# MRP PROTOCOL:

**RESEARCH INVOLVING HUMAN PARTICIPANTS**

INSTRUCTIONS:

1. Who should complete this Protocol Form?

This form should be completed by Graduate Students conducting research involving human participants for the purposes of a Major Research Paper (MRP).Research activities generally include**-** – but are not limited to - experiments, interviews, surveys, focus groups and participant observation**.**

Copies of approved protocols should be kept on file by the student researcher for a period of 2 years.

1. **Who Should NOT complete this form?**
2. **Graduate or Undergraduate Students conducting research for a course in which everyone in the class is conducting the same research should NOT complete this form**:

For courses in which all students are conducting the same/similar studies, Course Instructors only should complete the:

[Generic Protocol: Course Related Research Involving Human Participants](http://research.info.yorku.ca/ore/human-participants/#squelch-taas-accordion-shortcode-content-4)

Please consult your Course Instructor for further information.

1. **Graduate or Undergraduate students conducting individual projects as part of a course assignment should NOT complete this form:**

For courses in which graduate or undergraduate students are completing individualized research studies as part of a course assignment; or for the purposes of an undergraduate theses or individual projects, students should complete the:

[Individualized Protocol – Course Related Research Involving Human Participants](http://research.info.yorku.ca/ore/human-participants/#squelch-taas-accordion-shortcode-content-4)

1. **Students conducting research that must be reviewed by the HPRC should NOT complete this form.** To determine whether **your research must be reviewed by the HPRC,** please answer the following questions:
2. **Is your research funded?**  N  Y

*(Funded research refers to stand alone research funding and excludes student awards such as bursaries and scholarships.)*

1. **Is your research more than minimal risk?**  N  Y

*(What is minimal risk research? If potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research then the research can be regarded as within the range of minimal risk)*

1. **Does your research involve Aboriginal/Indigenous/Indigenous Peoples?**

N  Y

**The following questions may assist in determining whether your research involves Aboriginal/Indigenous/Indigenous peoples:**

|  |  |  |
| --- | --- | --- |
| 1. Will the research be conducted on Aboriginal/Indigenous land (Canada; international) for which permission and/or approval from an authority (such as a band council, First Nations Research Ethics Board etc.) may be required? | N | Y |
| 1. Will recruitment criteria include Aboriginal/Indigenous identity as either a factor for the entire study or for a subgroup of the study? | N | Y |
| 1. Will the research seek input from participants regarding an Aboriginal/Indigenous peoples’ cultural heritage, artefacts, or traditional knowledge? | N | Y |
| 1. Will research in which Aboriginal/Indigenous identity or membership in an Aboriginal/Indigenous community be used as a variable for the purpose of analysis of the research data? | N | Y |
| 1. Will interpretation of research\*\* results refer to Aboriginal/Indigenous communities, peoples, language, history or culture? | N | Y |

*(****NOTE:*** *“Research” does not include literary criticism and/or history (excluding oral history) and/or primarily textual activities). If you have answered* ***‘Yes’ to any of the above noted questions****, then your research involves Aboriginal/Indigenous/indigenous peoples and must be reviewed and approved by the HPRC.*

1. **Does your research involve Clinical Trial(s)?**  N  Y
2. **Does your research involve Animals?**  N  Y
3. **Does your research involve Biological Agents?**  N  Y
4. **Does your research involve Invasive procedures?**  N  Y
5. **Does your research involve collection of human bodily fluids?**  N  Y
6. **Does your research involved radioactive material?**  N  Y

**NOTE:** If you have answered “**yes”** to any of the questions noted above, **then this is NOT the correct form.** You are required to complete the HPRC protocol form and submit to the HPRC for review. Please contact the Office of Research Ethics ([ore@yorku.ca](mailto:ore@yorku.ca)) or 416-736-2100 ext 55201 for further assistance.

1. **Does this research require any other approvals?**

Research involving another institution (such as a school, university, business, government agency) may require additional ethics review and approval or permissions if using institutional resources (such as internal listservs, or conducting interviews on the premises of the institution).

|  |  |  |
| --- | --- | --- |
| 1. Does the research involve another institution or site?   ***If Yes:***Specify the institution(s)/site(s): | N | Y |
| 1. Do any of the institution(s)/site(s) require administrative permission? | N | Y |
| 1. Has any other REB cleared this project?   ***If Yes****, please submit the original application and provide a copy of the clearance letter.* | N | Y |

**NOTE:** If the research is to be conducted at a site requiring ethics approval or administrative permission, please include all draft informed consent forms/administrative permission requests. It is the responsibility of the researcher to determine what other means of clearance are required, and to obtain clearance prior to starting the project.

