# CSTE 2020 IRB WORKGROUP ASSESSMENT

## Assessment Summary

The Council of State and Territorial Epidemiologists (CSTE) Institutional Review Board (IRB) Workgroup was established in November 2019. Following the establishment of the workgroup, CSTE conducted an assessment of IRB processes in public health agencies from mid-February to early-April 2020. Questions focused on describing IRB statutes and rules, staffing, and protocol review practices. Due to COVID-19 pandemic response, the assessment was suspended at the beginning of April, receiving 20 state health department responses from the desired 58 state and local jurisdictions. Qualtrics and Excel were utilized for statistical analysis. Significant variation of IRB practices existed among the sample of IRBs received. Oftentimes, PH IRBs have limited resources, specifically dedicated and trained staff to support the work. A forum for PH IRB staff to share templates, experiences, and resources may improve understanding of policies and practices to increase compliance to federal rules while diffusing innovative strategies for quality improvement. Additional guidance and interpretation of federal rules by federal public health agencies, such as CDC, may provide needed clarity for consistent implementation by state and local departments of health.

**Table 1. Role of Respondent at Institutional Review Board**

| Role | Number(%) N=20 |
|---|---|
| **IRB Chair** | 8 (40.0%) |
| **IRB Vice Chair** | 0 |
| **IRB Member** | 2 (10.0%) |
| **IRB Staff (Administrative Support)** | 8 (40.0%) |
| **Other (IRB Chair and Administrator, Ethics Review Coordinator)** | 2 (10.0%) |

**Table 2. Type of Agency**

| Agency Type | Number (%) N=20 |
|---|---|
| **Covered entity** | 4 (20.0%) |
| **Hybrid entity** | 10 (50.0%) |
| **Other** | 6 (30.0%) |

Other responses: Part of agency is covered, but other part isn't (2), public Health authority (2), Non-covered (1), Covered but ends up being more hybrid (1)

**Table 3. Primary Institutional Review Board Utilized for State/Local Agencies**

| IRB Type | Number (%) N=20 |
|---|---|
| **Have IRB at health department** | 17 (85.0%) |
| **IRB that serves multiple agencies** | 1 (5.0%) |
| **Rely on external IRB** | 0 |
| **Make arrangements as necessary** | 1 (5.0%) |
| **Never needed an IRB** | 0 |
| **Other** | 1 (5.0%) |

Other responses: Initially established as health department IRB but since expanded to serve other agencies. *Percentage of protocols rely on external IRBs: 5% (N=1), rely on academic or hospital IRB(s). That agency always pays a fee for reviews to be conducted.*

**For the agency without an IRB, justification for external IRB included:**
Majority of work does not require IRB approval, so department does not host an IRB but has a Research and Ethics Review Committee.

**Table 4. IRB Accreditation Status for State/Local Agencies**

| Status | Number (%) N=19 |
|---|---|
| **AAHRPP Accredited** | 2 (10.5%) |
| **AAHRPP In Process** | 1 (5.3%) |
| **Other** | 1 (5.3%) |
| **None** | 15 (78.9%) |

Other: No IRB at Department

**Table 5. Reason for Not Pursuing AAHRPP Accreditation – Funding**

| Reason for Non-Accreditation is Funding | Number (%) N=16 |
|---|---|
| **Yes** | 10 (62.5%) |
| **No** | 6 (37.5%) |

Additional Comments on Accreditation:

- Department would be unable to afford application fee or renewal fee for accreditation at this time.
- Would consider pursuing if resources and time allowed.
- Interested in applying but unsure if department has resources and if department meets requirements.
- Benefits of accreditation unknown, other than ensuring IRB is in order.
- Need for accreditation is not present.

