Center for
Prevention Programs
and Partnerships

Institutional Review Board Frequently Asked Questions for TVTP Grantees and Applicants

09/27/2023

General IRB Questions

What is an IRB?

An Institutional Review Board (IRB) is an objective third party with the purpose of protecting and managing risk to human subjects involved in research. The IRB committee will include research scientists and subject matter experts with substantial research experience.

The term "human subject" means a living individual about whom an investigator is conducting research.

What does an IRB do?

In accordance with Title 45, Code of Federal Regulations Part 46 (45 CFR 46), 28 CFR 22, and other statutes and regulations, an IRB continually monitors research to minimize risk and has the authority to suspend or terminate research when human subjects' rights or welfare are not adequately protected. This includes:

- Reviewing all proposed research involving human subjects to ensure that they are treated ethically and that their rights and welfare are adequately protected.
- Determining whether the research activities meet the requirements of the Federal regulations and principles of human subjects protection.
- Continually monitoring and providing oversight of all approved research.
- Receiving reports on progress of the research, including adverse events or unanticipated problems, and requiring periodic review of ongoing research.[1]

An IRB has the authority to suspend or terminate research if the research fails to meet the requirements of human subjects protection.

What is the difference between research and evaluation?

The IRB is the deciding body on what studies require review. Federal regulations stipulate that IRB review is required for research studies that involve human subjects. Evaluation studies under certain circumstances do not require IRB review. These two types of studies have common elements (see below), and an IRB will determine whether the study is research or evaluation and whether IRB review is required.

- Research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."[2]

[1] Office for Human Research Protections (OHRP). HHS regulations for the protection of human subjects in research, Title 45 CFR 46 webpage. Available at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
[2] OHRP. Title 45 CFR 46, 2018 Common Rule webpage. Subpart A. Basic HHS Policy for Protection of Human Research Subjects. Available at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#subparta

- Evaluation studies are defined as a "systematic collection of information about the activities, characteristics and outcomes of programs to make judgments about the program (or processes, products, systems, organizations, personnel, or policies), improve effectiveness, and/or inform decisions about future program development."[3]

The following chart[4] compares and contrasts the common elements of research and evaluation studies.

Common Elements	
EVALUATION	**RESEARCH**
Establishes the merit or value of a process, product, or program	Aims to be value-free
Assessment of how well a process, product, or program is working to achieve stated objectives	Aims to produce or develop new knowledge
Designed to improve a process, product, or program and may include: • Needs assessment • Process, outcome, or impact evaluation • Cost-benefit or cost-effectiveness analyses	May be descriptive, relational, or causal
Designed to examine effectiveness of a process, product, or program	Designed to be generalized to a population beyond those participating in the study or contribute broadly to knowledge or theory *(i.e., designed to develop or contribute to generalizable knowledge)*
Assessment of a program or product as it would exist regardless of the evaluation	May include an experimental or non-standard intervention
Rarely subject to peer review	Often submitted for peer review
Activity related to process, product or program will rarely alter the timing or frequency of standard procedures or normal activities	Standard procedures or normal activities may be altered by an experimental intervention
Often, funding sources will be the entity in which the activity occurs	May have external funding

IRB Requirement Questions

How do I know if my project should be reviewed by an IRB?

All research projects involving human subjects should be reviewed by an IRB. The term "human subject" means a living individual about whom an investigator is conducting research. The IRB determines whether the project requires further IRB review.

Submission of an IRB protocol and supporting documentation is required for the IRB to review and to determine if the project qualifies for exemption.

[3] Patton MQ. Utilization-focused evaluation: The new century text. 3rd ed. Thousand Oaks, CA: Sage, 1997.
[4] University of Connecticut. Office of Vice President of Research webpage. Does Evaluation Require IRB Review? https://ovpr.uconn.edu/services/rics/irb-2/researcher-guide/does-evaluation-require-irb-review/#:~:text=Research%20studies%20involving%20human%20subjects,in%20concert%20with%20the%20IRB

The Department of Homeland Security (DHS) requires all projects working with vulnerable populations to undergo IRB review.

Who decides if a project is exempt?

Only the IRB can make this determination.

What does it mean if my study is deemed exempt?

A determination that a study qualifies for an Exemption (or is "exempt") means that the research has no or minimal risk to its human subjects. The study is exempt from most of the requirements for human subject protections (Title 45 CPF 46) but is still considered research.

