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| **Key Personnel and Research Team List** *Instructions.* The purpose of this list is to identify the appropriate individuals who are knowledgeable about your organization’s Human Research Protection Program (HRPP) and to help AAHRPP identify researchers and research staff to interview during a site visit.* AAHRPP is focusing on roles not titles, so please identify the person(s) who performs the activities described for that knowledge area or has the responsibility.
* Some people may have responsibilities in more than one of the areas identified below. Please identify that person for all the responsibilities they may perform.
* More than one person may share the responsibilities outlined. If the number of individuals who share the responsibility exceeds the number permitted to be listed, please list only those individuals who are most knowledgeable about policies and processes.
* For some knowledge areas or responsibilities, AAHRPP wants to interview multiple people (e.g., IRB/EC members). For example, list three people for the following: “Please identify no more than three people who oversee training and education for research teams about the protection of research participants.” If your organization does not have three people who perform this function, list as many personnel your organization has who perform this function, which may be one or two people. If your organization has more than three people who perform this function, only list three.
* If you have any questions about the Key Personnel and Research Team List, please contact AAHRPP at reporting@aahrpp.org.
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| **Knowledge Area/Responsibility** | **Key Personnel** |
| **Section I** |
| 1. Who is the person with **overall responsibility for the HRPP**? (Element I.1.B.)

NOTE: This individual may be the person listed as the “institutional official" when registering with regulatory agencies | Please identify the person who has overall responsibility for the HRPP and no more than one additional person if the person responsible for overall HRPP responsibility has delegated significant HRPP oversight responsibility to them.  | Person with overall responsibility for the HRPP:  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person to whom a significant HRPP oversight responsibility has been delegated:  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |

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| 1. Is the person(s) **who makes determinations regarding whether an activity meets the definition of research involving human participants someone other than an IRB/EC member** (including chairs and vice chairs) or **IRB/EC staff**? (Element I.1.A.)

NOTE: This includes HRPP staff; do not include researchers, if researchers make these determinations. | [ ]  **No.** Please include this person(s) below as one of the IRB/EC members or IRB/EC staff who will be interviewed. |
| [ ]  **Yes**. Please identify no more than two people who make determinations regarding whether an activity meets the definition of research involving human participants.  | Person who makes determinations regarding whether an activity meets the definition of research involving human participants (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who makes determinations regarding whether an activity meets the definition of research involving human participants (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who makes determinations regarding whether an activity meets the definition of research involving human participants.* |

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| 1. Who **oversees or conducts the training and education for research teams about the ethical principles and organizational policies the organization follows to protect human participants**? (Element I.1.E.)

NOTE: This should include individuals who conduct this training and education for the entire organization but also can include others who may do so for a certain group of researchers (e.g., clinical researchers, cancer researchers, or students). | Please identify no more than three people who oversee or conduct training and education for research teams about the protection of research participants. | Person who oversees or conducts the training and education for research teams (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees the training and education for research teams (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees training and education for research teams.* |
| Person who oversees the training and education for research teams (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who oversees training and education for research teams.* |

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| 1. Who **oversees or conducts the training and education of IRB/EC chairs, members, and staff**? (Element I.1.E.)
 | Please identify no more than three people who oversee or conduct training and education of IRB/EC chairs, members, and staff. | Person who oversees or conducts the training and education of IRB/EC chairs, members, and staff (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees or conducts the training and education of IRB/EC chairs, members, and staff (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees training and education for IRB/EC chairs, members, and staff.* |
| Person who oversees or conducts the training and education of IRB/EC chairs, members, and staff (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who oversees training and education for IRB/EC chairs, members, and staff.* |

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| 1. Does your organization have **a process separate from the IRB/EC to conduct scientific review or evaluate scholarly validity for some or all research**, such as a Scientific Review Committee or departmental review process? (Element I.1.F.)
 | [ ]  **No**. My organization’s IRB(s)/EC(s) are responsible for conducting scientific review and evaluating scholarly validity. |
| [ ]  **Yes**. Please identify the chair(s) of the Scientific Review Committee(s) or no more than three people involved in the scientific review or assessment of scholarly validity of human research. Note: organizations with Cancer Centers and those with Clinical & Translational Awards commonly have standalone scientific review committees, which should be identified. If academic, hospital, or other departments conduct scientific review, provide a sample of no more than three people. | Person who oversees scientific/scholarly review (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees scientific/scholarly review (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional Chair of a Scientific Review Committee or person involved in the scientific review or assessment of scholarly validity of human research.* |
| Person who oversees scientific/scholarly review (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional Chair of a Scientific Review Committee or person involved in the scientific review or assessment of scholarly validity of human research.* |

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| 1. Does your organization rely on **a process separate from the IRB/EC to evaluate the risks or scientific merit of the use of radiation** in human participants research? (Element I.1.F.)
 | [ ]  **No**. My organization’s IRB(s)/EC(s) are responsible for evaluating the risks and/or assessing the scientific merit of research involving exposure of participants to radiation for research purposes.OR[ ]  **Not Applicable**. My organization does not conduct research that would involve exposure of participants to radiation for research purposes. |
| [ ]  **Yes**. Please identify the chair(s) of the Radiation Safety/Use Committee(s) or no more than two people involved in the scientific review or assessment of radiation safety for research involving human participants. Do not include a process to review use of radiation in clinical care or other non-research use. | Person who oversees the scientific or safety review of research involving radiation (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees the scientific or safety review of research involving radiation (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional Chair of the Radiation Safety/Use Committee(s) or person involved in the scientific review or assessment of radiation safety for research involving human participants.* |