**Table 6. State (or County/City) Regulations Present that Define IRB Structure**

| Regulations Present | Number (%) N=19 |
|---|---|
| **Yes** | 9 (47.4%) |
| **No** | 9 (47.4%) |
| **Unknown** | 1 (5.3%) |

**Table 7. Authority IRB Operates Under to Make Decisions Among Those Without State/Local Regulations**

| Authority | Number (%) N=9 |
|---|---|
| **IRB Policies and Procedures** | 9 (100%) |
| **Other** | 0 |

**Table 8. Application of IRB Approval Criteria Defined by Federal Rules to Protocols**

| Protocols | Number (%) N=19 |
|---|---|
| **All Protocols** | 17 (89.5%) |
| **Federally Funded/Sponsored Protocols Only** | 2 (10.5%) |

**Table 9. Implementation of Revised Common Rule**

| Implementation Status | Number (%) N=19 |
|---|---|
| **Have Revised Procedures** | 7 (36.8%) |
| **In Process of Revision** | 11 (57.9%) |
| **Discussing Revisions** | 1 (5.3%) |
| **Have Not Discussed or Started Revisions** | 0 |

**Table 10. Planned Requirements for Protocols Using Single IRB to Submit Application to Department IRB When Involving Health Department Participation or Identifiable Data**

| Planned Requirements | Number (%) N=19 |
|---|---|
| **Always Rely on Single IRB** | 4 (21.1%) |
| **Statute/Rule Prohibits Reliance on Single IRB** | 3 (15.8%) |
| **Considering Statute/Rule Prohibiting Single IRB Reliance** | 1 (5.3%) |
| **If Compelled, Attempt to Obtain Federal Approval to Not Rely on Single IRB** | 3 (15.8%) |
| **Other** | 8 (42.1%) |

Other:

- Have not discussed yet
- Still review study to ensure meets criteria, but will accept reviews and approvals of single IRB when necessary
- Reviewed on a case by case basis
- Depends on data
- Researchers are required to submit an initial submission to our IRB in order to address conflicts of interest, verify human subjects protection training has been completed, and to assess the risk involved in the study to determine which IRB should be the single IRB

**Table 11. Agency Allowance of Identifiable Data Release from Some Programs to Outside Researchers**

| Allowance | Number (%) N=19 |
|---|---|
| **Do Not Release Any Line Level Data with Identifiers** | 0 |
| **With Approval, May Release Line Level Data with Indirect Identifiers** | 0 |
| **With Approval, May Release Line Level Data with Direct and Indirect Identifiers** | 16 (84.2%) |
| **Other** | 3 (15.8%) |

Other:

- Can release some data based on laws governing data;
- With privacy board approval, may release with direct and indirect identifiers;
- We may release line level data with indirect identifiers from some programs when the protocol is approved by an IRB.

**Table 12a. Agency Requirements for Verification of Security Controls as Condition of Release of Identifiable Data to Outside Researchers**

| Security Control | Number (%) N=19 |
|---|---|
| **Operating Systems and applications, supported and updated** | 6 (31.6%) |
| **Anti-Malware set to auto update and scan** | 4 (21.1%) |
| **Auto screen lock to password/code** | 7 (36.8%) |
| **Disk encryption** | 6 (31.6%) |
| **File encryption** | 9 (47.4%) |
| **No use of memory sticks/thumb drives for data storage** | 5 (26.3%) |
| **No use of laptops for data storage** | 2 (10.5%) |
| **Other** | 7 (36.8%) |
| **None of the above** | 2 (10.5%) |
| **Unknown** | 1 (5.3%) |

Other:

- Anyone who has access to the data must sign a Confidentiality/Non-Disclosure Agreement
- Our agency has a data use review committee that ensures adequate security procedures are in place
- Application with questions regarding recorded identifiers, safeguarding steps, procedures for storage and disposal of personal information
- The IRB requests information on security controls, but a separate compliance office sets requirement for security standards before data can be released
- Security is only addressed in our data use agreement language
- Agency security controls are through a Data Governance Committee not through the IRB
- Security controls are determined for each protocol separately.

