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| **Text  Description automatically generated** | | | |
| Response to the Draft Site Visit Report | | | |
| 1. **Organization Information** | | | |
| Legal name of Organization applying for accreditation (please consult with your general counsel):  Click or tap here to enter text. | | | |
| Organization name that should appear on AAHRPP’s website, if different from above:  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. |
| 1. **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. | | | | |
| 1. Application Contact (if different from the Person Submitting this Form) | | | | |
| **Check here if the Application Contact has changed since the Step 2 application for this organization was submitted to AAHRPP and provide the following information.** | | | | |
| 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. | | | | |

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| 1. Responsible Organizational 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 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. |
| 1. Certification |
| By submitting this form to AAHRPP, the person identified in section II.A. above certifies that the information contained in or accompanying this form provided to AAHRPP is accurate, complete, and not misleading in any way. |

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| **Instructions** |
| Use this form to provide the following to AAHRPP in response to the Draft Site Visit Report to describe the following:   * Changes made by the organization to address Areas of Concern in the Draft Site Visit Report.   + Changes should: * demonstrate the organization meets AAHRPP Standards, and * generally include education and training, and * confirm the organization meets the Standard or Element by providing a summary of monitoring. * Changes should be implemented prior to when the response is due, and * Planned actions that continue after the response is due, with a specific timeline.   *For supporting documents that accompany this response, create a* ***SINGLE PDF*** *file that contains:*   * Include a copy of the relevant portions of each supporting document ordered by reference number. * Include only one copy of a supporting document even when the document supports multiple Standards/Elements or Areas of Concern. * Use highlighting or track changes to point out specific revisions. Use highlighting or track changes to indicate revisions to previously submitted documents. |

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| **Changes to policies, and procedures, processes, if applicable:** | |
| **AAHRPP approved the organization’s policies and procedures during the Step 1 review and response. Consequently, changes to policies and procedures are generally not required.** | |
| 1. What was the change in policies and procedures, or the change to an IRB or HRPP process, if any? If there are revisions to policies and procedures, highlight the revisions. If there are revisions to electronic systems, highlight changes to forms, or provide descriptions of what specifically was changed. If there are revisions to IRB or HRPP processes, describe the process in place at the time of the site visit, and provide detailed comparisons of changes made to the process. 2. Describe how the change addresses the area of concern. 3. Specify the role of the person(s) who is responsible for implementing the change. 4. Provide a specific date(s) when the changes will be implemented. Changes should generally be implemented prior to sending the Response to the Draft Site Visit Report. 5. Attach supporting documentation (e.g., copies of revised policies with changes highlighted, copies of revised application forms with changes highlighted, descriptions of revised IRB/EC or HRPP processes with comparisons between the process prior to the site visit and the revised process. For changes not yet implemented provide highlighted documents showing planned changes. For changes not yet implemented, provide documentation of how the organization will address the area of concern while the planned changes are being implemented. | Example:  *To address the concern that protocol-specific determinations were not documented when reviewing research involving vulnerable populations, online reviewer forms were changed so that the text box for reviewers to provide protocol-specific reasons was mandatory, not optional. The system was revised to require IRB members to complete this information prior to submitting the form. Previously forms could be submitted without these fields being completed. Instructions were added to the form to remind reviewers that these fields must be completed before the reviewer form can be submitted. An error message was created if reviewers submitted forms without required information.*  Examples of supporting documentation:  Document 1: Revised forms showing instructions that the fields must be completed prior to submitting the form. (page xx)  Document 2: Screen shot of a pop-up error message showing the system requires reviewers to complete the fields prior to submitting the review form. (page xx)  Example:  *To address the concern that researchers were not informed that IRB approval expired, a database query was changed to correctly identify the date of IRB approval and pull the list of expired studies on the correct date and send notifications to researchers on the correct date.*  Examples of supporting documentation:  Document 1: Example of a report showing how the revised electronic system will report out expired studies on the date IRB approval expires. (page xx)  Document 2: Example of a notification sent to a researcher (redacted) showing the notification is sent on the correct date of study expiration. (page xx) |

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| **Education: In general, Organizations should provide all the information in items 1-6 below for each Standard or Element for which an Area of Concern was identified** | |