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| 1. Who conducts **ancillary reviews** (other than conflict of interest, radiation safety, and scientific reviews) and may need to communicate information to an IRB/EC to be considered during its review process? (Element I.1.F.)
 | [ ]  **Not Applicable**. My organization does not have **ancillary reviews** (other than conflict of interest, radiation safety, and scientific reviews) that may need to communicate information to an IRB/EC to be considered during its review process. |
| Please identify no more than three people who are part of ancillary review processes (other than conflict of interest and scientific reviews) that may need to communicate information to an IRB/EC. | Person who is part of ancillary review process related to IRB/EC review (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.Ancillary review that this person oversees: Click or tap here to enter text. |
| Person who is part of ancillary review process related to IRB/EC review (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.Ancillary review that this person oversees: Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional ancillary review process related to IRB/EC review.* |
| Person who is part of ancillary review process related to IRB/EC review (3): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.Ancillary review that this person oversees: Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional ancillary review process related to IRB/EC review.* |
| 1. Who **provides legal advice** (e.g., about state laws; who can act as a surrogate) to the HRPP staff, IRB/EC members, or researchers? (Element I.1.G.)
 | Please identify one person who serves as the legal counsel who advises the HRPP, IRB/EC, or researchers. | Person who provides legal advice:  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| 1. Who is responsible for **developing, evaluating, and providing education about the organization’s emergency response and preparedness plan** for human research? (Element I.1.H.)
 | Please identify no more than three people responsible for the HRPP emergency response and preparedness plan. | Person responsible for HRPP emergency preparedness (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person responsible for HRPP emergency preparedness (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person responsible for the HRPP emergency response and preparedness plan.* |
| Person responsible for HRPP emergency preparedness (3): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person responsible for the HRPP emergency response and preparedness plan.* |

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| 1. Who **has overall responsibility for responding to the concerns of research participants**? (Element I.4.A.)
 | Please identify no more than two people who are responsible for responding to the concerns of research participants. | Person who responds to research participant concerns (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who responds to research participant concerns (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person responsible for responsible for responding to the concerns of research participants.* |
| 1. Who **conducts activities designed to enhance understanding of human research by participants, prospective participants, or their communities**? This could include HRPP or IRB/EC staff, researchers (e.g., those involved in community-based participatory research), research participant advocates, and research support programs. (Element I.4.B.)
 | Please identify no more than three people who conduct activities designed to enhance understanding of human research by participants, prospective participants, or their communities. | Person who conducts participant/community outreach (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who conducts participant/community outreach (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person responsible for conducting participant/community outreach.* |
| Person who conducts participant/community outreach (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person responsible for conducting participant/community outreach.* |

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| 1. Who is **responsible for overseeing the process for measuring its HRPP’s compliance** with organizational policies and procedures and applicable laws, regulations, codes, and guidance, **and making improvements to increase compliance**, when necessary? (Element I.5.A)
 | Please identify no more than three people who are responsible for overseeing the process for measuring HRPP’s compliance and making improvements to increase compliance, when necessary. | Person who oversees HRPP compliance (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees HRPP compliance (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person responsible for overseeing the process for measuring HRPP compliance and making improvements, when necessary.* |
| Person who oversees HRPP compliance (3): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person responsible for overseeing the process for measuring HRPP compliance and making improvements, when necessary.* |
| 1. Who is **responsible for overseeing the quality, efficiency, and effectiveness of the HRPP**, and making improvements, when necessary, to **increase the quality, efficiency, and effectiveness of the program**? (Element I.5.B)
 | Please identify no more than three people who are responsible for overseeing the quality, efficiency, and effectiveness of the HRPP and making improvements to increase compliance, when necessary. | Person who oversees HRPP quality, efficiency, and effectiveness (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees HRPP quality, efficiency, and effectiveness (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person responsible for overseeing quality, efficiency, and effectiveness.* |
| Person who oversees HRPP quality, efficiency, and effectiveness (3): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person responsible for overseeing quality, efficiency, and effectiveness.* |
| 1. Who **responds to questions, concerns, or suggestions regarding the HRPP, including the ethics review process**? (Element I.5.C.)
 | Please identify no more than two people who respond to questions, concerns, or suggestions regarding the HRPP. | Person who responds to questions, concerns, or suggestions regarding the HRPP (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who responds to questions, concerns, or suggestions regarding the HRPP (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who responds to questions, concerns, or suggestions regarding the HRPP.* |
| 1. Who **assesses compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance for your organization’s HRPP, IRB(s)/EC(s), and research teams?** (Element I.5.D.)

NOTE: Examples might include auditors, post-approval monitors, compliance staff, HRPP or IRB/EC personnel, or others who audit or monitor study team or IRB/EC records. AAHRPP is focusing on roles not titles. | Please identify:* no more than two people who assess HRPP (including IRB/EC) compliance

AND* no more than two people who assess research team compliance (if your organization conducts human participants research)
 | Person who assesses HRPP/IRB/EC compliance (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who assesses HRPP/IRB/EC compliance (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who assesses HRPP (including IRB/EC) compliance.* |
| Person who assesses research team compliance (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A person was not identified because my organization does not conduct human research.* |
| Person who assesses research team compliance (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who assesses research team compliance.* |

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| 1. Who **can describe the process or program to identify, evaluate, manage, and minimize potential financial conflicts of interests that organizational leaders** may have related to human participants research? (Element I.6.A.)