1. **Who do I contact and where do I submit the MRP Protocol - Research Involving Human Participants?**

To find the appropriate contact within your Department, Graduate Program and/or Faculty/School/College to submit the protocol, Researchers (Course Instructors or Students) must consult the “[Chart of Contacts – Delegated Ethics Review Committees](http://research.info.yorku.ca/ore/contacts/)”.

Faculty and students conducting course-related research requiring ethics review in any of the units not listed in the chart should contact the Office of Research Ethics ([ore@yorku.ca](mailto:ore@yorku.ca)) or 55201 for further information.

1. **How long will the review process take?**

The average time to process minimal risk protocols is approximately twenty working days from the date of receipt by the Delegated Research Ethics Review Committee.

**NOTE:** **INCOMPLETE OR ILLEGIBLE PROTOCOLS WILL BE RETURNED TO THE RESEARCHER, WHICH WILL DELAY THE ETHICS REVIEW PROCESS.**

1. **Research Ethics Guidelines:**

Researchers are encouraged to review the various Research Ethics Guidelines to address any research specific questions they may have. Please visit the Research Ethics website to review [**Research Ethics Guidelines**](http://research.info.yorku.ca/ore/policies-guidelines/) that may be relevant to your research.

# MRP PROTOCOL FORM:

**PART A – COURSE INFORMATION**

|  |  |  |  |
| --- | --- | --- | --- |
| **Student Name:** |  | | |
| **Student Number:** |  | | |
| **Program:** |  | | |
| **Email:** |  | | |
| **Phone Number:** |  | | |
| **Faculty Advisor** |  | | |
| **Email:** |  | | |
| **Office:** |  | | |
| **Phone Number:** |  | | |
| **Title of Research Project\*:** |  | | |
| **Start date:** |  | **End Date:** |  |
| ***PRIVACY:*** *Personal information in connection with this form is collected under the authority of The York University Act, 1965 and will be used for educational, administrative and statistical purposes. If you have any questions about the collection, use and disclosure of personal information by York University, please contact: Office of Research Ethics, Kaneff Tower, Fifth Floor, 416 736 5201* | | | |

## PART B – EDUCATIONAL ELEMENT

In order to conduct research involving human participants, you are required to:

* Familiarize yourself with York University’s “[Senate Policy Research Involving Human Participants](http://secretariat-policies.info.yorku.ca/policies/ethics-review-process-for-research-involving-human-participants-policy/)”as well as the basic principles by which ethical research involving human participants is conducted. (E.g. lecture, case study, test etc.).
* Review the “[Student Researcher Responsibility Document](http://research.info.yorku.ca/ore/human-participants/#squelch-taas-accordion-shortcode-content-4)”
* Complete the [TCPS 2 Tutorial – Course on Research Ethics (CORE)](http://www.pre.ethics.gc.ca/eng/index/)

Please confirm the following:

I have reviewed and am familiar with the “[Senate Policy Research Involving Human Participants](http://secretariat-policies.info.yorku.ca/policies/ethics-review-process-for-research-involving-human-participants-policy/)”

I have reviewed and am familiar with the “[Student Researchers Responsibility” Document](http://research.info.yorku.ca/ore/human-participants/#squelch-taas-accordion-shortcode-content-4)”

I have completed the [TCPS tutorial](http://www.pre.ethics.gc.ca/eng/index/). TCPS Tutorial Certificate is attached

## PART C - PROTOCOL DOCUMENT CHECKLIST

Please attach the following items, if applicable, to the ***MRP Protocol: Research Involving Human Participants*** application.

**NOTE:** Please ensure ALL fields in this application are filled out. For sections that apply please mark with an “x”; for sections that do **not** apply, please mark as “n/a”.

