Council of State and Territorial Epidemiologists

Default Question Block

CSTE IRB Workgroup Assessment

Thank you for your interest in CSTE's IRB workgroup. The data you provide will inform the workgroup's activities. Please coordinate with your colleagues to ensure only one assessment is completed per jurisdiction. Please direct any questions to Jessica Arrazola at JArrazola@cste.org

Please enter your contact and agency information.

Name
Title
Agency
Email

1. What is your IRB role?

- ○ IRB chair
- ○ IRB vice chair
- ○ IRB member
- ○ IRB staff (administrative support)
- ○ Other (Please provide IRB title or describe role):

2. Approximately how many years have you been involved with IRBs (including years as an IRB member)?

3. What certifications do you hold that are relevant to your IRB work? *Select all that apply.*

- ☐ Certified IRB Professional (CIP®)
- ☐ Certified Healthcare Research Compliance (CHRC)
- ☐ Certified in Healthcare Privacy Compliance (CHPC)
- ☐ Certified IRB Manager (CIM)
- ☐ Certified Research Administrator (CRA)

- [ ] Other (please specify):

- [ ] None

4. In what part of the United States is your IRB(s) located? *Select all that apply.*

- [ ] HHS Region 1 (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont)
- [ ] HHS Region 2 (New Jersey, New York, Puerto Rico, and the Virgin Islands)
- [ ] HHS Region 3 (Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia)
- [ ] HHS Region 4 (Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee)
- [ ] HHS Region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin)
- [ ] HHS Region 6 (Arkansas, Louisiana, New Mexico, Oklahoma, and Texas)
- [ ] HHS Region 7 (Iowa, Kansas, Missouri, and Nebraska)
- [ ] HHS Region 8 (Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming)
- [ ] HHS Region 9 (Arizona, California, Hawaii, Nevada, American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Marshall Islands, and Republic of Palau)
- [ ] HHS Region 10 (Alaska, Idaho, Oregon, and Hawaii)

5. Who serves as the principal IRB (or equivalent) for your agency?

- ○ We have our own IRB at the health department
- ○ We participate in an IRB formally established to serve multiple agencies (e.g. governmental public health and human service agencies have a joint IRB)
- ○ We routinely rely on one or more an outside IRBs to review protocols on behalf of the health department
- ○ We occasionally encounter a situation where we need an IRB to review a protocol, and when this situation arises, we make the necessary arrangements for this to happen
- ○ To date, we have never needed an IRB to review a research protocol (please explain):

- ○ Other (please explain):

5a. For approximately what % of protocols do you rely on external IRB (s)?

0 10 20 30 40 50 60 70 80 90 100

5b. What type of external IRB do you primarily rely on?

- ○ Academic or hospital IRB(s)
- ○ Another state agency's IRB
- ○ Commercial IRB(s)
- ○ CDC IRB
- ○ Other (please specify):

5c. If you rely on an external IRB, are you charged a fee for reviews to be conducted?

- ○ Yes, we always pay a fee
- ○ Yes, we sometimes pay a fee
- ○ No, we never pay a fee
- ○ Other (please describe):

5d. If your agency does not have an IRB, what are the barriers to establishing one, if any?

6. Does your organization have IRB authorization agreements in place with any of the following categories of external organizations? *Select all that apply.*

- ☐ Local Health Departments
- ☐ Non-Profit Organizations
- ☐ Other (please specify):

6a. If your IRB is a state health department IRB, does your IRB routinely allow local health departments to submit protocols to your IRB for review and approval?

- ○ Yes, routinely (provide details):
- ○ Yes, occasionally (provide details):

- ○ No
- ○ Other (please describe):

6b. Under what conditions do you allow local health departments to submit to your IRB?

6c. Approximately what percentage of your total number of protocols do these reviews encompass?

0 10 20 30 40 50 60 70 80 90 100

7. Please indicate your IRB accreditation status:

- ○ Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation
- ○ In the process of receiving AAHRPP accreditation
- ○ Other (please specify):
- ○ None

8. Do you have state (or county/city) regulations that define your IRB structure and functions, criteria for protocol approval, etc.?

- ○ Yes
- ○ No

8a. Under what authority does your IRB operate, given that FWAs no longer cover non-federally funded/sponsored studies?

- ☐ IRB Policies and Procedures
- ☐ Other (please explain):

9. Do you apply all IRB approval criteria defined in federal rules to:

- ○ Federally funded/sponsored protocols only
- ○ All protocols

10. How many full board IRB review meetings did you hold in 2019?

▾

11. Approximately what percent of protocols are reviewed by the full IRB (convened meeting)?

0 10 20 30 40 50 60 70 80 90 100

12. Approximately how many new protocols were reviewed by your IRB each year for approval or determination (e.g. exempt research, non-human subjects research) in 2019?

▾

13. What was the approximate number of initial full board reviews of new studies conducted in 2019? Please do not include amendments, adverse events, and continuing reviews.