| * 1. What was the topic of education or training and how does the education or training address the Area of Concern identified?   2. Specify the role of the person(s) who conducted the education or training (e.g., IRB manager, QA manager etc.).   3. Provide a specific date(s) when the education or training occurred. Education or training in general should start prior to sending the Response to the Draft Site Visit Report.   4. Specify who was educated or trained (e.g., IRB members, contracts staff)?   5. Identify any additional education or training planned, if applicable.   6. Attach supporting documentation (e.g., list of persons educated or trained, dates when education occurred, agenda for education or training sessions). | Example:  *To address the concern that substantive changes were not being returned to the convened IRB or EC, the HRPP manager conducted education for staff who write minutes on September 5, 2022. The HRPP manager started to conduct education on September 15, 2022 for the chair and EC members on substantive versus minor changes, and the requirement that substantive changes be returned for review by the convened EC. Additional education for the chair and EC members is planned for EC meetings in October and November. Education will also occur at an annual retreat scheduled for February 2023.*  Examples of supporting documentation:  Document 1: List of EC members who have completed education (page xx)  Document 2: Confirmation of education of chairs and staff (page xx)  Document 3: Agenda for education sessions (page xx) |

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| **Monitoring to confirm the organization meets the Standard** | |
| 1. What evaluation or monitoring are you conducting to show this? When there are multiple concerns under a Standard or Element, describe what was evaluated to confirm each meets the Standard. 2. Who conducted monitoring to confirm the Standard is now being met in practice and, when applicable, confirming the organization is complying with applicable regulations? 3. When did monitoring start to confirm the program meets the AAHRPP Standard? Confirm your organization meets the Standard prior to sending the Response to the Draft Site Visit Report, when possible; otherwise provide a specific timeline of how you will confirm the Standard is met. 4. What additional monitoring is planned, if applicable? 5. Who reviewed results of the monitoring and assessed whether the education, training, or other actions taken were effective? 6. What changes were made, if any, as a result of the monitoring? 7. Who will review the results of future monitoring to evaluate whether additional changes, if any, are required? | Example:  *To confirm that when the IRB requests substantive changes they are returned to the convened IRB for approval, the IRB manager conducted retrospective monitoring of IRB minutes for the prior six months to establish a baseline and started to evaluate IRB minutes prospectively beginning with the September 15, 2022 meeting, which was the only meeting that occurred prior to when the Response was due. The IRB manager planned to continue monitoring each set of minutes for six months. The IRB manager and IRB chair met on September 30, 2022 to review the monitoring that had occurred so far, and determined that no changes to policies or written materials were required, but that additional education to ensure substantive changes are returned to the convened IRB for approval for staff writing IRB minutes was required.*  *The IRB manager and IRB chair planned to meet monthly to review ongoing monitoring. The IRB manager and IRB chair planned to meet in six months and determine, based on planned monitoring, if any changes are required.*  Examples of supporting documentation:  Document 1: Spreadsheet summarizing retrospective monitoring (page xx)  Document 2: Copies of relevant portions of minutes demonstrating minutes meet AAHRPP requirements, with relevant portions highlighted (page xx)  Document 3: Summary of meeting to review results, listing who attended (page xx) |
| If the Draft Site Visit Report identifies potential regulatory noncompliance, noncompliance should be reported to government agencies per regulatory requirements. Organizations must follow AAHRPP requirements for reporting to AAHRPP as described in the Accreditation Procedures available on the AAHRPP website at [www.aahrpp.org](http://www.aahrpp.org). | |

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| **DOMAIN I: ORGANIZATION** |
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| Standard I-1: The organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the organization are knowledgeable bout and follow the policies and procedures of the Human Research Protection Program. |
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| Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| Element I.1.C. The Organization has and follows written policies and procedures that allow the Institutional Review Board or Ethics Committee to function independently of other organizational entities in protecting research participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the Human Research Protection Program. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the Institutional Review Board or Ethics Committee, as appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.1.F.: The organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.1.G.: The organization has and follows written policies and procedures that identify applicable laws in the localities where it conducts human research, takes them into account in the review and conduct of research, and resolves differences between federal or national law and local laws. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.1.H.: The organization has and follows written policies and procedures specifically designed to protect the rights and welfare of research participants during an emergency. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| STANDARD I-2: The organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the organization conducts or oversees. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| STANDARD I-3: The organization’s transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the organization’s principal location while complying with local laws and taking into account cultural context. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD I-4: The organization responds to the concerns of research participants.** |
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| ELEMENT I.4.A.: The organization has and follows written policies and procedures that establish a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives that permits them to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research protocol or plan. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.4.B.: The organization conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities, when appropriate. These activities are evaluated on a regular basis for improvement. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.4.C.: The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD I-5: The organization measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program.** |