A determination that a study qualifies for an Exemption is made by the IRB *after* it receives and reviews the study's IRB protocol and supporting documents.

Who is required to complete training in human subjects research protection?

An IRB may require anyone who will have access to human subjects or identifiable data from human subjects to have a valid/non-expired training certificate.

The IRB may require individuals to complete this training through their institution (e.g., Collaborative Institutional Training Initiative [CITI] course) or through the Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services.

Who is DHS CAPO, and what is their role?

The DHS Science and Technology Directorate, Compliance Assurance Program Office (CAPO) provides compliance support and oversight functions to ensure DHS-funded activities are compliant with relevant international agreements, Federal regulations, DHS policies, and related standards and guidance. All IRB approval determinations, whether resulting from an expedited review or full committee review (see workflow in Appendix A), **must also be reviewed by CAPO prior to the initiation of any data collection activities** regarding human subjects.

When submitting protocols to an IRB for review, grantees must also submit their protocols to their Center for Prevention Programs and Partnerships (CP3) Grant Manager. During the IRB review process, the grantee should discuss any changes in protocol with their CP3 analyst.

Upon receipt of IRB approval (see workflow on page 13), grantees must forward the following materials to their CP3 Grant Manager, who will transmit their materials to CAPO for review and concurrence.

- IRB Determination Letter
- Complete study package, including all recruitment, consenting, and data collection materials (surveys, program design materials, etc.) that were provided to the IRB for their review
- CP3 will liaise with CAPO until concurrence is received and may follow up with the grantee if additional information is required to answer any questions that arise during CAPO's review. Grantees should budget approximately 4 weeks for the CAPO review and concurrence process into their project timeline.

IRB approval (or determination of exempt status) and CAPO review and concurrence are required before data collection can begin.

What changes in study procedures require IRB review?

All changes to study protocols, instruments, consent forms, or other study materials must be reviewed by the IRB before those changes are implemented.

Investigators are required to submit a modification explaining the proposed changes and any updated materials to the IRB. Minor changes in previously approved studies can usually be reviewed and approved by Expedited Review in a short period of time. Grantees must forward all documentation regarding any IRB modification to their CP3 Grant Manager, who will transmit these to DHS CAPO for review and concurrence. CAPO review is required before the grantee implements the proposed modifications.
Submitting a modification form is required for studies that have been approved by the IRB and studies that have been deemed exempt or not human subjects research (NHSR). Exempt and NHSR studies require modifications and IRB review to ensure the proposed changes do not alter the study's status.
Any last-minute or real-time changes to protocol that were not reviewed by the IRB should be reported as an unanticipated problem (see below).

What is the difference between consent and assent?

Consent is an individual giving researchers or affiliated program staff permission to engage in research activities with them and to collect and use their data (as described in the informed consent form). Only individuals who have reached the legal age of consent in their state may legally consent to this. For individuals less than the legal age of consent who may participate in a program or study, consent is required from the parent or legal guardian. Emancipated minors may also be able to solely give informed consent, but the regulations vary by state.

Youth may agree to participate in a research study (assent) if they are mature enough to understand the program and what information will be collected and how it will be used. They may also not agree, or dissent. Assent may not be required by law (check your state and local regulations), but most IRBs require it. Additionally, if a child/minor does not object, it should not be viewed as assent unless they confirm agreement to participate in the research.

IRB Timeline and Process Questions

How long does an IRB review take?

This will depend on the IRB.

Initial review may take as few as one to two weeks, or it may take longer. The timing of the next steps will depend on the IRB's initial assessment of your protocol—whether it is exempt, eligible for expedited review, or requires full review. (See workflow on page 13.)

The timing will also depend on the completeness and thoroughness of your protocol. The IRB may have questions that will require a written response before a determination is made. The questions may ask for additional information or clarification about your protocol.

Upon receipt of the IRB determination, grantees should include up to four additional weeks into their project timeline for review and concurrence from DHS CAPO.

How long is my IRB approval good for?

The IRB approval is good for one year unless the IRB deems it necessary to reduce this period of time. Programs may apply for continuing review to extend their status for another year.

When should I submit for continuing review?

This may depend on the IRB, but plan to submit your application for continuing review about one month before your status expires.

What is an expedited review, and can I request one?

An expedited review is a review conducted by one or more members of the IRB instead of the full board. Only certain types of studies are able to be reviewed using expedited procedures.

