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| Unanticipated Problem Reporting(Protocol Deviation, Adverse Event or Incidental Findings) |

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| The following is a guideline for reporting Unanticipated Problems during research related activities. Researchers are required to report all unanticipated occurrences associated with their research which includes:Protocol deviations:*Protocol deviations* are changes to a study that have not undergone ethics review and clearance. These are normally unanticipated or unintentional changes.**Minor protocol deviations** generally impact administrative and logistical aspects of the study such as a study participant missing an appointment or changes in appointment dates.**Major protocol deviations** may impact the research protocol, informed consent documentation or other study materials, which usually cannot be anticipated ahead of time and are often necessary to ensure the safety and welfare of the participants. Examples of major protocol deviations include:* Changes in procedures required to eliminate immediate risk to participants
* Enrolment of participants outside the protocol inclusion/exclusion criteria
* Significant deviation in the informed consent process such as use of incorrect version of the letter or form

Adverse events:Any undesirable experience or response by a study participant is considered an *adverse event*. They may be emotional, psychological, physical or physiological in nature and include injury or a detrimental incident experienced by a research participant. These events are usually related to study participation or a result of the research procedures.Incidental or secondary findings:

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| *Incidental findings* are defined as previously undiagnosed medical conditions that are discovered unintentionally and may have health implications for the participant but are unrelated to the current medical condition or reason for which the individual is being treated or undergoing the MRI procedure. An incidental finding does not constitute a clinical diagnosis.**Information regarding Unanticipated Problem Reporting can be found at the following links …*** **Protocol Deviations**

<https://www.uwo.ca/research/_docs/ethics/hsreb_guidelines/Guidance_Document_Protocol_Deviation_Violation_2019Aug8.pdf>* **Adverse Events** <https://www.uwo.ca/research/_docs/ethics/hsreb_guidelines/Unanticipated_Problem_Reporting_Adverse_Event_Guidance_v10July2018.pdf>
* **Incidental Findings**

<https://cfmm.uwo.ca/resources/uploads/sops_pdf/UnanticipatedProblemReporting.pdf> |

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| Reporting: |
| Should this be reported to the REB: [ ]  YES [ ]  NO |

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| Contact Information: |
| Principal Investigator:       | Email:       |
| Department:       | Campus Extension:       |

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| Please also indicate the following: |
| Study Name (as indicated on the CFMM MRI Schedule):       |
| Date of Study:       |
| Participant ID Number:       |
| Indicate nature of Unanticipated Problem:[ ]  Protocol Deviation[ ]  Adverse Event[ ]  Incidental Finding |
| 1. In brief, please provide the general details related to the Unanticipated Problem:

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| 1. Provide details of the actions taken immediately following identification of the Unanticipated Problem.

      1. Was medical or any other intervention necessary? [ ]  YES [ ]  NO

If yes, provide the name of and contact information for, any medical or other personnel involved.       |

I confirm that the details of this report are an accurate account of the Unanticipated Problem that occurred on the date noted.

By: By:

 [signature] [signature]

Name:       Name:

Title: MRI Operator Title: Principal Investigator