NOTE: Examples of individuals who might oversee this process include a director of compliance, a chief operating officer, a legal counsel, medical director, director of grants and contracts, technology transfer officer, or conflicts of interest officer. | Please identify no more than three people involved with the management of organizational conflicts of interest.  | Person involved with the management of organizational conflicts of interest (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person involved with the management of organizational conflicts of interest (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who is involved with the management of organizational conflicts of interest.* |
| Person involved with the management of organizational conflicts of interest (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who is involved with the management of organizational conflicts of interest.* |

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| 1. Does your organization **have a process separate from the IRB/EC to identify, evaluate, manage, and minimize potential financial conflicts of interests that researchers and research teams** may have related to human participants research, such as a Conflict of Interest Committee? (Element I.6.B.)
 | [ ]  **No**. My organization’s IRB(s)/EC(s) are responsible for identifying, evaluating, managing, and minimizing potential financial conflicts of interests researchers and research teams. |
| Please identify the chair of the Conflict of Interest Committee or no more than two people in charge of managing researcher financial conflicts of interest. | Person in charge of managing researcher financial conflicts of interest (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person in charge of managing researcher financial conflicts of interest (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who is in charge of managing researcher financial conflicts of interest.* |

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| 1. Does your organization **have a person or program outside of the IRB/EC that facilitates compliance with applicable regulations related to research involving investigational or unlicensed test articles** (including drugs, biologics, and devices) to ensure the test articles have appropriate regulatory approval or meet exemptions for such approval? (I.7.A.)

NOTE: This could be a person or program that advises IRB(s)/EC(s), such as an FDA compliance program or a clinical research support office, or a person or department that assists researchers with IND or IDE applications such as for investigator initiated research. | [ ]  **No**. My organization’s IRB(s)/EC(s) are responsible for evaluating compliance with applicable regulations related to research involving investigational or unlicensed test articles, which include drugs, biologics, and devices.OR[ ]  **Not Applicable**. My organization does not conduct research that involves investigational or unlicensed drugs, biologics, or devices. |
| [ ]  **Yes**. Please identify no more than three people who provide regulatory support and/or oversee the compliance program for unlicensed test articles.  | Person who provides regulatory support and/or oversees the compliance program for unlicensed test articles (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who provides regulatory support and/or oversees the compliance program for unlicensed test articles (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who provides regulatory support and/or oversees the compliance program for unlicensed test articles.* |
| Person who provides regulatory support and/or oversees the compliance program for unlicensed test articles (3): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who provides regulatory support and/or oversees the compliance program for unlicensed test articles.* |

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| 1. Does your organization **have a centralized process to manage research involving unlicensed or investigational drugs?** (I.7.B.)
 | [ ]  **No**. Although my organization conducts or manages research involving investigational or unlicensed drugs, research teams are responsible for managing investigational or unlicensed drugs.[ ]  **Not Applicable**. My organization does not conduct or manage research involving investigational or unlicensed drugs. |
| [ ]  **Yes**. Please identify no more than three people who oversee the research pharmacy program or provide pharmacy support for the management and storage of investigational drugs used in human participants research.  | Person who oversees the research pharmacy program or provides pharmacy support for the management and storage of investigational drugs used in human participants research (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees the research pharmacy program or provides pharmacy support for the management and storage of investigational drugs used in human participants research (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees the research pharmacy program or provides pharmacy support for the management and storage of investigational drugs used in human participants research.* |
| Person who oversees the research pharmacy program or provides pharmacy support for the management and storage of investigational drugs used in human participants research (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who oversees the research pharmacy program or provides pharmacy support for the management and storage of investigational drugs used in human participants research.* |

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| 1. Does your organization **have a centralized process to manage research involving unlicensed or investigational devices?** (I.7.B.)
 | [ ]  **No**. Although my organization conducts or manages research involving investigational or unlicensed devices, we do not have a centralized process to manage them.[ ]  **Not Applicable**. My organization does not conduct or manage research involving investigational or unlicensed devices. |
| [ ]  **Yes**. Please identify no more than three people who oversee the centralized program or provide support for the management and storage of investigational devices used in human participants research. | Person who oversees the centralized program or provides support for the management and storage of investigational devices used in human participants research (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees the centralized program or provides support for the management and storage of investigational devices used in human participants research (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees the centralized pharmacy program or provides support for the management and storage of investigational devices used in human participants research.* |
| Person who oversees the centralized program or provides support for the management and storage of investigational devices used in human participants research (3): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who oversees the centralized pharmacy program or provides support for the management and storage of investigational devices used in human participants research.* |