Expedited doesn't mean "fast." It simply means that your study does not have to be reviewed by the full board during a convened meeting. The timeframe described above (under "How long does an IRB review take?") applies to studies that are reviewed using expedited review procedures.

The type of review required (expedited or full board) is determined by the IRB.

What types of studies are not eligible for expedited review?

Several types of studies are not eligible for expedited review and must be reviewed by the IRB at a convened meeting. This includes studies that present more than minimal risk to human subjects and/or involve vulnerable populations requiring special considerations. According to OHRP, "The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be

stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal."[5]

Information on the types of research categories eligible for expedited review are available through OHRP; however, the website notes that just because the activity is eligible for expedited review does not automatically mean that the activity is deemed minimal risk. The IRB will determine this.

If my study was determined to be exempt or not human subjects research (NHSR), is my work with the IRB finished?

It depends. Studies that are determined to be exempt or NHSR are not required by Federal regulations to undergo continuing review, so if your study is implemented as described in your IRB submission and there are no changes, you do not need to contact the IRB. It should be noted though that many IRBs do have policies that require at least an annual check-in on study progress.

However, you are required to contact the IRB if you make any changes to your study protocol, instruments, procedures, communications, or other study materials. Contact your IRB for guidance when considering these changes or no later than after deciding on these changes. ***You must submit a modification so that the IRB can review the materials before you implement any changes.***

You are required to contact your IRB if an adverse event or unanticipated problem occurs. It is important to note that all studies determined to be exempt or NHSR are still expected to adhere to ethical principles including the following when appropriate: informed consent; privacy and confidentiality protections; and sound design and procedures.

What is an unanticipated problem?

The Office for Human Research Protections considers unanticipated problems (UAP) "to include any incident, experience, or outcome that meets all of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized."[6]

[5] OHRP. Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998). Available at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html.
[6] OHRP. Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007). Available at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2.

Examples of UAPs include but are not limited to:

- Data with the participants' personally protected information is stolen.
- Incarceration of a participant when your protocol is not approved for prisoners.
- Enrolling a participant that does not fit inclusion criteria (e.g., enrolling a 15-year-old when the criteria is age 16–20 years).
- Someone gets hurt while participating in the program (e.g., trip and fall).
- Complaints from participants.
- Any unplanned change to the research protocol or plan taken without IRB review.

Grantees must notify the IRB and their CP3 analyst of any UAP within 48–72 hours of its occurrence; the timeframe will be specified by your IRB.

What is an adverse event?

An adverse event (AE) refers to physical and/or psychological harm that has occurred in the context of your research. An AE could be something you anticipate, or it could be unanticipated. Anticipated risks should be described in the risks section of your protocol along with your plans to address the risks should they occur. Examples of AEs may include but are not limited to:

- Participant experiencing unexpected and negative psychological reaction to the program content or data collection activity.
- An unexpected death of a participant and therefore loss of research participant, which is not related to their participation (and most likely an underlying condition).
- Participants' social standing at work or school is threatened.

Grantees must notify the IRB and their CP3 analyst of any AE within 48–72 hours of its occurrence; the timeframe will be specified by your IRB.

Am I required to report adverse events or unanticipated problems to the IRB if my study was determined to be exempt or NHSR?

Yes. The IRB is tasked with monitoring the safety of human subjects and it examines each AE and UAP to ensure we learn from each event and our studies utilize best practices.

How do I close out my project with the IRB?

An IRB will usually have a process for closing a study that the investigator will need to follow. Activities to close your project with the IRB may include documentation of completed activities or a notice to the IRB.

Other IRB-Related Questions

How do I find an IRB for my project?

If the organization leading the study has an IRB, that IRB will support your project. Otherwise, you may request (or procure) IRB services from a university or independent IRB. *(Search online for "independent IRB for social science research.")* Local government agencies should check if their state government has an IRB that can support their project.

What should I consider when procuring IRB services?

Before signing on with an independent IRB or partnering with a university, it is important for you to understand the terms of the agreement and how that may impact your project. While all IRBs work with the same regulations, their processes and timelines will vary. Ask questions to help you decide which IRB best fits your needs. Also consider how these affect your budget and timeline. Questions may include but are not limited to:

- **What are the requirements for submitting an IRB protocol for review?**

  This may include a signed contract or teaming agreement, principal investigator credentials, and human subjects research training for project staff, among other requirements.

