|  |  |  |
| --- | --- | --- |
|  | | |
| Reportable Events | | |
| **Organization Information** | | |
| Name of Organization:  Click or tap here to enter text. | | |
| City:  Click or tap here to enter text. | State/Province/Territory:  Click or tap here to enter text. | Country/Region:  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. |
| Telephone (including country code): 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 * Planned corrective actions with timeline   Supporting documents include but are not limited to:   * letters from a government oversight agency * information about litigation, if public * press coverage   Email this form and copies of supporting documents as a single PDF 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)   **If it is unclear whether a particular item is reportable to AAHRPP, please contact** [**reporting@aahrpp.org**](mailto:reporting@aahrpp.org)**.** | **Do you need to make the following updates?**   * **New Application Contact or Organizational Official** * **Change of organization name or address** |
| If yes, log into the AAHRPP Online Accreditation Management System (OAMS) to make these changes at <https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system>. The OAMS is now your home for updating information about Application Contacts, Organizational Officials, Billing Contacts, and organizational information (e.g., name, address). |

|  |
| --- |
| **EVENTS THAT REQUIRE REPORTING WITHIN 48 HOURS** |
|  |
| **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: |
|  |

|  |
| --- |
| **2. Any litigation, arbitration, or settlements** **initiated related to human research protections** |
|  |
| 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: |
|  |

|  |
| --- |
| **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: |
|  |

|  |
| --- |
| **EVENTS THAT REQUIRE REPORTING WITHIN 30 DAYS** |

|  |
| --- |
| **Changes in corporate structure (e.g., mergers and acquisition) or organization ownership should be reported to AAHRPP promptly. Please identify the types of changes below and provide relevant details.**  If the reported event(s) results in a change to the Application Contact, Alternate Application Contact, Organization Official, or organizational preferred or legal name, please update this information in the AAHRPP Online Accreditation Management System (OAMS). The OAMS login and instructions are at <https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system>. |

|  |
| --- |
| **Change of corporate structure:** |
| If the change in corporate structure includes any merger(s) and/or acquisitions, describe the plan and timeframe for consolidating different HRPPs into a single integrated HRPP, including:   * the effective date of the change in ownership * the accreditation status of all organizations, including the Council date for review of reaccreditation (see Accreditation Status letters or contact AAHRPP) * implementation of a single set of policies and procedures, and whether these policies were previously approved as part of the accreditation * implementation of a single IRB/EC application management system * change in the number or type of IRBs/ECs * decisions to start relying on external IRBs/ECs, or review for external organizations * conducting or reviewing new types of research not previously reviewed by AAHRPP * changes in key HRPP leadership (e.g., person responsible for daily IRB/EC or other key HRPP functions) * other information you believe will help AAHRPP understand plans to merge the HRPPs and create a single integrated HRPP (see Standard I-1) |
| Please describe the changes and expected or potential effects on your HRPP:  Click or tap here to enter text. |
| As a result of the change in corporate structure:   * Has there been or will there be a change to the organization’s legal name?   Yes\*  No   * Has the organizational official changed or will there be a change to who serves as the organizational official?   Yes\*  No |
| \*If there is a change in the organization’s name or information about the organizational official, please log into the AAHRPP Online Accreditation Management System (OAMS) to update that information. The OAMS login and instructions are at <https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system>. |

|  |
| --- |
| **Change of ownership or control of the organization:** |
| If the change in corporate ownership or control includes any merger(s) and/or acquisitions, describe the plan and timeframe for consolidating different HRPPs into a single integrated HRPP, including:   * the effective date of the change in ownership * the accreditation status of all organizations, including the Council date for review of reaccreditation (see Accreditation Status letters or contact AAHRPP) * implementation of a single set of policies and procedures, and whether these policies were previously approved as part of the accreditation * implementation of a single IRB/EC application management system * change in the number or type of IRBs/ECs * decisions to start relying on external IRBs/ECs, or review for external organizations * conducting or reviewing new types of research not previously reviewed by AAHRPP * changes in key HRPP leadership (e.g., person responsible for daily IRB/EC or other key HRPP functions) * other information you believe will help AAHRPP understand plans to merge the HRPPs and create a single integrated HRPP (see Standard I-1) |
| Please describe the changes and expected or potential effects on your HRPP:  Click or tap here to enter text. |
| As a result of the change in control of the organization:   * Has there been or will there be a change to the organization’s legal name?   Yes\*  No   * Has the organizational official changed or will there be a change to who serves as the organizational official?   Yes\*  No |
| \*If there is a change in the organization’s name or information about the organizational official, please log into the AAHRPP Online Accreditation Management System (OAMS) to update that information. The OAMS login and instructions are at <https://www.aahrpp.org/resources/for-accreditation/additional-resource/online-accreditation-management-system>. |

|  |
| --- |
| **OTHER EVENTS THAT REQUIRE PROMPT REPORTING (DISCUSS WITH AAHRPP IN ADVANCE)** |

|  |  |
| --- | --- |
| **Change in organization type** | |
| **Current organization type**  *Click [here](https://www.aahrpp.org/resources/for-accreditation/procedure/procedure-doc-1/accreditable-organizations) to find out how organization types are defined and [here](https://www.aahrpp.org/find-an-accredited-organization) to see how AAHRPP classifies your organization.*    Academic institution  Academic medical center  Contract research organization  Dedicated research site  Government agency  Health System  Hospital  Independent IRB or Independent Ethics Committee  Private Entity | **Requested new organization type**  *Select the one category that best describes your organization*  Academic institution  Academic medical center  Contract research organization  Dedicated research site  Government agency  Health System  Hospital  Independent IRB or Independent Ethics Committee  Private Entity |
| Please describe the reason for the request in change in organization type and expected or potential effects on your HRPP:  Click or tap here to enter text. | |
| **Other** | |
| Please describe the changes and expected or potential effects on your HRPP:  Click or tap here to enter text. | |