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| ELEMENT I.5.A.: The organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The organization makes improvements to increase compliance, when necessary. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.5.B.: The organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.5.C.: The organization has and follows written policies and procedures so that Researchers and research staff may bring forward to the organization concerns or suggestions regarding the Human Research Protection Program, including the ethics review process. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.5.D.: The organization has and follows written policies and procedures for addressing allegations and findings of non-compliance with Human Research Protection Program requirements. The organization works with the Institutional Review Board or Ethics Committee, when appropriate, to ensure that participants are protected when non-compliance occurs. Such policies and procedures include reporting these actions, when appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD I-6: The organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.** |
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| ELEMENT I.6.A.: The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the organization that could influence the conduct of the research or the integrity of the Human Research Protection Program. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.6.B.: The organization has and follows written policies and procedures to identify, manage, and minimize or eliminate individual financial conflicts of interest of Researchers and research staff that could influence the conduct of the research or the integrity of the Human Research Protection Program. The organization works with the Institutional Review Board or Ethics Committee in ensuring that financial conflicts of interest are managed and minimized or eliminated, when appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD I-7: The organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.** |
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| ELEMENT I.7.A.: When research involves investigational or unlicensed test articles, the organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.7.B.: The organization has and follows written policies and procedures to ensure that the handling of investigational or unlicensed test articles conforms to legal and regulatory requirements. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.7.C.: The organization has and follows written policies and procedures for compliance with legal and regulatory requirements governing emergency use of an investigational or unlicensed test article. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD I-8: The organization works with public, industry, and private sponsors to apply the requirements of the Human Research Protection Program to all participants.** |
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| ELEMENT I.8.A.: The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury, when appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.8.B.: In studies where sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the organization has a written agreement with the sponsor that the sponsor promptly reports to the organization findings that could affect the safety of participants or influence the conduct of the study. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.8.C.: When the sponsor has the responsibility to conduct data and safety monitoring, the organization has a written agreement with the sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the organization. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.8.D.: Before initiating research, the organization has a written agreement with the sponsor about plans for disseminating findings from the research and the roles that researchers and sponsors will play in the publication or disclosure of results. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT I.8.E.: When participant safety could be directly affected by study results after the study has ended, the organization has a written agreement with the sponsor that the researcher or organization will be notified of the results in order to consider informing participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| STANDARD I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **DOMAIN II: INSTITUTIONAL REVIEW BOARD OR ETHICS COMMITTEE** |
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| **STANDARD II-1: Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.** |
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| ELEMENT II.1.A.: The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC regularly reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.1.B.: The IRB or EC has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.1.C.: The organization has and follows written policies and procedures to separate competing business interests from ethics review functions. |
| **Areas of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.1.D.: The IRB or EC has and follows written policies and procedures so that members and consultants do not participate in the review of research protocols or plans in which they have a conflict of interest, except to provide information requested by the IRB or EC. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.1.E.: The IRB or EC has and follows written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD II-2: The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.** |
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| ELEMENT II.2.A.: The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB or EC. Such policies and procedures indicate that exemption determinations are not to be made by researchers or others who might have a conflict of interest regarding the studies. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.B.: The IRB or EC has and follows written policies and procedures for addressing protection of participants in research that is exempt from applicable laws and regulations. These functions may be delegated to an entity other than the IRB or EC. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.C.: The IRB or EC has and follows written policies and procedures to conduct limited IRB or EC review, if such procedure is used. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.D.: The IRB or EC has and follows written policies and procedures to conduct meetings by the convened IRB or EC. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.E.: The IRB or EC has and follows written policies and procedures to conduct reviews by the convened IRB or EC.  