- **If the IRB is at a university, does it require that its faculty or staff be a member of the project team and in what role?**

  Most universities have an IRB, but they often require that someone from their faculty or staff be involved with the project—often, but not always, as a principal investigator. Make sure the individual(s) has/have subject matter expertise related to your project topic, population, and/or setting and/or technical expertise (e.g., research design, data analysis). Partnering with a university may require a subcontract or teaming agreement, which you should factor into your budget.

- **If the IRB is independent, does it provide IRB services for social science research (not just clinical research)?**
- **Does the IRB have individuals with expertise in your area of research and with any special populations or settings required for your study?**

  Ensure that there is at least one member of the committee or that the IRB can partner with someone to serve on their committee, who has knowledge and experience working with the special population or setting noted in your protocol. This individual should understand the nuances of working with this group or setting and be familiar with any required safeguards.

- **What is the cost structure for IRB services?**

  This will vary greatly. Some IRBs may not charge for studies performed by their organization's researchers, considering it as part of overhead. Others may charge a flat fee, annual fee, or it may be based on another factor such as type of review and monitoring required or length of project. Potential applicants and grantees are encouraged to refer directly to the IRB Cost Structure Guidance (Appendix B) and Example IRB Fee Schedule (Appendix C) for additional information, including detailed guidance on estimated ranges for different services associated with IRB review, as well as an example budget for a Targeted Violence and Terrorism Prevention grantee.

- **Is human subjects protection training available through the organization? Is it included in the cost or separate?**

- **What is the organization's workflow and timeline for IRB review?**

  - *Ask about the steps in their process and the approximate timeframe for each step.*
  - *Ask how often the IRB meets for full review. This can impact your timeline if full review is needed.*
  - *Ask about the process and timeline for submitting a modification to your protocol.*
  - *Ask about the organization's continuing review process.*

- **Does the organization provide resources or technical assistance for preparing the IRB protocol?**

  This may be especially important if you do not have someone on your team with IRB experience. Consider partnering with someone who does.

- **What is required for monitoring?**

  - *Do you need to participate in regular calls or meetings?*
  - *Do you need to submit any written documentation?*
  - *How often are you required to check in with the IRB?*

- **Is the IRB registered with OHRP? Does the IRB have Federal Wide Assurance?**

  Federal Wide Assurance (FWA) documents the institution's guarantee that it will follow HHS regulation for human subjects found in 45 CFR 46. Before it can obtain an FWA, the institution must register its IRB with OHRP. Knowing that the IRB that you select is registered with OHRP and has FWA will help you be compliant with these Federal regulations. Studies funded with Federal dollars will usually require review by an IRB holding an FWA.
  You can confirm an IRB's registration with OHRP and its FWA status at:
  https://ohrp.cit.nih.gov/search/irbsearch.aspx?styp=bsc.

What additional safeguards are required when my project involves populations more vulnerable to coercion or undue influence?

Federal regulations have identified certain populations as "vulnerable to coercion or undue influence." This includes pregnant women and fetuses, children under the age of 18, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged. It may also include employees, military personnel, refugees, individuals with limited English proficiency, and students. These segments of the population are considered vulnerable because they do not have the capacity to give consent (e.g., minors), may be unjustly swayed by the benefits or incentives (e.g., economically disadvantaged), or may feel that there will be negative consequences for not participating (e.g., employees, prisoners, refugees).
It is important to include these groups in research, so the requirement of additional protections should not discourage research with vulnerable populations or those requiring special considerations. However, the requirements may evolve over time, so please consult with your IRB for the latest guidance. In addition, this document does not cover state or local laws or regulations (including tribal law), which may provide additional protections for these populations.

Children

Per 45 CFR 46, "children" is defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."[7] The safeguard requirements for research with children is available in 45 CRF 46, Subpart B (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html).

Note: In situations where children are also prisoners, 45 CFR 46 Subpart C requirements also apply (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html).

Educationally or economically disadvantaged persons

Individuals who are educationally or economically disadvantaged are at greater risk of coercion or undue influence due to their circumstances. However, their inclusion in research is important and they should not be excluded due to the need for additional safeguards. "For the inclusion of economically or educationally disadvantaged persons, the benefits must not be so great that the subjects disregard the risks. Alternatively, the benefits of participation in comparison to the risk, must not be so minimal such that only those who are economically or educationally disadvantaged want to participate. Studies should not be skewed toward either extreme."[8]

Refugees, individuals with limited English proficiency, prisoners, and minors may also fit within one or more of these subpopulations requiring additional safeguards.