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| 1. Does your organization **enter into arrangements with industry sponsors** to conduct research involving human participants (e.g., clinical trials agreements)? (Standard I-8)
 | [ ]  **No**. **My organization does not enter into arrangements with industry sponsors to conduct research involving human participants.** |
| [ ]  **Yes**. Please identify no more than two people in charge of ensuring that human participants protections are present in contracts or funding agreements with industry sponsors.  | Person who oversees industry contracts/funding agreements (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees industry contracts/funding agreements (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person in charge of ensuring that human participants protections are present in contracts or funding agreements with industry sponsors.* |
| 1. Does your organization **rely upon external IRBs/ECs** to review at least some of your organization’s human research? (Standard I-9)
 | [ ]  **No**. **My organization does not rely upon external IRBs/ECs.** |
| [ ]  **Not applicable. My organization is an independent IRB/EC and does not conduct research.** |
| [ ]  **Yes**. Please identify no more than two people responsible for overseeing the process to rely on external IRBs/ECs, including selection of IRBs/ECs, execution and implementation of reliance agreements, and provision of local context information to the reviewing IRBs/ECs. | Person who oversees the process for reliance on external IRBs/ECs (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees the process for reliance on external IRBs/ECs (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees the process for reliance on external IRBs/ECs.* |

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| **Section II** |
| 1. Does your organization **have an internal IRB(s)/EC(s**)?
 | [ ]  **No.** This section (Section II) is not completed because my organization does not have an internal IRB/EC and is not an independent IRB/EC.  |
| [ ]  **Yes.** Please complete this section (Section II) about IRB/EC members and staff. |
| 1. Does your organization **act as a Reviewing IRB/EC** for other organizations? (Standard I-9)
 | [ ]  **No**. **My organization does not act as a Reviewing IRB/EC for other organizations.** |
| [ ]  **Yes.** Please identify no more than two people responsible for execution and implementation of reliance agreements and the process for collection of information relevant to IRB/EC review from relying institutions. | Person who oversees working with external organizations who rely on your organization’s IRB/EC (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees working with external organizations who rely on your organization’s IRB/EC (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees working with external organizations who rely on my organization’s IRB/EC.* |
| 1. Does your organization **serve as an IRB** for a US Veterans Affairs (VA) hospital or facility that does not have an internal IRB? (Standard I-9)
 | [ ]  **No**. **My organization does not serve as the IRB for a US VA hospital or facility that does not have an internal IRB.** |
| [ ]  **Yes.** Please identify:* The Research Compliance Officer (RCO) for the VA
* The Associate Chief of Staff for Research & Development (ACOS/R&D) or Deputy ACOS/R&D for the VA
* The chair of the VA Research and Development Committee (R&DC)

Note: If you serve as the IRB for multiple VAs, the representatives for the three positions identified can be from the same or different VAs. | Affiliated VA RCO:  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Affiliated VA ACOS/R&D or Deputy ACOS/R&D:  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Affiliated VA R&DC chair:  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |

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| 1. Who serves as the IRB/EC member(s) that represents the **general perspective of participants**? (Element II.1.A.)

Note: This person could be a scientific or non-scientific member and may be affiliated or unaffiliated with your organization.  | * For organizations that have three or fewer IRBs/ECs (or IRB/EC panels or subgroups), please identify no more than three IRB/EC member(s) who represent the general perspective of participants; if your organization has multiple IRBs/Ecs (or IRB/EC panels or subgroups), provide at least one member from each IRB/EC (or IRB/EC panel or subgroup) unless the same person represents the general perspective of participants for all IRBs/Ecs (or IRB/EC panels or subgroups).
* For organizations that have more than three IRBs/Ecs (or IRB/EC panels or subgroups), please identify a sample of IRB/EC members from different IRBs/Ecs (or IRB/EC panels or subgroups).
* For all IRB/EC members listed, please identify the IRB(s)/EC(s) they serve on, whether they are scientists or non-scientists, and whether they are affiliated or unaffiliated with your organization.

Note: If your organization has distinct IRBs/Ecs (e.g., dedicated biomedical or dedicated social/behavioral/education), be sure to include members that represent each specialized IRB/EC. | IRB/EC member who represents the general perspective of participants (1): This IRB/EC member is considered (check all that apply):[ ]  a scientist [ ]  a non-scientist[ ]  affiliated [ ]  unaffiliated | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text. |
| IRB/EC member who represents the general perspective of participants (2): This IRB/EC member is considered (check all that apply):[ ]  a scientist [ ]  a non-scientist[ ]  affiliated [ ]  unaffiliated | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A second IRB/EC member was not identified because my organization does not have an additional IRB/EC member who represents the general perspective of participants.* |
| IRB/EC member who represents the general perspective of participants (3): This IRB/EC member is considered (check all that apply):[ ]  a scientist [ ]  a non-scientist[ ]  affiliated [ ]  unaffiliated | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A third IRB/EC member was not identified because my organization does not have an additional IRB/EC member who represents the general perspective of participants.* |

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| 1. Who serves as **non-scientific member(s) of your IRB(s)/EC(s)**? (Element II.1.A.)
 | * Please identify IRB/EC members who are not also IRB/EC staff for these interviews. If the only non-scientific IRB/EC member(s) is also IRB/EC staff, then include that person(s) here.
* For organizations that have three or fewer IRBs/ECs (or IRB/EC panels or subgroups), please identify no more than three non-scientific members of the IRB/EC; if your organization has multiple IRBs/ECs (or IRB/EC panels or subgroups), provide at least one member from each IRB/EC (or IRB/EC panel or subgroup) unless the same person serves as the non-scientific member for all IRBs/ECs (or IRB/EC panels or subgroups).
* If your organization has more than three IRBs/ECs (or IRB/EC panels or subgroups), provide a sample of three non-scientific members from different IRBs/ECs (or IRB/EC panels or subgroups).