▾

14. What was the approximate number of initial expedited reviews of new studies conducted in 2019? Please do not include amendments, adverse events, and continuing reviews.

▾

15. Approximately how many continuing reviews did your IRB perform in 2019?

▾

16. Approximately how many amendments/modifications to existing protocols did your IRB review in 2019?

▾

17. Were the numbers of all review types performed by your IRB in 2019 higher or lower than the average for the past 5 years?

- ○ Far above average
- ○ Somewhat above average

- ○ Average
- ○ Somewhat below average
- ○ Far below average
- ○ Other (please explain):

18. When a protocol is submitted to your IRB that is ready for expedited review, what is the estimated average time it takes for the review to be completed?

19. When a protocol is submitted to your IRB that is ready for full board review, what is the estimated average time it takes for the review to be completed?

20. Currently, how would you assess your IRB-related workload in relation to your staffing?

- ○ Too little
- ○ About right
- ○ Too much

21. Do you use IRB software to manage IRB submission?

- ○ Yes
- ○ No

21a. What software do you use to manage IRB submissions?

22. Does your IRB charge a fee for reviews?

- ○ Yes
- ○ No
- ○ Sometimes

22a. Please explain whether there are different fee structures for different review types and/or applicant groups.

23. To what extent have you implemented revised policies and procedures as a result of new federal (OHRP) Common Rule regulations (the Revised Common Rule)?

24. Do you plan to require federally funded/supported cooperative studies using a single IRB to also submit an application for study approval to your IRB, when the study involves health department participation or release of identifiable health department data?

- ○ We plan always rely on the single IRB identified for the study
- ○ We have a statute or rule that prohibits health department reliance on the single IRB
- ○ We are considering implementing a statute or rule that prohibits reliance on the single IRB
- ○ If we identify a compelling reason, we will attempt to not be required to rely on the single IRB
- ○ Other (please explain):

25. How many paid FTEs staff your IRB (to perform administrative functions, e.g. IRB coordinator), not including the Chair, Vice-chair, and other IRB members?

26. Is your IRB chair paid to perform this function?

- ○ Yes
- ○ No

26a. What percentage FTE is your IRB chair paid to perform this function?

0 10 20 30 40 50 60 70 80 90 100

27. Does your IRB have a vice-chair?

- ○ Yes
- ○ No

27a. Is your IRB vice-chair paid to perform this function?

- ○ Yes
- ○ No

27b. What percentage FTE is your IRB vice-chair paid to perform this function?

0 10 20 30 40 50 60 70 80 90 100

28. How many of the following members does your IRB have, not including any alternate members?

Note: These categories are not mutually exclusive.

Full members (including chairs):	▾
Community members:	▾
Non-scientific members:	▾
Prisoner representatives:	▾

29. Does your agency allow release of identifiable data from at least some programs to outside researchers?

Definitions:
What is a Direct Identifier?
Information that relates specifically to an individual. HIPAA designates the following as direct identifiers: names; postal address information other than town or city, state, and zip code; phone numbers; fax numbers; email addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers including license plate numbers; device identifiers and serial numbers; URLs; IP addresses; biometric identifiers; and full face photographic images and any comparable images.

What is an Indirect Identifier?
Information that can be combined with other information to potentially identify a specific individual. HIPAA designates the following as indirect identifiers: city, state, and zip codes; elements of dates; and other numbers, characteristics, or codes not HIPAA-designated as direct identifiers.

- ○ We do not release any line level data with HIPAA identifiers to outside researchers
- ○ After health department IRB approval, we release line level data from some or all programs to outside researchers, but only limited data sets (no HIPAA direct identifiers)
- ○ After health department IRB approval, we release line level data from some or all programs with direct and indirect HIPAA identifiers to outside researchers
- ○ Other (please explain):

30. Does your IRB specifically require verification of any of the following security controls as a condition of release of identifiable data to outside researchers?

- ○ Operating systems and applications that are supported and updated
- ○ Anti-Malware installed and set to auto update and scan

- ○ Auto screen lock to password/code
- ○ Disk encryption
- ○ File encryption
- ○ No use of memory sticks/thumb drives for identifiable data storage
- ○ No use of laptops for identifiable data storage
- ○ Other (please specify):

31. If any of these security controls are required, who do you have verify they are in place?

- ○ Investigator
- ○ IT official at investigator's institution
- ○ Other (please specify):

32. Does your IRB review DUAs prior to execution and or after execution? *Select all that apply.*

- ☐ We review all DUAs prior to execution
- ☐ We review all DUAs after execution
- ☐ We do not routinely review DUAs as part of our our IRB review and approval process
- ☐ Other (please describe):

33. What topics would you like to be addressed through the CSTE IRB workgroup?

34. Are there topics you would like to present on to the group or share about your experience?

Thank you for providing input for the CSTE IRB workgroup.

Please click the blue arrow below to submit your responses.