- **Educationally disadvantaged persons** may have educational deficits or learning disabilities that limit their communication with the research team as well as their ability to fully understanding the research, including risks and benefits. Safeguards include ensuring that the consent form and all other study materials are written in a language that is easily understood by the participants, including foreign languages if limited or no English proficiency if a factor. Materials should also match the literacy level of the participants. For individuals with limited reading and/or writing skills, the research team should make accommodations to enable free and open communication between

[7] OHRP. Title 45 CFR 46, 2018 Common Rule webpage. Subpart D. Additional Protections for Children Involved as Subjects in Research. Available at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html
[8] University of Kentucky. University of Kentucky IRB Guidance on Research Involving Economically or Educationally Disadvantaged Persons. n.d. Available at: https://www.research.uky.edu/uploads/ori-d1390000-research-involving-economically-or-educationally-disadvantaged-persons

themselves and the (potential) participant. This may include an interviewer or interpreter to read materials and document responses.

- **Economically disadvantaged persons** are those with low socioeconomic status, who may accept a greater research risk than those in other socioeconomic strata because the benefit or incentive from participation meets one or more physiological or safety needs (e.g., cash; gift cards or vouchers for food, transportation, etc.; or other items). Safeguards for this group include making sure the incentives or financial gains for participation are proportionate to the risks, discomfort, and/or inconveniences they may experience and are not overly persuasive. However, reimbursement or vouchers for childcare or transportation may be provided to enable participation in the research study. Note that economically disadvantaged persons may also be educationally disadvantaged; safeguards for this factor are also required (see above)

Persons with diminished mental capacity

Individuals with diminished mental capacity may not have the ability to truly or to legally consent to participation in a research study. The National Institute of Health (NIH) notes that "A wide variety of diseases, disorders, conditions, and injuries can affect a person's ability to understand such information, to weigh the advantages and disadvantages of participation in research, and to reach an informed decision regarding study participation. An individual's capacity to provide truly informed consent can be affected by other types of vulnerability such as poverty and deficits in education. … Consent capacity can be impaired, for example, by mental disorders, neurological disorders such as stroke or dementia, metabolic impairments, psychoactive medications, substance abuse, and head trauma. It is important to recognize that in some situations, these conditions may produce substantial impairment of capacity, while in other situations they may not affect an individual's understanding of key informed consent elements."9

Gauging an individual's capacity to consent may involve asking them to describe parts of the research to ensure their understanding. This includes asking them to describe the purpose of the study, what they will be asked to do, the risks or benefits of participation, and voluntary nature of and alternatives to participation. If an individual does not have the mental capacity to consent, consent may be given by a legally authorized representative, such as a family member or friend, with power of attorney for the individuals. Please check your state and local statutes for additional guidance on legally authorized representation.

Pregnant women and human fetuses

Research can pose additional and/or unknown risks to pregnant women, human fetuses, and neonates, so 45 CFR 46, Part B requires additional protections for these populations. The safeguard requirements for research with pregnant and human fetuses is available in 45 CRF 46, Subpart B (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html). Additional information about research with pregnant and lactating women is available from the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) (https://www.nichd.nih.gov/about/advisory/PRGLAC).

[9] National Institutes of Health. Research Involving Individuals with Questionable Capacity to Consent: Points to Consider. November 2009. Available at: https://grants.nih.gov/grants/policy/questionablecapacity.htm

Prisoners

Safeguards for the protection of prisoners are required because this population may not feel free to make a truly voluntary and uncoerced decision about participating in research. These safeguards are found in 45 CFR 46, Subpart C (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html) and applies to any individual who is or becomes a prisoner while participating in a research study.

Student, military personnel, and employees

Students, employees, and military personnel are often part of hierarchical organizations which may compromise or influence their ability to consent or dissent (not consent to participate), especially if they feel that the benefit or risk to not participating will impact their grade or employment status.