Note: If your organization has distinct IRBs/ECs (e.g., dedicated biomedical or dedicated social/behavioral/education), include non-scientific members that represent each specialized IRB/EC. | Non-scientific IRB/EC member (1):[ ]  Check here if this IRB/EC member is also an IRB/EC staff member | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text. |
| Non-scientific IRB/EC member (2):[ ]  Check here if this IRB/EC member is also an IRB/EC staff member | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A second IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a non-scientist.* |
| Non-scientific IRB/EC member (3): [ ]  Check here if this IRB/EC member is also an IRB/EC staff member | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A third IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a non-scientist.* |

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| 1. Who **serves as IRB/EC members with scientific expertise**? (Element II.1.A.)
 | Please identify no more than six scientific members of the IRB/EC and the IRB(s)/EC(s) they serve on.Note: * If your organization has six or fewer IRBs/ECs (or IRB/EC panels or subgroups), provide at least one member from each IRB/EC (or IRB/EC panel or subgroup) unless the same person serves as the scientific members for all IRBs/ECs (or IRB/EC panels or subgroups).
* If your organization has more than six IRBs/ECs (or IRB/EC panels or subgroups), provide the six scientific members from different IRBs/ECs (or IRB/EC panels or subgroups).
* If your organization has distinct specialized IRBs/ECs (e.g., dedicated biomedical or dedicated social/behavioral/education), include scientific members that represent each specialized IRB/EC (or IRB/EC panels or subgroups).
* If any of your scientific members conduct expedited review, identify at least **one** IRB/EC scientific member who conducts expedited review.
 | Scientific IRB/EC member (1): [ ]  Check here if this IRB/EC member conducts expedited reviews | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text. |
| Scientific IRB/EC member (2): [ ]  Check here if this IRB/EC member conducts expedited reviews | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A second IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a scientist.* |
| Scientific IRB/EC member (3): [ ]  Check here if this IRB/EC member conducts expedited reviews | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A third IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a scientist.* |
| Scientific IRB/EC member (4): [ ]  Check here if this IRB/EC member conducts expedited reviews | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A fourth IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a scientist.* |
| Scientific IRB/EC member (5): [ ]  Check here if this IRB/EC member conducts expedited reviews | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A fifth IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a scientist.* |
| Scientific IRB/EC member (6): [ ]  Check here if this IRB/EC member conducts expedited reviews | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A sixth IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a scientist.* |

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| 1. Does your organization’s IRB(s)/EC(s) review **research involving prisoners**? (Element II.1.A.)
 | [ ]  **No**. My organization does not review research involving prisoners. |
| [ ]  **Yes.** Please identify no more than three individuals who serve as prisoner representatives and which of your organization’s IRB/EC(s) they serve on.Note: * If your organization has three or fewer IRBs/ECs (or IRB/EC panels or subgroups), provide at least one member from each IRB/EC (or IRB/EC panel or subgroup) unless the IRB(s)/EC(s) have the same person who serves as the prisoner representative.
* If your organization has more than three IRBs/ECs (or IRB/EC panels or subgroups), provide a sample of no more than three IRB/EC members who serve as prisoner representatives from different IRBs/ECs (or IRB/EC panels or subgroups).
* If your organization has distinct IRBs/ECs (e.g., dedicated biomedical or dedicated social/behavioral/education), please identify prisoner representatives for each IRB/EC.
 | IRB/EC member who is a prisoner representative (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text. |
| IRB/EC member who is a prisoner representative (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A second IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a prisoner representative.* |
| IRB/EC member who is a prisoner representative (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A third IRB/EC member was not identified because my organization does not have an additional IRB/EC member who is a prisoner representative.* |

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| 1. Who is **responsible for leading IRB/EC meetings**, such as IRB/EC chairs and including vice chairs? (Element II.2.D.)
 | * For organizations that have three or fewer IRB(s)/EC(s) (or IRB/EC panels or subgroups), please identify no more than three IRB/EC chairs or other person(s) responsible for leading IRB/EC meetings, each from a different IRB/EC unless the same people serve as chairs or vice-chairs for multiple IRB/ECs (or IRB/EC panels or subgroups)
* For organizations that have more than three IRBs/ECs (or IRB/EC panels), please identify a sample of IRB/EC chairs or other person(s) responsible for leading IRB/EC meetings

Note: If your organization has distinct specialized IRBs/ECs (e.g., dedicated biomedical or dedicated social/behavioral/education), please identify chairs/vice chairs for each IRB/EC. | IRB/EC Chair or Vice Chair (1): Activities this person performs:[ ]  Not human participants research determinations[ ]  Exemption determinations[ ]  Expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text. |
| IRB/EC Chair or Vice Chair (2): Activities this person performs:[ ]  Not human participants research determinations[ ]  Exemption determinations[ ]  Expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A second IRB/EC Chair or Vice-Chair was not identified because my organization does not have an additional IRB/EC Chair or Vice-Chair.* |
| IRB/EC Chair or Vice Chair (3): Activities this person performs:[ ]  Not human participants research determinations[ ]  Exemption determinations[ ]  Expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.IRB(s)/EC(s) this person is a member of:Click or tap here to enter text.[ ]  *A third IRB/EC Chair or Vice-Chair was not identified because my organization does not have an additional IRB/EC Chair or Vice-Chair.* |