**Table 12b. Verifications for Required Security Controls**

| Person Verifying Controls in Place | Number (%) N=14 |
|---|---|
| **Investigator** | 11 (78.6%) |
| **IT official at investigator's institution** | 0 |
| **Other** | 3 (21.4%) |

Other:

- Could be either, but it depends
- The IRB requests information from the investigator, but a separate compliance office conducts verification before data is released
- Agency security controls are through a Data Governance Committee not through the IRB.

**Table 13. Review of Data Use Agreements Prior to Execution and/or After Execution**

| | Number (%) N=19 |
|---|---|
| **Review all DUAs prior to execution** | 10 (52.6%) |
| **Review all DUAs after execution** | 1 (5.3%) |
| **Do not routinely review DUAs** | 4 (21.1%) |
| **Other** | 6 (31.6%) |
| **Unknown** | 0 |

Other:

- We have a separate committee that reviews all DUAs. The IRB does not review DUAs
- DUA's are not completed until the submission is approved. No data is provided until the DUA is fully executed
- We require there is a support but there is another process for review of other criteria;
- Review draft DUAs if possible
- The IRB typically reviews a draft DUA, but a separate compliance office approves DUA language. The compliance office will not permit execution of a DUA without IRB approval
- The IRB may indicate when a data use agreement is necessary, but they do not review the data use agreement language. The language is reviewed, negotiated, and approved by the Privacy Officer prior to sharing of any data.

**Table 14. Discontinuation or Plans of Discontinuation of IRB Review for Minimal Risk Research**

| Discontinued Minimal Risk Research Review | Number (%) N=19 |
|---|---|
| **Yes** | 2 (10.5%) |
| **No** | 6 (31.6%) |
| **Have implemented or will implement less burdensome process** | 7 (36.8%) |
| **Other** | 4 (21.1%) |

Other:

- I am not sure if this have been decided
- Only as allowed in the common rule
- Continuing review is required for all protocols required to comply with the Pre-2018 Requirements. Currently, protocols approved under the 2018 Requirements are individually assessed for the need of Continuing Review
- Almost all of our protocols are minimal risk and we do review all of them (although the full IRB doesn't always vote).

**Table 15. Number of Full Board IRB Review Meetings Held in 2019**

| | Number (%) N=15 |
|---|---|
| **0** | 0 |
| **1-3** | 2 (13.3%) |
| **4-6** | 4 (26.7%) |
| **7-9** | 1 (6.7%) |
| **10-12** | 7 (46.7%) |
| **13+** | 1 (6.7%) |

**Table 16. Percentage of Protocols Reviewed by Full IRB Board (N=16)**

| | Percentage |
|---|---|
| **Mean (SD)** | 26.4% (28.8) |
| **Median** | 14.5% |
| **Range** | 1% - 90% |

**Table 17. Number of Requests for Exempt Research or Non-Human Subjects Research Determination in 2019**

| | Number (%) N=16 |
|---|---|
| **0** | 0 |
| **1-10** | 4 (25.0%) |
| **11-20** | 8 (50.0%) |
| **21-30** | 0 |
| **31+** | 4 (25.0%) |

**Table 18. Number of New Applications Submitted to IRB in 2019, Including Non-Reviewed, Exempt, Expedited, and Full Board**

| | Number (%) N=16 |
|---|---|
| **0** | 0 |
| **1-10** | 2 (12.5%) |
| **11-20** | 2 (12.5%) |
| **21-30** | 0 |
| **31-40** | 6 (37.5%) |
| **41-50** | 0 |
| **51-60** | 1 (6.3%) |
| **61-70** | 0 |
| **71-80** | 1 (6.3%) |
| **81-90** | 1 (6.3%) |
| **91-99** | 0 |
| **100+** | 3 (18.8%) |