**Incomplete forms will not be accepted for review.**

1. **ALL protocol forms must have the following documents attached:**
2. An informed consent form (or multiple consent forms and/or assent forms if relevant)
3. Certificate of completion of the CORE (TCPS) ethics tutorial
4. **Consent documents (check all that are applicable):**

|  |  |
| --- | --- |
|  | Substitute Consent form (Parental/Guardian consent) — required if your research participants are under 16 years of age or without capacity to consent. |
|  | Assent Form — required if your research involves substitute consent |
|  | Verbal Consent Script — required if you plan to seek verbal consent for any of the research participants |
|  | On–line Consent Script — required if participants are asked to consent online |
|  | Consent for Audio/Visual/ Taping Form — required if you plan to use audio recording or photographs of participants. This may be included in the regular consent form as an additional check box. |

1. **External permissions and approvals (if applicable):**

|  |  |
| --- | --- |
|  | Decisions Needed From Other REB Boards — required if your research requires ethics approval from an institution other than York University |
|  | External REB approval required – certificate attached |
|  | External institutional permission required – documentation provided |
|  | Internal institutional permission/approval required (e.g., OIPA) – documentation provided |
|  | Medical Directive |
|  | Research Agreement(s) – append all copies |
|  | Data Use Agreements (for use in secondary data analysis) |

1. **Test Instruments (if applicable):**

|  |  |
| --- | --- |
|  | Questionnaires and Test Instruments |
|  | Draft interview questions, focus group questions |

1. **Recruitment (if applicable):**

|  |  |
| --- | --- |
|  | Recruitment Materials: Posters, Letters, Participant Pool Advertisement, etc. |

1. **Debriefing (if applicable):**

|  |  |
| --- | --- |
|  | Debriefing Letter – required if your research involves deception (see section 10, Informed Consent form for details) |
|  | Debriefing Consent Document – required following administration of debriefing statement (if your research involves deception) |

1. **OTHER (if applicable):**

|  |  |
| --- | --- |
|  | Reviewed: Clinical Trial Research Guidelines |
|  | Provenance of Anonymous data |
|  | Research Team Member Confidentiality Agreement |
|  | Participant Images Informed Consent Addendum |

## PART D – RESEARCH INFORMATION

1. **PROJECT DESCRIPTION**

**In layperson’s terms, please provide a general and brief description of the research (e.g., hypotheses, goals and objectives, etc.).**

1. **PARTICIPANTS**
2. **State who the participant(s) will be:** *Describe the participants that will be recruited and about whom personal information will be collected (i.e., numbers, age, special characteristics, etc.). Describe the size of the group from which participants will be recruited and the estimated number needed for the research (minimum/maximum). Where active recruitment is required, please describe inclusion and exclusion criteria. Where the research involves extraction or collection of personal information, please describe from whom the information will be obtained and what it will include (include permission letters).*

1. **Please indicate if this study will be using a participant pool**  N  Y

***If ‘Yes’***, please indicate which pool(s):

URPP

Schulich Marketing pool

School of Administrative Studies participant pool

KURE

Glendon Participant Pool

Other:

1. **RECRUITMENT**
2. **How will participants be recruited (e.g., snowball technique, random sampling, previously known to interviewer, telephone solicitation, etc.)?**
3. **Will you be using any advertisements, flyers, posters, email scripts, social media postings, etc. for recruitment purpose?**

N

Y - ***If ‘Yes,****’ please attach a copy of each with your application.*

1. **INDUCEMENTS:**
2. **Will you be offering inducements to participate (e.g., money, gift certificates, academic credit, etc.)?**

N

Y - ***If ‘Yes,****’ please check all that apply:*

Financial

In-kind

Draw

Participant Pool Bonus Points

Other:

1. **If compensation is provided, please provide the source of funding for the compensation/incentive:**

1. **METHODS:**
2. **Please indicate all the research methods that apply:**

Action Research  Ethnography

Observation  Survey

Documentary/Filmmaking  Focus Group

Experimental Lab Study  Interview

Oral/Life History  Human Tissues

Experimental Behavioural Study  Online Research

Other:

1. **Do any of the methods involve:**

Audio Recording  N  Y

Still Recording  N  Y

Video Recording  N  Y

***NOTE:*** *Explicit consent is required to use these methods of recording. Please see Section 10, “Informed Consent” for details.*

1. If you are using recordings, please account for how they will be safely stored, eventually destroyed or archived, and how, if used in research dissemination, confidentiality will be maintained:
2. **What will be required of the participant(s).** *Clearly specify in a step-by-step outline exactly what the participant(s) will be asked to do in each methodology. A separate outline is required for each methodology. Include the settings, types of information to be involved, and how data will be analyzed. Include details about identifying participants, recruitment, procedures participants will undertake, etc. Include copies of study instruments. Please also include the estimated time commitment required of participants for each method.*

