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)

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? *Please 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.*

- [ ] Mid-Atlantic (Delaware, Maryland, New Jersey, New York, Pennsylvania, Washington DC, West Virginia)
- [ ] Midwest (Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin)
- [ ] Northeast (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont)
- [ ] South (Alabama, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Virginia)
- [ ] Southwest/Mountain: (Arizona, Arkansas, Colorado, Kansas, Nevada, New Mexico, Oklahoma, Texas, Utah)
- [ ] West (Alaska, California, Hawaii, Idaho, Montana, Oregon, Washington, Wyoming)
- [ ] Outside the United States

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

- ○ We rely on an outside IRB to review protocols
- ○ We have our own IRB at the health department
- ○ We participate in a multi-agency IRB (e.g. health and human service agencies have a joint IRB)
- ○ Other (please explain):

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

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

5b. For approximately what % of protocols do you rely on the outside IRB?

0 10 20 30 40 50 60 70 80 90 100

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

6. Does your organization serve as an IRB of record for external organizations?

- ○ Yes
- ○ No

6a. What percentage of your total number of protocols does this 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)
- ○ 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?

- ☐ 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 the last 12 months?

▾

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
0 10 20 30 40 50 60 70 80 90 100

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

13. What was the approximate number of initial full board reviews of new studies conducted in the last 12 months? 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 the last 12 months? Please do not include amendments, adverse events, and continuing reviews.

15. Approximately how many continuing reviews did your IRB perform in the last 12 months?

16. How many amendments/modifications to existing protocols did your IRB review in the last 12 months?

17. Were the numbers of all review types performed by your IRB in the last 12 months higher or lower than the average for the past 5 years?

- Far above average
- Somewhat above average
- Average
- Somewhat below average
- Far below average

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. If your IRB is a state health department IRB, does your IRB routinely allow local health departments to submit to your IRB?

- Yes
- No
- Not Applicable

22a. Under what conditions do you allow local health departments to submit to your IRB?

23. Does your IRB charge a fee for reviews?

- Yes
- No
- Sometimes

23a. Please explain whether there are different fee structures for different review types and/or applicant groups.

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

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:	

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

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

33. 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.