**Table 19. Number of Initial Full Board Reviews of New Studies in 2019, Excluding Amendments, Adverse Event Reports, and Continuing Reviews**

| | Number (%) N=16 |
|---|---|
| **0** | 2 (12.5%) |
| **1-10** | 10 (62.5%) |
| **11-20** | 2 (12.5%) |
| **21-30** | 0 |
| **31+** | 2 (12.5%) |

**Table 20. Number of Initial Expedited Reviews in 2019, Excluding Amendments, Adverse Event Reports, and Continuing Reviews**

| | Number (%) N=16 |
|---|---|
| **0** | 1 (6.3%) |
| **1-10** | 7 (43.8%) |
| **11-20** | 4 (25.0%) |
| **21-30** | 1 (6.3%) |
| **31+** | 3 (18.8%) |

**Table 21. Number of Continuing Reviews in 2019**

| | Number (%) N=15 |
|---|---|
| **0** | 0 |
| **1-10** | 0 |
| **11-20** | 4 (26.7%) |
| **21-30** | 4 (26.7%) |
| **31-40** | 0 |
| **41-50** | 2 (13.3%) |
| **51-60** | 2 (13.3%) |
| **61-70** | 0 |
| **71-80** | 1 (6.7%) |
| **81-90** | 1 (6.7%) |
| **91-99** | 0 |
| **100+** | 1 (6.7%) |

**Table 22. Number of Amendments/Modifications to Existing Protocols Reviewed in 2019**

| | Number (%) N=16 |
|---|---|
| **0** | 0 |
| **1-10** | 3 (18.8%) |
| **11-20** | 2 (12.5%) |
| **21-30** | 3 (18.8%) |
| **31-40** | 2 (12.5%) |
| **41-50** | 2 (12.5%) |
| **51-60** | 0 |
| **61-70** | 1 (6.3%) |
| **71-80** | 1 (6.3%) |
| **81-90** | 0 |
| **91-99** | 0 |
| **100+** | 2 (12.5%) |

**Table 23. Comparison of Number of Reviews Conducted in 2019 to Previous 5 Years**

| | Number (%) N=16 |
|---|---|
| **Far above average** | 1 (6.3%) |
| **Somewhat above average** | 3 (18.8%) |
| **Average** | 11 (68.8%) |
| **Somewhat below average** | 1 (6.3%) |
| **Far below average** | 0 |
| **Unknown** | 0 |

**Table 24. Estimated Time for IRB Review Completion for Expedited Reviews**

| | Number (%) N=16 |
|---|---|
| **Less than 1 week** | 5 (31.3%) |
| **1 – 3 weeks** | 8 (50.0%) |
| **1 month** | 2 (12.5%) |
| **2 months** | 1 (6.3%) |
| **3 months** | 0 |
| **4-6 months** | 0 |
| **More than 6 months** | 0 |

**Table 25. Estimated Time for IRB Review Completion for Full Board Reviews**

| | Number (%) N=16 |
|---|---|
| **Less than 1 week** | 2 (12.5%) |
| **1 – 3 weeks** | 2 (12.5%) |
| **1 month** | 8 (50.0%) |
| **2 months** | 3 (18.8%) |
| **3 months** | 0 |
| **4-6 months** | 1 (6.3%) |
| **More than 6 months** | 0 |

**Table 26. Use of IRB Software to Manage IRB Submissions**

| | Number (%) N=16 |
|---|---|
| **Yes** | 4 (25.0%) |
| **No** | 12 (75.0%) |

Softwares Utilized: IRBNet, iMedRIS, KetNet

**Table 27. Fee Charges for IRB Review**

| | Number (%) N=16 |
|---|---|
| **Yes** | 2 (12.5%) |
| **No** | 14 (87.5%) |
| **Sometimes** | 0 |

Fee structures mentioned: Flat fee of $1,500; Different fee structure based on review type and applicant group.