1. **What is the experience of the researcher/research team with this kind of research?** *Please provide a description of the individual team members’ experience with the proposed methods, participant population, etc.*

**6. RISK:**

Please indicate potential risks that the participants as individuals or as part of an identifiable group or community might experience by being part of this research project *(***NOTE:** *Checking ‘Minimal’ indicates that the risk associated with the method meets the definition of minimal risk as set out in the TCPS-2)*:

**No known/anticipated risks**

**Y – *If ‘Yes,*’ please complete the following:**

|  |  |  |
| --- | --- | --- |
| 1. Physical risks (including any bodily contact; administration of any substance)? | N | Y |
| 1. Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious, upset)? | N | Y |
| 1. Social risks (including possible loss of status, privacy and/or reputation)? | N | Y |
| 1. Data security (i.e., risk to participant from data exposure)? | N | Y |
| 1. Tied to deception involved in the study? (See DEBRIEFING section below) | N | Y |
| 1. OTHER: | | |

**Please describe how each of the potential risks described above will be managed and/or minimized:**

**7. BENEFITS**

**What, if any, are the benefits to the participants? Or,**  **No benefits**

1. Discuss any potential direct benefits to the participants from their involvement in the project; these might include education about research methods, useful knowledge gained about self, etc.

1. Comment on the (potential) benefits to the scientific/scholarly community or society that would justify involvement of participants in this study.

**8. SECONDARY ANALYSIS OF DATA:**

**NOTE:** Secondary Data Analysis is described as the analysis of data collected for a purpose other than that for which it was originally collected in order to pursue a research interest which is distinct from that of the original work. Researchers are advised to review the “[**Secondary Data Analysis Guidelines**](http://research.info.yorku.ca/ore/policies-guidelines/)” for further information on requirements related to use of secondary data for research purposes.

1. **Are you conducting secondary data analysis?**

**N – *If ‘No,*’ please go to Question 9**

**Y**

**If ‘Yes,’ please** answer the following questions:

1. Are you using **Anonymous Data**? (data which never included personal identifiers)

N

Y - ***If ‘Yes,’*** please provide a description of the provenance of the data set:

***NOTE:*** *Research that relies* ***solely*** *on secondary analysis of anonymous data is exempt from ethics review.*

1. Are you using **Anonymized data**? (Data which has been stripped of personal identifiers; no potential for data linkage.)

N

Y - ***If ‘Yes,***’ please provide a description of the provenance of the data set:

1. Are you using **Identifiable data**?

N

Y - ***If ‘Yes,’*** please provide a description of the provenance of the data set:

1. **If you are conducting secondary analysis using IDENTIFIABLE DATA, please address the following:**
2. Do you plan to link this identifiable data to other data sets?

N

Y - ***If ‘Yes,’*** please describe:

1. What type of identifiable data from this data set are you planning to access and use?

Student records (please specify in the space below)

Health records/clinic/office files (please specify in the space below):

Other personal records. Please specify:

1. What personally identifiable data (e.g., name, student number, telephone number, date of birth, etc.) from this data set do you plan on using in your research? Also, please explain why you need to collect this identifiable data and justify why each item is required to conduct your research.

1. Describe the details of any agreement you have, or will have, in place with the owner of this data to allow you to use these data for your research. ***(You must submit a copy of any data use/access agreements.)***

1. When participants first contributed their data to this data set, were there any known preferences expressed by participants at that time about how their information would be used in the future?

N

Y - ***If ‘Yes,’*** please explain:

1. How will you obtain consent from the participants whose identifiable data you will be accessing? Please explain:

***NOTE:*** *Consent of participants is required for research involving secondary analysis of data that includes personal identifiers. Waiver of consent may only be considered if researchers meet the additional criteria. Please consult the* [***Secondary Data Analysis guidelines***](http://research.info.yorku.ca/ore/policies-guidelines/) *for further information.*

1. If you do ***not***intend to seek consent of participants for use of identifiable data for secondary analysis, please provide a rationale as to why:

**9. CONFLICT OF INTEREST:**

1. **Is there a possibility of an apparent, actual or potential conflict of interest on the part of researchers, the University or sponsors? (e.g. commercialization of research findings; self-funded research)**