Element II.2.E.1. – Initial review  Element II.2.E.2. – Continuing review  Element II.2.E.3. – Review of proposed modifications to previously approved research |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.F.: The IRB or EC has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used.  Element II.2.F.1. – Initial review  Element II.2.F.2. – Continuing review  Element II.2.F.3. – Review of proposed modifications to previously approved research |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.G.: The IRB or EC has and follows written policies and procedures for addressing unanticipated problems involving risks to participants or others, and for reporting these actions, when appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.H.: The IRB or EC has and follows written policies and procedures for suspending or terminating IRB or EC approval of research, if warranted, and for reporting these actions, when appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.2.I.: The IRB or EC has and follows policies and procedures for managing multi-site research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes, and guidance.** |
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| ELEMENT II.3.A.: The IRB or EC has and follows written policies and procedures for identifying and analyzing risks and identifying measures to minimize such risks. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.3.B.: The IRB or EC has and follows written policies and procedures for reviewing the plans for data and safety monitoring, when applicable, and determines that the data and safety monitoring plan provides adequate protection for participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.3.C.: The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.3.D.: The IRB or EC has and follows written policies and procedures to evaluate the proposed arrangements for protecting the privacy interests of research participants, when appropriate, during their involvement in the research. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.3.E.: The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.3.F.: The IRB or EC has and follows written policies and procedures to evaluate the consent process and to require that the researcher appropriately document the consent process. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.3.G.: The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.** |
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| ELEMENT II.4.A.: The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.4.B.: The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.4.C.: The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD II-5: The IRB or EC maintains documentation of its activities.** |
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| ELEMENT II.5.A.: The IRB or EC maintains a complete set of materials relevant to the review of the research protocol or plan for a period of time sufficient to comply with legal and regulatory requirements, sponsor requirements, and organizational policies and procedures. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT II.5.B.: The IRB or EC documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, sponsor requirements (if any), and organizational policies and procedures. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **DOMAIN III: RESEARCHER AND RESEARCH STAFF** |
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| **STANDARD III-1: Standard III-1: In addition to following applicable laws and regulations, researchers and research staff adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, researchers and research staff have the protection of the rights and welfare of research participants as a primary concern.** |
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| ELEMENT III.1.A.: Researchers and research staff know which of the activities they conduct are overseen by the Human Research Protection Program, and they seek guidance when appropriate. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.1.B.: Researchers and research staff identify and disclose financial interests according to organizational policies and regulatory requirements and, with the organization, manage, minimize, or eliminate financial conflicts of interest. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.1.C.: Researchers employ sound study design in accordance with the standards of the discipline. Researchers design studies in a manner that minimizes risks to participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.1.D.: Researchers determine that the resources necessary to protect participants are present before conducting each research study. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.1.E.: Researchers and research staff recruit participants in a fair and equitable manner. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.1.F.: Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.1.G.: Researchers and research staff have a process to address participants’ concerns, complaints, or requests for information. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| **STANDARD III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the organization’s policies and procedures for protecting research participants; and the IRB’s or EC’s determinations.** |
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| ELEMENT III.2.A.: Researchers and research staff are qualified by training and experience for their research roles, including knowledge of applicable laws, regulations, codes, and guidance; relevant professional standards; and the organization’s policies and procedures regarding the protection of research participants. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.2.B.: Researchers maintain appropriate oversight of each research study, as well as research staff and trainees, and appropriately delegate research responsibilities and functions. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.2.C.: Researchers and research staff follow the requirements of the research protocol or plan and adhere to the policies and procedures of the organization and to the requirements or determinations of the IRB or EC. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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| ELEMENT III.2.D.: Researchers and research staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes, and guidance; the organization’s policies and procedures; and the IRB’s or EC’s requirements. |
| **Area of Concern (paste here):** |
| Changes to policies and procedures, or processes, if applicable: |
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| Education and training: |
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| Confirmation of change in practice (monitoring) |
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