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| Reportable Events | | | |
| **Organization Information** | | | |
| Name of Organization:  Click or tap here to enter text. | | | |
| Organization address line 1  Click or tap here to enter text. | | | |
| Organization address line 2  Click or tap here to enter text. | | | |
| Organization address line 3  Click 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](mailto:reporting@aahrpp.org) * [esummers@aahrpp.org](mailto:esummers@aahrpp.org) * [mfeige@aahrpp.org](mailto:mfeige@aahrpp.org) * [rhood@aahrpp.org](mailto: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 |
|  |
| 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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| **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: |
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| Education and training completed or planned: |
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| 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: |
|  |
| 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. |