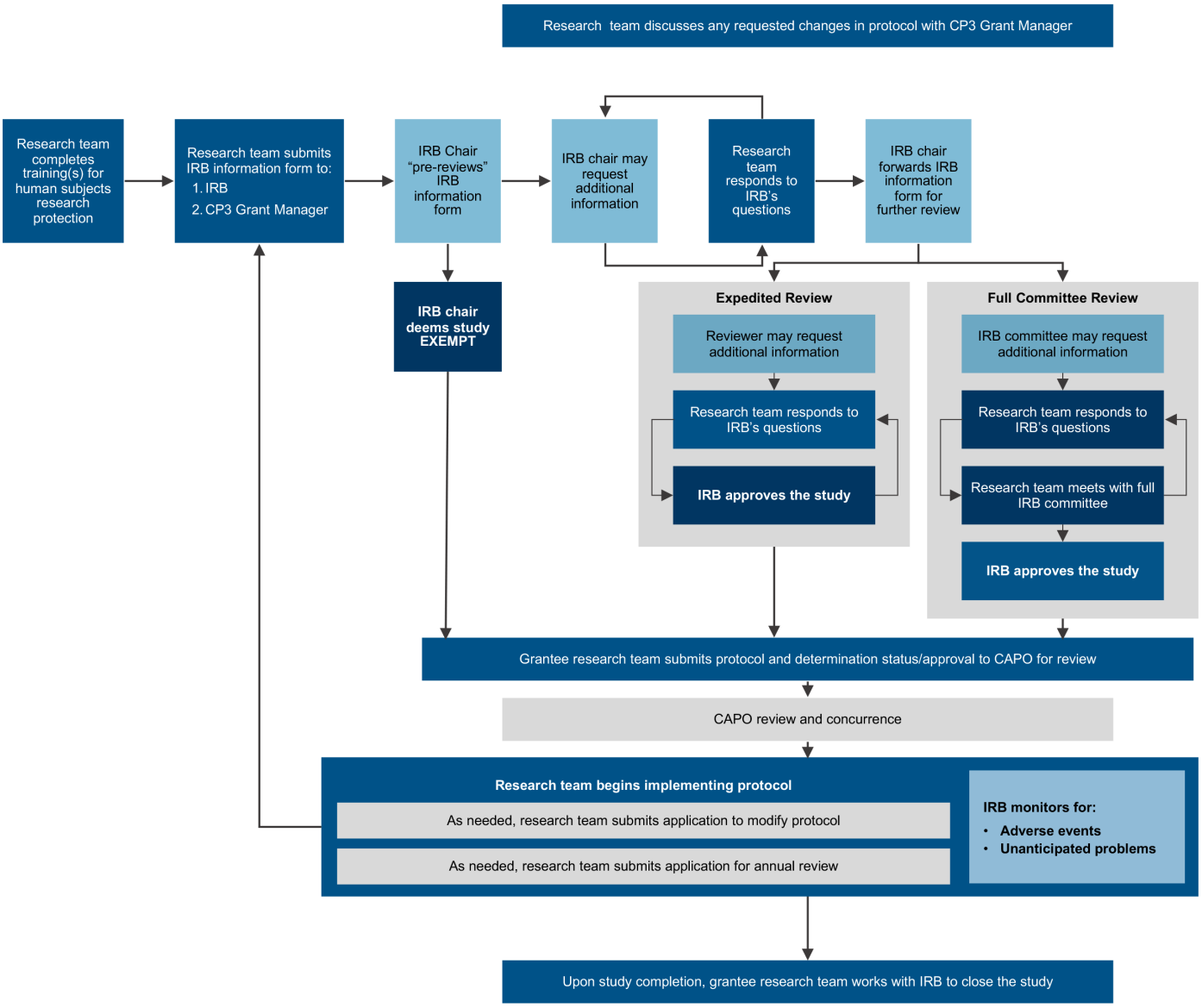
- ***Student*** participation in a research study should not be a course or class requirement and one's consent or dissent should not influence their grade. Furthermore, researchers should ensure that the opportunity to participate is made available to all students and not limited to students in a particular course (unless that course is the focus of the study).

- ***Employee*** participation in a research study should not be required for employment nor impact their employment status. While employers may make accommodations for staff to participate in a study (e.g., provide time off without penalty or provide space in their facility), neither consent nor dissent should be a factor for merit increase or decrease, nor promotion or demotion. Researchers may opt to "blind" employers from knowing who is participating in the study.

- ***Military persons*** should be treated similar to employees, as the hierarchical command structure of the military may put undue pressure on its personnel to participate or not participate in a study.