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| 1. Is the person(s) who **oversees administrative support for the HRPP (e.g., HRPP Director) the same as the person who is responsible for overseeing administrative support for the IRB/EC** (e.g., IRB Office Director, IRB Director, or IRB Manager), including any IRB staff? (Element II.1.B.)
 | [ ]  **No**. The person(s) who oversees administrative support for the HRPP is different from the person(s) who is responsible for overseeing administrative support for the IRB(s)/EC(s). |
| [ ]  **Yes**. Please identify no more than two people who oversee administrative support for the HRPP, including administrative support for the IRB(s)/EC(s). | Person who oversees HRPP administrative support, including for the IRB(s)/EC(s) (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees HRPP administrative support, including for the IRB(s)/EC(s) (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees IRB/EC administrative support.* |
| 1. Who **oversees the administrative support for the IRB(s)/EC(s)** (e.g., IRB Office Director, IRB Director, or IRB Manager), including any IRB/EC staff? (Element II.1.B.)
 | [ ]  **Not applicable**. The person(s) who oversees administrative support for the IRB(s)/EC(s) is the same as the person(s) who is responsible for overseeing administrative support for the HRPP. |
| Please identify no more than two people who oversee IRB/EC administrative support. | Person who oversees IRB/EC administrative support (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Person who oversees IRB/EC administrative support (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who oversees IRB/EC administrative support.* |

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| 1. Who **provides staff support to the IRB(s)/EC(s**)?
 | Please identify no more than six IRB/EC staff and what activities they perform.Note: * If your organization has distinct specialized IRBs/ECs (e.g., dedicated biomedical or dedicated social/behavioral/education), please identify IRB staff for each IRB/EC (or IRB/EC panels or subgroups).
* If your organization has more than three IRBs/ECs (or IRB/EC panels or subgroups), identify six IRB/EC staff who provide support for different IRBs/ECs (or IRB/EC panels or subgroups).
 | Person who provides staff support to the IRB(s)/EC(s) (1): Check all activities that this person performs[ ]  Makes exempt human participants research determinations[ ]  Conducts pre-review of IRB/EC applications[ ]  Writes minutes for convened IRB/EC meetings[ ]  Serves as an IRB/EC member who conducts expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  No personnel were identified here because m*y organization does not have an additional person who provides staff support to the IRB(s)/EC(s).* |
| Person who provides staff support to the IRB(s)/EC(s) (2): Check all activities that this person performs[ ]  Makes exempt human participants research determinations[ ]  Conducts pre-review of IRB/EC applications[ ]  Writes minutes for convened IRB/EC meetings[ ]  Serves as an IRB/EC member who conducts expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who provides staff support for its IRB(s)/EC(s).* |
| Person who provides staff support to the IRB(s)/EC(s) (3): Check all activities that this person performs[ ]  Makes exempt human participants research determinations[ ]  Conducts pre-review of IRB/EC applications[ ]  Writes minutes for convened IRB/EC meetings[ ]  Serves as an IRB/EC member who conducts expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who provides staff support for its IRB(s)/EC(s).* |
| Person who provides staff support to the IRB(s)/EC(s) (4): Check all activities that this person performs[ ]  Makes exempt human participants research determinations[ ]  Conducts pre-review of IRB/EC applications[ ]  Writes minutes for convened IRB/EC meetings[ ]  Serves as an IRB/EC member who conducts expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A fourth person was not identified because my organization does not have an additional person who provides staff support for its IRB(s)/EC(s).* |
| Person who provides staff support to the IRB(s)/EC(s) (5): Check all activities that this person performs[ ]  Makes exempt human participants research determinations[ ]  Conducts pre-review of IRB/EC applications[ ]  Writes minutes for convened IRB/EC meetings[ ]  Serves as an IRB/EC member who conducts expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A fifth person was not identified because my organization does not have an additional person who provides staff support for its IRB(s)/EC(s).* |
| Person who provides staff support to the IRB(s)/EC(s) (6): Check all activities that this person performs[ ]  Makes exempt human participants research determinations[ ]  Conducts pre-review of IRB/EC applications[ ]  Writes minutes for convened IRB/EC meetings[ ]  Serves as an IRB/EC member who conducts expedited review | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A sixth person was not identified because my organization does not have an additional person who provides staff support for its IRB(s)/EC(s).* |

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| **Section III.** |
| 1. Are there any other people at your organization, including any entities you identified, that you would like the site visitors to speak with to highlight your HRPP’s strengths or initiatives?

Feel free to include any person who you think could highlight your organization’s efforts related to the HRPP. You are welcome to think broadly and creatively about who you might want to include. For example, if your organization has a Cancer Center or Clinical & Translational Science Award programs or researchers conducting cutting edge clinical trials, you might identify individual(s) from those programs.  | [ ]  **No. My organization does not have additional personnel to identify for this category.** |
| If yes, please describe the role(s) of the individual(s). | Role(s):Click or tap here to enter text. | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Role(s):Click or tap here to enter text. | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Role(s):Click or tap here to enter text. | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |

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| **Section IV. Research Teams** **Please do not include any individuals below who are researchers or research staff, but also serve on an IRB/EC at your organization or have been identified as Key Personnel above.**  |
| 1. Do any of your **researchers or IRBs/ECs review studies involving any of these potentially vulnerable populations?**
* Pregnant women
* Neonates of uncertain viability or nonviable neonates
* Children
* Prisoners
* Adults with impaired decision-making capacity
 | ***Select the most appropriate response for your organization.***[ ]  **No. Researchers at my organization do not conduct studies and my organization’s IRBs/ECs do not review research involving pregnant women, neonates of uncertain viability, nonviable neonates, children, prisoners, or adults with impaired decision-making capacity.**[ ]  **No. Researchers at my organization do not conduct studies involving pregnant women, neonates of uncertain viability, nonviable neonates, children, prisoners, or adults with impaired decision-making capacity and my organization does not have an internal IRB(s)/EC(s).**[ ]  **No. My organization is an independent IRB/EC but does not review research involving pregnant women, neonates of uncertain viability, nonviable neonates, children, prisoners, or adults with impaired decision-making capacity.** |
| [ ]  **Yes.** Pleaseidentify:* two researchers who have conducted greater than minimal risk research involving vulnerable populations

AND * two researchers who have conducted minimal risk research involving vulnerable populations
 | Researcher who conducts **greater than minimal risk research** (1): Check the relevant population(s) involved in this researcher’s studies[ ]  Pregnant women[ ]  Neonates of uncertain viability or nonviable neonates[ ]  Children[ ]  Prisoners[ ]  Adults with impaired decision-making capacity | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who conducts **greater than minimal risk research** (2):Check the relevant population(s) involved in this researcher’s studies[ ]  Pregnant women[ ]  Neonates of uncertain viability or nonviable neonates[ ]  Children[ ]  Prisoners[ ]  Adults with impaired decision-making capacity | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher who conducts greater than minimal risk research involving the vulnerable populations identified at left.* |
| Researcher who conducts **minimal risk research** (1):Check the relevant population(s) involved in this researcher’s studies[ ]  Pregnant women[ ]  Neonates of uncertain viability or nonviable neonates[ ]  Children[ ]  Prisoners[ ]  Adults with impaired decision-making capacity | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who conducts **minimal risk research** (2):Check the relevant population(s) involved in this researcher’s studies[ ]  Pregnant women[ ]  Neonates of uncertain viability or nonviable neonates[ ]  Children[ ]  Prisoners[ ]  Adults with impaired decision-making capacity | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher who conducts minimal risk research involving the vulnerable populations identified at left.* |

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| 1. Do any of your researchers conduct or your IRBs/ECs review **research that involves testing drugs, devices, vaccines, or nutritional supplements?**
 | ***Select the most appropriate response for your organization.***[ ]  **No. My organization’s researchers do not conduct and my IRBs/ECs do not review research that involves testing drugs, devices, vaccines, or nutritional supplements.**[ ]  **No. My organization’s researchers do not conduct research that involves testing drugs, devices, vaccines, or nutritional supplements and my organization does not have an internal IRB(s)/EC(s).**[ ]  **No. My organization is an independent IRB/EC but does not review research that involves testing drugs, devices, vaccines, or nutritional supplements.** |
| [ ]  **Yes.** Pleaseidentify three researchers who conduct research that involves testing drugs, devices, vaccines, or nutritional supplements. NOTE: If your organization conducts or reviews drug and device research, please identify at least 1 researcher who has a study testing drugs and at least 1 researcher who has a study testing devices. | Researcher who conducts clinical research (1): [ ]  This researcher conducts studies that test **drugs**. [ ]  My organization does not have any researchers who conduct studies that involve testing drugs. The researcher identified conducts studies that involve the at least one of the following (select all that apply):[ ]  Devices[ ]  Vaccines[ ]  Nutritional supplements | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who conducts clinical research (2): [ ]  This researcher conducts studies that test **devices**. [ ]  My organization does not have any researchers who conduct studies that involve testing devices. The researcher identified conducts studies that involve the at least one of the following (select all that apply):[ ]  Drugs[ ]  Vaccines[ ]  Nutritional supplements | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher who conducts research that involves testing drugs, devices, vaccines, or nutritional supplements.* |
| Researcher who conducts clinical research (3):Check the relevant product(s) involved in this researcher’s studies:[ ]  Drugs[ ]  Devices[ ]  Vaccines[ ]  Nutritional supplements | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third researcher was not identified because my organization does not have an additional researcher who conducts research that involves testing drugs, devices, vaccines, or nutritional supplements.* |
| 1. Do any of your **researchers conduct or your IRBs/ECs review transnational research**?
 | ***Select the most appropriate response for your organization.***[ ]  **No. None of my organization’s researchers conduct and my organization’s IRBs/ECs do not review transnational research.**[ ]  **No. None of my organization’s researchers conduct transnational research and my organization does not have an internal IRB(s)/EC(s).**[ ]  **No. My organization is an independent IRB/EC but does not review transnational research.** |
| [ ]  **Yes.** Pleaseidentify two researchers who conduct transnational research. | Researcher who conducts transnational research (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who conducts transnational research (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher who conducts transnational research.* |

