**BRUYÈRE HEALTH RESEARCH ETHICS BOARD –**

**REPORT OF PROTOCOL DEVIATIONS**

This form is for the mandatory reporting of any Protocol Deviation as defined below. This information is used by the Bruyère Health 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](https://www.bruyere.org/en/researchethicsboard), 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 contact the Bruyère Health REB office immediately to discuss.

This Form must be submitted within **5 business days** of the occurrence of the deviation, or of the PI becoming aware of it as per the guidance below. Complaints received from anyone affected by a Bruyère Health REB approved study should be promptly reported to the Bruyère Health REB by email.

Email: REB@bruyere.org

**Definition of a Protocol Deviation**

Any change or alteration from the study procedures provided in the REB-approved study protocol, consent documents, or other study materials. A Protocol Deviation may be deliberate (e.g. to avoid potential harm) or unplanned (e.g. by error or oversight, or in response to unexpected circumstances). For example, by oversight, a participant signs an out-of-date version of the consent form, or there is a change of location of a research activity. A deviation may increase risk or decrease benefit, affect the participant’s rights, safety, or welfare, or the integrity of the data. Please see below for guidance on reporting.

**Reporting Guidance**

As per TCPS2 (Article 6.14) and N2 SOP 404 (S. 5.25), all **minor and major deviations** are considered reportable to the REB that meet the following criteria:

* Deviations that in the opinion of the Researcher jeopardize the safety of research participants, or that jeopardize the research efficacy or data integrity;
* Any sponsor-approved waivers to the participant eligibility criteria;
* Any change in the approved process for obtaining consent (e.g., improper translation, current ICF not implemented);
* Any deviations that lead to an SAE (deviations that lead to an SAE should be reported with a timely manner);
* Minor deviations from the research (e.g., a slight increase or decrease of testing time, a wording adjustment on a question);

**Do Minor Deviations Have to be Reported Immediately?**

In accordance with TCPS2 (Article 6.14), minor deviations (as per the definition above) should not require immediate reporting to the REB but may be summarized in annual status reports. When you are submitting your annual renewal request to the Bruyère Health REB, you may also submit a deviation report (summarizing all of the minor deviations that occurred throughout the year). If you are unsure of whether the deviation is minor, please contact the REB for guidance.

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| **REB #** | **DATE OF REPORT** |
|  |  |
| **STUDY TITLE** |
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| **NAME OF PERSON FILLING OUT REPORT** | **PRINCIPAL INVESTIGATOR or BRUYÈRE HEALTH SITE INVESTIGATOR** |
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| 1. **DESCRIPTION OF THE EVENT AND RESPONSE**
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| Date of Event:  | Where did the event take place? |
| Describe the event of problem, 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? |
| Have any participants withdrawn, or been required to withdraw, because of the reported event? [ ]  Yes [ ]  NoIf yes, please describe:  |
| As a result of this event, describe any corrective action to avoid future recurrence of a similar event. For example, any enhanced training for study personnel or change to study procedures.[ ]  Not Applicable |
| Who was made aware of the event? (For example: privacy officer, sponsor, study partner, third party, funding agency, etc.) |
| 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 [ ]  NoIf yes, please describe – (note that amended study procedures may not be initiated until the amendment is approved by the REB). |
| Please provide any other information or detail relevant to the reported event. |
| 1. **CERTIFICATION OF PRINCIPAL INVESTIGATOR OR BRUYÈRE HEALTH SITE INVESTIGATOR**
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| As the PI or Bruyère Health Site 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 Health Site Investigator:**  |
| **Signature:**  | **Date:**  |