Appendix A. IRB Workflow

The following is a generic depiction of the IRB review process. Each IRB may have a slightly different review process



Appendix B. IRB Cost Structure Guidance

Grantees should contact IRBs to discuss their DHS-CP3 project and request a fee schedule or tailored cost estimate. The following provides general guidance on IRB cost structures, including factors or services that may be needed over the course of the project. DHS encourages grantees to include costs for potential modifications to protocols, changes in staff, and adverse events or unanticipated problems, as these must be reported to DHS *and* to the IRB to be compliant with Federal guidelines. Non-compliance may result in a study suspension and investigations.

Disclaimer: The pricing amounts are a general guideline provided by a sampling of IRBs based on wide-ranging conversations. Each IRB offered a different cost structure, with some services grouped and some separated. For additional information and a more accurate estimate, please contact the IRB for specific pricing, based on your project needs. These costs are subject to change at any time and should be viewed as a guide for considerations when securing an IRB. See the FAQ section on securing an IRB for additional questions to ask when requesting a quote or cost estimate.

Service	Fee per Unit Range	Fee per Unit Average
INITIAL REVIEW		
1. Determination of non-human subjects	$500–$1,155	$766
If deemed to be human subjects research, some IRBs may apply this cost to the subsequent phase of review.		
2. Review of IRB exemption (initial review)*	$975–$1,500	$1,237.50
If not deemed exempt, some IRBs may apply this cost to the expedited or full board review.		
3a. Expedited review (initial review)*	$1,000–$2,500	$1,680
3b. Full board review (initial review)*	$1,450–$2,875	$2,234
** Each step within the initial review (for IRB exemption, expedited review, and full board review) will have a base cost and may include additional costs for the following services based on the grantee's project. The range for each service is included below. Note that some IRBs may add a percentage or hourly fee to these costs.*		
▪ Each additional co-principal investigator	$175–$1,500	$838
▪ Each additional staff member	$45	$45
▪ Each additional consent form	$150–$600	$359
▪ Each additional protocol (instrument, recruitment, and/or research material)	$185–$425	$303
▪ Each translation attestation/certificate[10]	$90	$90
▪ Vulnerable population fee	$195	$195
▪ Mitigated conflict of interests (costs may vary if the conflict is minor or major)[11]	$340–$760	$550

[10] An IRB must certify each translated document to ensure that it conveys the information correctly and is understandable to potential participants. Translation services may be offered separately and are listed under Other Fees.

[11] A conflict of interest (COI) is when an individual, organization, or institution has two or more potentially competing obligations or interests. Conflicts can be financial or non-financial. Grantees must declare any potential COI to the IRB. The IRB will assess the COI and determine the measures needed to manage or mitigate the conflict.

Service	Fee per Unit Range	Fee per Unit Average
▪ Each additional conflict of interest fee	$175	$175
▪ Regulatory oversight fee	$750	$750
▪ Legal consultation/check	$200	$200
▪ Review of revisions/amendments	$250–$695	$440
▪ Review of revisions post full board review	$465	$465
MONITORING & REPORTING		
Adverse events	$100–$545	$316
Protocol deviations	$1,030–$1,360	$2,390
MODIFICATIONS		
The costs for modification may vary based on the type of review required, and will include one or more the following based on how the IRB structures its fees:		
Review of protocol modifications (each)	$550–$750	$597
Review of consent modifications (each)	$300–$550	$425
Full board review of amendment (if reviewed with already convened board)	$725	$725
Full board review of amendment for greater than minimal risk studies	$735	$735
Review of advertisements or other documents post- approval (each)	$175–$185	$180
Change in PI	$400–$1,500	$1,018
Review of EACH additional or modified study personnel	$175	$175
Review of EACH personnel removal	$50	$50
Review of EACH translation attestation/certificates	$90	$90
ANNUAL REVIEWS		
IRB approval is applicable for one year. A request for annual review must be submitted before the approval status requires. Please check with your IRB for when the application for annual review is to be submitted to avoid an expired study fee.		
Annual review/study continuation	$1,400–$2,680	$1,856
Expired study fee	$650	$650
STUDY CLOSURE		
Review of each study site closure	$200–$450	$332
OTHER FEES		
IRBs may include separate fees for any of the following services. Note that this list is not inclusive and that some IRBs may add a percentage or hourly fee to these costs.		
Advisory review (review of draft before submission)	$225–$675	$450
IRB of Record Letter or Letter of Intent Review	$150–$340	$245
Certified translation services	$530–$600	$565
Adverse event or other investigation	$1,085	$1,085
IRB administrative investigation conference	$500	$500