N

Y - ***If ‘Yes,’*** *please elaborate and outline how the potential or real conflict of interest will be addressed*:

1. **Do any members of the research team have multiple roles with potential participants (such as researcher and therapist, researcher and teacher, student/supervisor, etc.)**

N

Y **- *If ‘Yes,***’ please review  [**Research Involving Investigators’ Students**](http://research.info.yorku.ca/research-services/research-ethics/human-participants/)

1. Describe the nature of the multiple roles between researcher(s) and any participants:

1. Describe how the potential conflict of interest that will emerge as a result of the dual roles will be minimized or managed:

1. **Are there any restrictions regarding access to or disclosure of information/results/data at any point during the study including completion that the funder/sponsor has placed on the researchers?** (These include controls placed by sponsors, funding sources, advisory or steering committees.) ***If ‘Yes,’*** please describe:

**10. INFORMED CONSENT**

1. **Is there a relationship between participants and either of the following:**

Person obtaining consent:  N  Y

Investigator(s):  N  Y

***If ‘Yes,’*** *what steps will be taken to avoid the perception of undue influence in obtaining free and informed consent:*

1. **Ongoing consent is required if the research occurs over multiple occasions or over an extended period of time. Does the research occur over multiple occasions and/or over an extended period of time?**

N

Y

***If ‘Yes,’*** *please describe the process of how you intend to obtain ongoing consent:*

1. **Is substitute consent involved (e.g., children, youths under 16, those without capacity to consent)?**

N

Y

***If ‘Yes,’*** *please elaborate on how consent and assent will be obtained (an assent form/ script must also be provided):*

1. **Is Deception involved? Specifically, do you intend to withhold any information from and/or intentionally mislead the research participants?**

N – Please go to Question E

Y

***If ‘Yes:’***

1. **Please provide a description of the nature of the deception and whether it is full or partial:**

**Please provide a rationale as to why deception (in whole or part) is required:**

1. **Please append a copy of the debriefing statement.**

*The debriefing statement needs to explain three elements:*

1. *Why the experiment was developed and why the deception was necessary.*
2. *What the current research says about the topic, which includes providing two references (text, article, on-line reference) that the participants can reasonably access and understand (if you have an academic and non-academic population, you may need to provide more than one version of the debriefing statement or make sure that the references can be accessed by the least educated of the population).*
3. *Any additional resources that would be useful for the participant. Resources need to be appropriate and accessible for the participants. For example, if you are conducting a study on parenting, you could include community resources for parenting classes or recommendations for parenting guides. (Source: Univ. Virginia, IRB).*

Researchers must re-obtain consent from the participants once the debriefing statement has been provided. Participants shall be provided with and sign the **“**[**Debriefing Consent Form**](http://research.info.yorku.ca/ore/human-participants/#squelch-taas-accordion-shortcode-content-4)**.”**

1. **If a debriefing statement will not be provided to the participants, please provide a rationale as to why a statement will not be provided:**

1. **For studies that are not deceptive**, briefly describe the process and nature of any immediate post-study information that will be provided to participants and the rationale for providing this information (e.g., counseling or trauma resources, information links, etc.):

1. **How will informed consent be obtained? (Please check all that are applicable):**

Informed Consent Form (please attach draft version) (and assent form if relevant)

Verbally\* (please attach draft approximation of what participants will be verbally told)

Online Consent Form\*\* (please attach draft version)

***\*If informed consent is being obtained verbally, please provide a rationale regarding why a written informed consent form is not being used:***

***\*\*If online consent is being obtained, please indicate the website where the questionnaire/ survey will be hosted:***

1. **DATA SECURITY:**

Privacy refers to an individual’s right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society. The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. Security refers to measures used to protect information. It includes physical, administrative and technical safeguards.