**Table 28. Payment to IRB Members for Duties Performed**

| | Number (%) N=16 | Mean % FTE Paid | Range % FTE Paid |
|---|---|---|---|
| **IRB chair** | 7 (43.8%) | 23% (n=5) | 10% - 50% |
| **IRB vice chair** | 3 (18.8%) | 20% (n=1) | 20% |
| **Administrative staff** | 10 (62.5%) | 68.6% (n=7)[1] | 10% - 100% |
| **None of the above** | 6 (37.5%) | - | - |

[1]More responses were received, but outside 0-100% range

**Table 29. Number of Members in IRB, Including Chair(s) and Vice Chair(s)**

| | Mean | Range |
|---|---|---|
| **Scientific** | 7.2[1] | 2 – 20+ |
| **Non-scientific** | 4.4 | 1 – 15 |
| **Non-Affiliated (Community)** | 2.4 | 1 – 5 |
| **Alternates** | 2.4 | 0 – 13 |

[1]20+ calculated as 20, so mean presented is minimum value

**Table 30. IRB Authorization Agreements in Place for External Organizations**

| | Number (%) N=16 |
|---|---|
| **Local Health Departments** | 4 (25.0%) |
| **Non-Profit Organizations** | 4 (25.0%) |
| **Other** | 2 (12.5%) |
| **None** | 11 (68.8%) |

Other organizations: Academic institutions/Universities, Healthcare organizations

**Table 31. Percentage of Total Number of Protocols Originating from External Organizations Among Jurisdictions Allowing External Applications (N=7)**

| | Percentage |
|---|---|
| **Mean** | 58.6% |
| **Range** | 20% - 97% |

**Table 32. Routine Allowance of Local Health Department Protocol Submission to State IRB**

| | Number (%) N=16 |
|---|---|
| **Yes, routinely allow** | 6 (37.5%) |
| **Yes, sometimes allow** | 6 (37.5%) |
| **No** | 1 (6.3%) |
| **Other** | 1 (6.3%) |
| **Not Applicable** | 2 (12.5%) |

Other: With the exception of two county health departments, all other county offices are part of our state health dept and are subject to IRB review procedures for human subject research activities.

**Table 33. Interest in CITI Training through Organization or Obtaining at Reduced Rate**

| | Number (%) N=17 |
|---|---|
| **Yes, although already have access** | 7 (41.2%) |
| **Yes, do not have access** | 5 (29.4%) |
| **No** | 3 (17.7%) |
| **Other** | 2 (11.8%) |

Other: Don’t have funding for training; Unlikely to be able to pay for any training

**Desired Topics for CSTE IRB Workgroup to Address:**

- Running an IRB in an environment that has been shut down by Covid- 19. Collaborations with academic IRBs.
- What Public Health IRBs are doing in place of minimal risk reviews. How are they handling the Single IRB.
- Single IRBs revision to the Common Rule HIPAA
- Streamlining IRB processes-- best practices more shared resources among IRBs how to make the blackboard site more useful/increase its use CDC IRB perspective on research vs non research Where CDC is headed with research vs non research determination for PRAMS, medical monitoring project (MMP).
- I look forward to learning how other, similar institutions provide oversight of research without impeding the routine practice of public health. I'm also interested in best practices for informed consent utilizing language understandable to populations with low literacy and/or numeracy. Also, I think it will be helpful to have a forum to learn about and to try to assist with problems that have come up or might come up related to human research protections and IRB operations that are unique to state health and human services agencies.
- Criteria for determining a project is "public health surveillance activities" vs. human subjects research.
- How do other IRB/s manage all the different roles required in Federal Regulations such as Human Research Protections Administrator, IRB Chair, Institutional Official and clerical support? Do other IRB's monitor the research projects and if so how do they manage that?
- All aspects of IRB. Training has been limited to the IRB Chair.
- Engagement, evaluation vs research
- Use of reliance agreements by relying institutions in Single IRB situations