**BRUYÈRE RESEARCH ETHICS BOARD –**

**REPORT OF MATERIAL INCIDENTAL FINDINGS AND RELEVANT NEW INFORMATION**

This form is for the mandatory reporting of any Material Incidental Finding or Relevant New Information as defined below. This information is used by the Bruyère REB to ensure that the study is proceeding safely, respectfully, and according to its accepted protocol procedures. If the event is an adverse event or other unanticipated safety problem, then submit instead the Serious Adverse Event/Unanticipated Problem Reporting Form, and follow the related [Guidelines.](https://www.bruyere.org/en/researchethicsboard)

If you are unsure whether a Report is required, or if the event gives rise to an imminent threat of harm or breach of data security, please call or email the Bruyère REB immediately to discuss.

Email: [REB@bruyere.org](mailto:REB@bruyere.org)

This Form must be submitted within **5 business days** of the occurrence of the event or finding, or of the PI becoming aware of it.

Complaints received from anyone affected by a Bruyère REB approved study should be promptly reported to the Bruyère REB by email: REB@bruyere.org

**Definitions:**

**Material Incidental Finding:** Any unanticipated discovery made in the course of research that is outside the scope of the research but that will, or may, appreciably increase the level of risk to participants, or that may affect participants’ welfare or willingness to continue to participate in the study, or may adversely affect data integrity. For example, a finding of suspected child abuse or that a participant has suicidal ideation, or some possibly significant cardiac abnormality on an ECG unrelated to the study objectives.

**Relevant New Information:** The discovery of new information, not including an adverse event that will, or may, appreciably increase the level of risk to participants or that may affect participants’ welfare or willingness to continue to participate in the study, or may adversely affect data integrity.

|  |  |
| --- | --- |
| **REB #** | **DATE OF REPORT** |
|  |  |
| **STUDY TITLE** | |
|  | |
| **NAME OF PERSON FILLING OUT REPORT** | **PRINCIPAL INVESTIGATOR/BRUYÈRE INVESTIGATOR** |
|  |  |
| 1. **TYPE OF REPORT** | |
| Material Incidental Findings | Relevant New Information |
| 1. **DESCRIPTION OF THE EVENT AND RESPONSE** | |
| Date of Event: | Where did the event take place? |
| Describe the event or finding, and its effect on participants, if applicable: | |
| What actions, if any, were taken, or will be taken, to address or remedy adverse consequences for participants? | |
| What actions, if any, were, or will be taken, to inform the participant and their healthcare provider? | |
| If the healthcare provider will not be informed of the incidental finding, why not? | |
| Have any participants withdrawn, or been required to withdraw, because of the reported event?  Yes  No  If yes, please describe: | |
| Is a change to the Protocol (including an amendment to any Consent Form, recruitment or other materials) needed to properly address this issue or event?  Yes  No  If yes, please describe – (note that amended study procedures may not be initiated until the Amendment is approved by REB): | |
| Please provide any other information or detail relevant to the reported event: | |
| 1. **CERTIFICATION OF PRINCIPAL INVESTIGATOR OR BRUYÈRE INVESTIGATOR** | |
| As the PI or Bruyère Investigator, I have reviewed and confirm the accuracy of the information included in this report. I confirm that this study will continue to be conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (TCPS2), all applicable privacy legislation and other regulatory requirements. | |
| **Name of PI or Bruyère Investigator:** | |
| **Signature:** | **Date:** |