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| 1. Have any of your **researchers conducted or IRBs/ECs reviewed a study involving a waiver of informed consent or waiver of documentation of informed consent**?
 | ***Select the most appropriate response for your organization.***[ ]  **No. None of my organization’s researchers have conducted and my organization’s IRBs/ECs have not reviewed a study involving a waiver of informed consent or waiver of documentation of informed consent.**[ ]  **No. None of my organization’s researchers have conducted a study involving a waiver of informed consent or waiver of documentation of informed consent and my organization does not have an internal IRB(s)/EC(s).**[ ]  **No. My organization is an independent IRB/EC but has not reviewed a study involving a waiver of informed consent or waiver of documentation of informed consent.** |
| [ ]  **Yes.** Pleaseidentify two researchers who have conducted a study involving a waiver of informed consent or waiver of documentation of informed consent. | Researcher who has conducted a study involving a waiver of informed consent or waiver of documentation of informed consent (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who has conducted a study involving a waiver of informed consent or waiver of documentation of informed consent (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher has conducted a study involving a waiver of informed consent or waiver of documentation of informed consent.* |

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| 1. Does your organization have **researchers who have had studies reviewed by your organization’s internal IRB/EC**? (Domain III)
 | ***Select the most appropriate response for your organization.***[ ]  **Not Applicable. My organization does not have an internal IRB/EC.**[ ]  **Not Applicable. My organization is an independent IRB/EC and does not conduct research.** |
| [ ]  **Yes.** Please identify:* One researcher who has had 1-2 studies reviewed by an internal IRB/EC

AND* One researcher who has had a large number of studies reviewed by an internal IRB/EC
 | Researcher who has had 1-2 studies reviewed by an internal IRB/EC: | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *My organization does not have a researcher who has had 1-2 studies reviewed by an internal IRB/EC.* |
| Researcher who has had a large number of studies reviewed by an internal IRB/EC: | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *My organization does not have a researcher who has had a large number of studies reviewed by an internal IRB/EC.* |
| 1. Does your organization have **researchers who have had studies reviewed by an IRB/EC external to your organization with which your organization executed a reliance arrangement for IRB/EC oversight**? (Standard I-9)
 | ***Select the most appropriate response for your organization.***[ ]  **No. None of my organization’s researchers have conducted research overseen by an external IRB/EC.**[ ]  **Not Applicable. My organization is an independent IRB/EC and does not conduct research.** |
| [ ]  **Yes.** Pleaseidentify two researchers who have had a study(ies) reviewed by an IRB/EC external to your organization. | Researcher who has had a study reviewed by an external IRB/EC (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who has had a study reviewed by an external IRB/EC (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher who has had research overseen by an external IRB/EC.* |

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| 1. Does your organization have **researchers who conduct investigator-initiated research (i.e., studies that are not developed by industry, government, or other private sponsors)**? (Domain III)
 | ***Select the most appropriate response for your organization.***[ ]  **No. None of my organization’s researchers have conducted investigator-initiated research.**[ ]  **Not Applicable. My organization is an independent IRB/EC and does not conduct research.** |
| [ ]  **Yes.** Pleaseidentify two researchers who have conducted investigator-initiated research. | Researcher who has conducted investigator-initiated research (1): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Researcher who has conducted investigator-initiated research (2): | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second researcher was not identified because my organization does not have an additional researcher who has conducted investigator-initiated research.* |

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| 1. Research staff who **prepare IRB/EC submissions whether for an internal or external IRB/EC** (Domain III)
 | [ ]  **Not provided. My organization is an independent IRB/EC.** |
| Please identify three research staff whoprepare IRB/EC submissions, whether for internal or external IRB(s)/EC(s).  | Research staff who prepare IRB/EC submissions, whether for internal or external IRB(s)/EC(s) – (1):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Research staff who prepare IRB/EC submissions, whether for internal or external IRB(s)/EC(s) – (2):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who prepares IRB/EC submissions.* |
| Research staff who prepare IRB/EC submissions, whether for internal or external IRB(s)/EC(s) – (3):  | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who prepares IRB/EC submissions.* |

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| 1. Research staff who interact with research participants or **coordinate multisite studies** (Domain III)
 | [ ]  **Not provided. My organization is an independent IRB/EC.** |
| * Research staff who obtain informed consent and/or recruit research participants.
* Research staff who coordinate a multisite study.
* Research staff who interact with vulnerable populations (e.g., children, prisoners, adults with impaired decision-making capacity, pregnant women).
 | Research staff (1): [ ]  This research staff person obtains informed consent and/or recruits research participants[ ]  My organization does not have a research staff person who obtains informed consent and/or recruits participants, but this person performs at least one of the following activities (select all that apply):[ ]  Coordinates a multisite study[ ]  Interacts with vulnerable participant populations | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text. |
| Research staff (2): [ ]  This research staff person coordinates a multisite study[ ]  My organization does not have a research staff person who coordinates a multisite study, but this person performs at least one of the following activities (select all that apply):[ ]  Obtains informed consent and/or recruits research participants[ ]  Interacts with vulnerable participant populations | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A second person was not identified because my organization does not have an additional person who obtains informed consent and/or recruits research participants, interacts with research participants or coordinates multisite studies.* |
| Research staff (3): [ ]  This research staff person interacts with vulnerable participant populations[ ]  My organization does not have a research staff person who interacts with vulnerable participant populations, but this person performs at least one of the following activities (select all that apply):[ ]  Obtains informed consent and/or recruits research participants[ ]  Coordinates a multisite study | First Name, Last Name, Degree(s), Position Title Click or tap here to enter text.[ ]  *A third person was not identified because my organization does not have an additional person who obtains informed consent and/or recruits research participants, interacts with research participants or coordinates multisite studies.* |