For a fuller description of researcher obligations surrounding confidentiality, privacy and data security issues, please consult the **[Data Security Guidelines for Research Involving Human Participants.](http://research.info.yorku.ca/ore/policies-guidelines/" \t "_blank)**

In light of the above, please address the following questions:

1. **Will the data be treated as confidential?**  N  Y

If ‘No,’ please provide a rationale as to why not:

1. **Will the participant(s) be anonymous?**   N  Y

If ‘No,’ please provide a rationale:

1. **Describe the procedures to be used to ensure anonymity/confidentiality of participants or informants (where applicable) -or- the confidentiality of data during the conduct of research and dissemination of results.**

1. **Explain how written records, video/audio recordings, artefacts, and questionnaires will be secured, how long they will be retained, and provide details of their final disposal or storage. Describe the standard data security procedures for your discipline and provide a justification if you intend to store your data for a longer period of time. If the data may have archival value, discuss this and whether participants will be informed of this possibility during the consent process.**

1. **Please describe how you plan to store hard copy data, i.e., consent forms and other written records.**

Locked filing cabinet

Other:

1. **Please describe how you plan to store electronic data (such as video/audio recordings and document files)**

Encrypted and/or password-protected USB keys, laptops and/or other portable electronic data devices

Secure Server

Other:

1. **Please describe how you plan to store other formats of data (if applicable):**

1. **If you plan to destroy research data:**
   1. Please provide a firm date by which the data will be destroyed:

* 1. Provide details of their final disposal:
     1. for hard copy data (e.g., cross-cut shredder, etc.):

* + 1. for electronic data (e.g., deletion and overwriting of drives; destruction of drives; etc.):

1. **If you plan to retain data indefinitely, please provide a justification (e.g., data use for future research):**

1. **Describe any limitations to protecting the confidentiality of participants whether due to the law, the methods used, the nature of the sample population, or other reasons (e.g., duty to report).**

1. **Identify all parties who will have access to the data.**

Primary Investigator/student

Supervisor

Other (please specify):

1. **Uses of the data: Please describe all forms of output that are anticipated to result from this research (e.g., presentations, written papers, placing data in an archive, creative works, documentary films, etc.). Describe how any potentially identifying information will be handled in each form of output.**

1. **Subsequent use of data: Will the data potentially be used for other purposes in the future (e.g., teaching, future analysis, publishing of dataset, archiving in an institutional repository, etc.)?**   
    N  Y

***If ‘No,****’ the data will be solely used for the purposes describe in this application and will not be used for other purposes in the future.*

***If ‘Yes,***’ *participants must be informed of this possibility during the consent process. Subsequent use of the data for new purposes may require additional review by the REB.*

1. **Please describe how the data will be prepared to make it suitable for future use (e.g., anonymization, storage, archiving, etc.). Please describe what future uses might occur (e.g., use within the PIs research group, transmission to other researchers, publication of the dataset, etc.). Please identify any known repositories to which data may be submitted. (The REB recognizes that all potential future uses cannot be anticipated; but does expect that data will be prepared in a manner for future uses that respects the conditions under which the data were originally collected).**

# STUDENT RESEARCHER DECLARATION

I have reviewed and am familiar with the guidelines and principles detailed by the HPRC, the Delegated Ethics Review – [Student Researcher Responsibilities Information Sheet](http://research.info.yorku.ca/ore/human-participants/#squelch-taas-accordion-shortcode-content-4) and with the [***Senate Policy on Research Involving Human Participants***](http://secretariat-policies.info.yorku.ca/policies/ethics-review-process-for-research-involving-human-participants-policy/), and affirm that, to the best of my knowledge this research conforms thereto.

I hereby certify that the course-based research involving human participants is unfunded and minimal risk research, does not involve Aboriginal/Indigenous/Indigenous Peoples or Clinical Trials and that all information on this form and all statements in the attached documentation are correct and complete. I affirm that I am aware of my responsibilities as a researcher as it speaks to the conduct of research involving human participants and as outlined in [***Senate Policy on Research Involving Human Participants***](http://secretariat-policies.info.yorku.ca/policies/ethics-review-process-for-research-involving-human-participants-policy/). I am aware that all human participants in the research must have signed a written consent form or have provided oral consent for their participation in the research. I am aware that the approved protocol and signed consent forms have to be retained for two years following the completion of the research.

I hereby undertake to notify the Delegated Ethics Review Committee to which I am submitting this protocol in the event that I make any changes to the **approved *MRP Protocol – Research Involving Human Participants.*** I am aware that a further ethics review may be required as a result of such changes and that research shall be suspended pending clarification and/or resolution. I will also notify the Delegated Ethics Review Committee if any unforeseen risks not specified in the research proposal appear. In such a case, the study will be suspended pending clarification.

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**Signature, Student Researcher Date**