Service	Fee per Unit Range	Fee per Unit Average
Study suspension fee	$2,000	$2,000
Investigation fee	$2,500	$2,500
Board convening for review of suspension/investigation	$2,000	$2,000
Appeal of board determination	$2,500	$2,500
Rapid board convening	$500–$1,495	$997
Full board review of amendment	$735	$735
Investigation of participant complaints	$300	$300
Late submission fee	$500–$525	$513
Withdrawal of submission or cancellation	$225–$1,000	$517
Rush fee	$750	$750
Acknowledgement and distribution of safety reports	$75–$95	$85
IRB informed consent waiver determination	$400	$400
Full or partial waiver of privacy authorization/HIPAA	$500	$500

Appendix C. Example IRB Fee Schedule

The following is a *hypothetical* case scenario and IRB fee schedule/final costs based on their situation. DHS encourages grantees to include costs for potential modifications to protocols, changes in staff, and adverse events or unanticipated problems, as these must be reported to DHS *and* to the IRB to be compliant with federal guidelines. Non-compliance may result in a study suspension and investigations.

Disclaimer: The pricing amounts are a general guideline provided by a sampling of IRBs based on wide ranging conversations. Each IRB offered a different cost structure, with some services grouped and some separated. For additional information and a more accurate estimate, please contact the IRB for specific pricing, based on your project needs. These costs are subject to change at any time and should be viewed as a guide for considerations when securing an IRB. See the FAQ section on securing an IRB for additional questions to ask when requesting a quote or cost estimate.

Case Scenario: ABC Center (the DHS-funded grantee) is partnering with one other organization to carry out this two-year project. Year 1 involves identifying key informants (KI) (individuals who have previously been members of or have close ties to extremist groups) to administer knowledge, attitude, beliefs, and behavior (KABB) surveys and interviews. Findings from surveys and interviews are used to develop a community training program to identify and prevent targeted recruitment and violence by extremist groups. In Year 2, the KIs help recruit community members for a training program that administers a pre/post survey. The IRB determined that full board review was required as the KIs, because of their history or ties to extremist groups, are a potentially vulnerable population. The KIs' involvement with the program *may* make them a target of extremist groups and/or law enforcement.

- The project has 3 data collection protocols (KABB survey, KI interview guide, and pre/post training survey); 3 consent forms (1 per protocol); 2 recruitment flyers; and a training curriculum. All materials are in English.
- After the grantee's initial submission to the IRB, the primary reviewer determined that full board review is required. The grantee was required to revise their protocol twice, once after initial review and once after meeting with the full IRB committee.
- At the time of IRB submission, the project team (from the grantee and partner organization) included 6 individuals: 2 co-principal investigators (PIs) and 4 staff members. Over the course of the project, 2 staff members join the team and 1 staff member leaves. One co-PI leaves and is replaced.
- During its period of performance, the grantee reported one unanticipated problem that required a minor modification to one consent form. This modification did not require full board review but did require informed consent waiver determination.
- The grantee applied for continuing review (also referred to as annual review) after one year.

Example Fee Schedule (after completion of the study)

Service	Fee per Unit	Number of Units	Cost
INITIAL REVIEW			
Full board review (initial review)*			
Initial review	$2,225	1	$2,225
Each additional co-principal investigator	$825	1	$825
Each additional staff member	$45	4	$180
Each additional consent form	$360	2	$720
Each additional protocol (instrument, recruitment, and/or research material)	$315	2	$630
Regulatory oversight fee	$750	1	$750
Vulnerable population fee	$195	1	$195
Legal consultation/check	$200	1	$200
Review of revisions/amendments	$440	1	$440
Review of revisions post full board review	$475	1	$475
MONITORING & REPORTING			
Adverse events	$320	1	$320
MODIFICATIONS			
Review of consent modifications (each)	$425	1	$425
Change in PI	$1,025	1	$1,025
Review of EACH additional study personnel	$175	3	$525
Review of EACH personnel removal	$50	2	$100
ANNUAL REVIEWS			
Annual review/study continuation	$1,850	1	$1,850
STUDY CLOSURE			
Review of each study site closure	$335	1	$335
OTHER FEES			
IRB informed consent waiver determination	$400	1	$400
TOTAL COST			**$11,620**

Given the grantee's circumstances, ABC Center's costs for IRB services was $11,620. Based on this, it budgeted $15,000 for its next grant, which is very similar to the project described in the scenario. The center included a small buffer for additional staff changes and other unanticipated events.