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| Reportable Events |
| **Organization Information**  |
| Name of Organization: Click or tap here to enter text. |
| Organization address line 1Click or tap here to enter text. |
| Organization address line 2Click or tap here to enter text. |
| Organization address line 3Click or tap here to enter text. |
| City:Click or tap here to enter text. | State:Click or tap here to enter text. | Country:Click or tap here to enter text. | Zip/Postal Code:Click or tap here to enter text. |
| **Contact Information**  |
| 1. Person Submitting this Form
 |
| Name: Click or tap here to enter text. |
| Degree(s): Click or tap here to enter text. |
| Title: Click or tap here to enter text. |
| Department: Click or tap here to enter text. |
| Address, if different from above: Click or tap here to enter text. |
| Telephone (including country code): Click or tap here to enter text.  |
| Fax: Click or tap here to enter text.  |
| Email: Click or tap here to enter text. |
| **Instructions** |
| Use this form to provide a summary of the issue(s) that require reporting. If applicable, include:* Immediate actions taken to protect participants, if applicable
* Planned corrective actions with timeline, if applicable

If it is unclear whether a particular item is reportable to AAHRPP, please contact the AAHRPP office.Email this form and PDF copies of supporting documents to:* reporting@aahrpp.org
* esummers@aahrpp.org
* mfeige@aahrpp.org
* rhood@aahrpp.org

 Supply copies of supporting documents, including but not limited to:* letters from a government oversight agency
* information about litigation, if public
* press coverage
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| **EVENTS THAT REQUIRE REPORTING WITHIN 48 HOURS** |
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| **1. Any negative actions by a government oversight office** |
| [ ]  US Office for Human Research Protections (OHRP) Determination Letters[ ]  US Food and Drug Administration (FDA) Warning Letters[ ]  US FDA 483 Inspection Reports with official action indicated[ ]  US FDA Restrictions Placed on IRBs[ ]  US FDA Restrictions Placed on researchers[ ]  Other US government agency restrictions (such as state government actions)[ ]  Compliance actions taken by non-US authorities (e.g., government agencies) related to human research protections ***Provide a copy of the government agency letter(s) in PDF format with your report.*** |
| Provide a summary of the issue(s), and immediate corrective actions and timeline, when appropriate |
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| Changes to policies and procedures, or processes taken or planned, if applicable: |
|  |
| Education and training completed or planned: |
|  |
| Confirmation of change in practice (monitoring) completed or planned: |
|  |
| **2. Any litigation, arbitration, or settlements** **initiated related to human research protections** |
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| Provide a summary of the issue(s), and immediate corrective actions and timeline, as appropriate |
|  |
| Changes to policies and procedures, or processes taken or planned, if applicable: |
|  |
| Education and training completed or planned: |
|  |
| Confirmation of change in practice (monitoring) completed or planned: |
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| **3. Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature** **regarding the Organization’s Human Research Protection Program** |
| ***For press coverage in a language other than English, provide a translation along with the original coverage.***  |
| [ ]  **Source (including but not limited to radio, TV, newspaper, online publications): Click or tap here to enter text.**Date aired or published: Click or tap here to enter text.Webpage / URL if available: Click or tap here to enter text. |
| Provide a summary of the issue(s), and immediate corrective actions and timeline, as appropriate |
|  |
| Changes to policies and procedures, or processes taken or planned, if applicable: |
|  |
| Education and training completed or planned: |
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| Confirmation of change in practice (monitoring) completed or planned: |
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| **EVENTS THAT REQUIRE REPORTING WITHIN 30 DAYS** |
| [ ]  Change of corporate structure (including mergers and acquisitions):Please describe the changes and expected or potential effects on your HRPP: Click or tap here to enter text. |
| [ ]  Change of ownership (including mergers and acquisitions):Please describe the changes and expected or potential effects on your HRPP: Click or tap here to enter text. |
| [ ]  Change of leadership / new organizational official:Please describe the changes and expected or potential effects on your HRPP, including contact information:Click or tap here to enter text. |
| **Contact Information for New Official:** |
| Name: Click or tap here to enter text. |
| Degree(s): Click or tap here to enter text. |
| Title: Click or tap here to enter text. |
| Department: Click or tap here to enter text. |
| Address, if different from organization address above: Click or tap here to enter text. |
| Telephone (including country code): Click or tap here to enter text.  |
| Fax: Click or tap here to enter text.  |
| Email: Click or tap here to enter text. |
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| [ ]  Change of organization name:Please provide the new legal organization name:Click or tap here to enter text. [ ]  Indicate if, in addition to the change in legal name, there is a change in preferred name for the Organization (e.g., how the Organization is listed on the AAHRPP website and certificates):Click or tap here to enter text. |
| [ ]  Other (discuss with AAHRPP in advance) Please describe the changes and expected or potential effects on your HRPP:Click or tap here to enter text. |