Additional Reportable Events Form

Use this form to submit a summary of relevant audit findings, privacy breaches, participant complaints, or other reportable events which meet HREBA reporting criteria.

Do not include any individually identifying health information.

Submit the completed form and any supporting documents using the reportable event feature for files within IRISS, or e-mail to the committee for files on paper.

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| 1. **STUDY INFORMATION** | | | | | |
| Ethics #: | Protocol #: | | | | |
| Principal Investigator: | | | | | |
| Study Title: | | | | | |
| Study Progress:  Recruiting  Participants on study intervention  Follow-up | | | | No. subjects enrolled: | |
| 1. **EVENT CATEGORY** | | | | | |
| **Audit** *(findings which may adversely affect research participants or the conduct of the research)*  **Privacy Breach** *(any unauthorized collection, use, or disclosure of participant person information i.e. individually identifying health information)*  **Participant Complaint** *(where participant has concerns about their rights or ethical issues related to the research)*  **Other** *(e.g. change in risk/benefit, safety labelling, event that could significantly impact the conduct of research)*  **DSMB/Interim Analysis Report Requiring Site Action** | | | | | |
| 1. **REPORTING TIMELINES** *(within 15 calendar days)* | | | | | |
| Date study team became aware of the event: | | | | | |
| If this report was not submitted within reporting timelines, explain the lapse: | | | | | |
| 1. **EVENT DETAILS** | | | | | |
| Summary of the event: | | | | | |
| Action taken by your site: | | | | | |
| 1. **SIGN-OFF** *(not required for files within IRISS)* | | | | | |
| **Person Completing Form** | | | | | |
| Name: | | E-mail: | | | Date: |
| **Principal Investigator** | | | | | |
| Signature: | | | Name (printed): | | |
| E-mail: | | |
| Date: | | |

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| CHAIR/DESIGNATE USE ONLY | | |
| ⬜ No further action required  ⬜ Request more information  ⬜ Committee discussion required | Comments/Concerns: | |
| Signature: | | Date of Review: |