigator must attach his/her Curriculum Vitae to this application form.

DATE

CO-INVESTIGATOR/STUDY COORDINATOR

DATE

INVESTIGATORS' INFORMATION:

PRINCIPAL INVESTIGATOR (INCLUDE DEGREES)	DEPARTMENT/DIVISION	E-MAIL	PHONE
OTHER INVESTIGATORS (INCLUDE DEGREES)	DEPARTMENT/DIVISION	E-MAIL	PHONE
ADMINISTRATIVE CONTACT	DEPARTMENT/DIVISION	E-MAIL	PHONE

1. SPONSOR, OTHER ORGANISATIONS INVOLVED & FUNDING

1a. SPONSOR: If the NWRHA is NOT the sponsor, tick No and give the name/s of the sponsor below.

I confirm that NWRHA is the sponsor of this study YES NO

Sponsor

1b. OTHER ORGANISATIONS: Please provide details of any other organisations involved in the project and state their role (e.g. collaborator, gatekeeper). The responsibilities of each organisation should be outlined, include any approach letters to gatekeeper organisations and confirm that permission letters are available for inspection if requested for audit purposes.

1c. Other Organization(s)

FUNDING: If the research will be funded by direct or in-kind support by any person or organization outside of the researcher, state what the sources of funding are and what expectations, expressed or implicit, which may arise from the funding. State whether the study will result in financial payment in kind to the department or NWRHA. If the project is self-funded or funded by solely by NWRHA this should be stated.

1d. Funding

2. OTHER APPROVALS REQUIRED

2a. Has ethical approval been sought and obtained from any external body?

YES NO

2b. If yes, give details and say when these will be obtained. If they have already been obtained, **please attach a copy of the external ethics approval.**

3. PURPOSE OF THE STUDY (Statement of "why" the study is being conducted, or the goal of the study)

4. DESCRIBE (i) STUDY DESIGN, (ii) METHODOLGY AND (ii) DATA ANALYSIS (The research design refers to the overall strategy chosen to integrate the different components of the study in a coherent and logical way, thereby, ensuring it will effectively address the research problem; it constitutes the blueprint for the collection, measurement, and analysis of data.)

5. STATE ETHICAL CONSIDERATIONS (Include informed consent, voluntary participation, do no harm, confidentiality, anonymity, assess relevant components to the study)

6. PARTICIPANTS TO BE STUDIED

6a. State the number of volunteers needed to conduct the study. If relevant, indicate numbers of males and females.

TOTAL PARTICIPANTS (MALE PARTICIPANTS FEMALE PARTICIPANTS)

6b. State the upper age limit and lower age limit (if an upper age limit is needed please give the justification).

UPPER AGE LIMIT LOWER AGE LIMIT

6c. Provide a justification for the sample size and age limits.

7. SELECTION CRITERIA (Explain the selection of the research subjects)

8. RECRUITMENT (Describe procedures that will be followed regarding participant recruitment)

Describe how participants will be (i) identified (ii) approached and (iii) recruited

- (i)
- (ii)
- (iii)

9. PARTICIPANT CONSENT

9a. Describe the process to be used when seeking and obtaining consent.

9b. **A copy of the (i) Participant Information Sheet and (ii) Consent Form (where applicable) must be attached.** NWRHA templates for these are at the end of this application and must be modified where necessary, do not use another institutions' information sheet and consent form.

9c. Will the participants be from any of the following groups? Tick as appropriate and for each group indicated describe the measure to ensure that these participants are competent to consent to take part in the study. **Attach any correspondence with parents, guardians, carers, key workers etc.**

- Persons under 18
- Children (subjects less than 18 years old)
- Those with a learning disability
- Those suffering from dementia
- Prisoners
- Embryos, foetuses or abortuses
- Those who could be considered to have a particularly depend relationship with the investigator (e.g. those in care homes, student, employees)
- Non-English-speaking subjects
- Other vulnerable groups

9d. Are there any special pressure that might make it difficult for people to refuse to take part in the study (e.g. are the potential participants, students or colleagues of the investigator)?

9e. How will this issue be addressed such issues?

10. PARTICIPANTS' INVOLVEMENT: RISK, REQUIREMENTS & BENEFITS

10a. What are the potential hazards, risks or adverse effects associated with this study?

10b. Does this study involve invasive procedures (e.g. blood taking, muscle biopsies or the administration of a medicinal product?) If yes, provide details below.

YES NO

10c. Does this study involve genetic analysis or manipulation? If yes, please attach documents required in Appendix E.

YES (Appendix E attached) NO

10d. List the experience of the investigators in the use of the procedures outlined in (10b) and (10c).

10e. If medical devices are to be used on any participant, please confirm that they comply with the requirements of the medical devices instructions for use and outline what the levels of risk associated with using the device/s are and how they will be dealt with.

10f. Describe how investigators will deal with any adverse reactions or untoward incidents.

10g. Name the locations or sites where the work will be done.

10h. What is the potential for participants suffering pain, discomfort, distress, inconvenience or changes to lifestyle as a result of participation?

10i. Will the group or individual interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? If yes, please list these topics and explain how volunteer discomfort will be prevented and responded to.

YES NO

10j. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct) could take place during this study? If yes, give details of what procedures will be put in place to deal with these issues. The Information Sheet should make it clear under which circumstances action may be taken by the researcher.

YES NO

10k. Describe any expected benefits to the research participant.

10l. Under what circumstances might a participant discontinue participation with the study or the study be terminated in part or as a whole?

11. FINANCIAL INCENTIVES, EXPENSES AND COMPENSATION

11a. Will travelling expenses be given? If yes, this should be stated on the Information Sheet.

YES NO

11b. Is any financial reward, apart from travelling expenses being given to participants? If yes, please provide details and a justification for this.

YES NO

11c. Is the study in collaboration with a pharmaceutical company or an equipment or medical device manufacturer or other for-profit organization? If yes, please give the name of the company and indicate what arrangement exist for compensation patients or health volunteers for adverse effects resulting from their participation in the study. A copy of the Indemnification Form (required in Appendix B) should be submitted with the application.

YES NO

12. CONFIDENTIALITY, ANONYMITY & DATA STORAGE

12a. What steps will be taken to ensure confidentiality? Include the confidentiality and physical security of the research data. Give details of the anonymization procedures to be used and at what stage they will be introduced.

12b. Who will have access to any records and resulting data?

12c. Confirm that any recordings (e.g. audio, video) will be deleted upon completion of the project or will this study be using Appendix D of this application form to seek consent for storage and future use. If No, indicate what alternative arrangements will be put in place.

YES NO N/A

13. INFORMATION SHEET AND CONSENT FORM

The information sheet and consent form for participants should be adjusted from attached templates and submitted with application (if study requires human subject participants).

14. SUMMARY/ABSTRACT OF PROPOSED PROJECT (all application fields are required to be completed – this is mandatory or application will not be reviewed)

Appendix 1 – APPLICATION CHECKLIST

RECEIVED
TABLED
DECISION

The following, where applicable, are attached to this form (please tick):

1. [] Participant Information Sheet & Consent Form
2. [] Appendix A - Attach documents relating to medical products
3. [] Appendix B - Attach Certificate of Indemnity (for pharmaceutical company collaborators)
4. [] Appendix C - Attach documents relating to studies involving radiation
5. [] Appendix D - Attach documents relating to storage and further use of recordings of participants
6. [] Appendix E - Attach documents relating to studies involving Genotyping
7. [] Letter to general practitioners
8. [] Letter to parents/guardians/key caregivers/social services
9. [] Letter of Ethical Committee approval or other approvals/authorisations
10. [] Copy of email recruitment circular/poster/press advertisement.
11. [] Evidence of permission from organisation (i.e. school, company, shop) where research is to take place
12. [] Questionnaire/ topic guide/ interview questions – MANDATORY IF USED. If this is not attached note that review of application may be delayed. Researcher designed instruments should always be submitted.

Key Definitions

Principal Investigator

The lead of the study who has a track record in research and with whom the responsibility for the study lies e.g. Lecturer, Professor, etc. Where the topic is patient centred it is expected that this person is at the level of a Consultant Clinician.

Co-Investigator

Other parties involved in the study who also have a track record in conducting research)

Study Coordinator

The student or person who will be conducting the research

GUIDELINES FOR SUBMISSIONS

- Proposals should take the APA format, and should be complete including hypothesis, rationale, background, method.
- All fields in the Ethics Application Form must be completed and the relevant signatures affixed.
- Proposals should be endorsed by Supervisors. Heads of Departments should be appraised of research proposed (for NWRHA staff members).
- Proposals should be submitted to Ethics Committee at least three months before project commencement if it is to be considered for approval. For U.W.I. Medical students who have projects that must be completed (as a part of their course work) within a short time frame, special consideration will be given and the three month rule will be adjusted provided agreement is reached among committee members.
- **The NWRHA Ethics Committee must be notified upon completion of study, a copy of completed research MUST be submitted upon completion.**

**THE NORTH WEST REGIONAL HEALTH AUTHORITY
INFORMATION SHEET FOR PARTICIPANTS TEMPLATE**

– PLEASE MODIFY & SUBMIT IF REQUIRED

TITLE OF STUDY

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

We would like to invite you to participate in this original/undergraduate/postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

- Aims of the research and possible benefits
- Who you are recruiting (including exclusion criteria)
- What will happen if the participant agrees to take part (when, where, how long etc)
- Any risks (e.g. need for disclosure of information to a third party, possibility for distress, potential adverse reactions)
- Possible benefits (it is good practice to offer participants a copy of the final report)
- Arrangements for ensuring anonymity and confidentiality (this relates to information that is identifiable or could potentially be linked back to an individual).
- Name and contact details of the researcher (please note that the use of personal contact details can cause problems).

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason.

If you have concerns about this study, you can contact the NWRHA using the details below for further advice and information: **NAME & CONTACT DETAILS OF RESEARCHER/SUPERVISOR**

- Statements which researchers may need to include: **Please cut and paste as required and then delete this section.**
- A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.
- If you agree to take part you will be asked whether you are happy to be contacted about participation in future studies. Your participation in this study will not be affected should you choose not to be re-contacted.
- You may withdraw your data from the project at any time up until it is transcribed for use in the final report/INSERT DATE.
- Recordings of interviews will be deleted upon transcription.
- If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.
- Submission of a completed questionnaire implies consent to participate.
- As participation is anonymous it will not be possible for us to withdraw your data once you have returned your questionnaire.
- If you do decide to take part, please let us know beforehand if you have been involved in any other study during the last year.

THE NORTH WEST REGIONAL HEALTH AUTHORITY
CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES
TEMPLATE

– PLEASE MODIFY & SUBMIT IF REQUIRED

Title of Study: _____

NWRHA Research Ethics Committee Approval Number: _____

Please sign this form after you have read the Information Sheet and/or listened to an explanation about the research.

- Thank you for considering taking part in this research. The person organizing the research must explain the project to you before you agree to take part.
- If you have any questions arising from the **Information Sheet** or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this **Consent Form** to keep and refer to at any time.
- I understand that if I decide at any other time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from this study immediately.
- I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated confidential.

Participant's Statement:

I _____ agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

.....
Signature

.....
Date

Investigator's Statement:

I _____ confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the volunteer.

.....
Signature

.....
Date