



Marjorie A. Speers, Ph.D.
President and CEO

Accreditation of Research Sites: The AAHRPP Program



AAHRPP[®]

Association for the Accreditation of
Human Research Protection Programs, Inc.[®]

AAHRPP

- Non-profit organization founded in 2001
 - Founding members
 - Association of American Medical Colleges
 - Association of American Universities
 - Association of Public and Land-grant Universities
 - Consortium of Social Science Associations
 - Federation of American Societies for Experimental Biology
 - National Health Council
 - Public Responsibility in Medicine and Research
 - Pharma's role in the founding of AAHRPP
- Sole accrediting body in the United States
- Offer accreditation worldwide



Accredited organizations

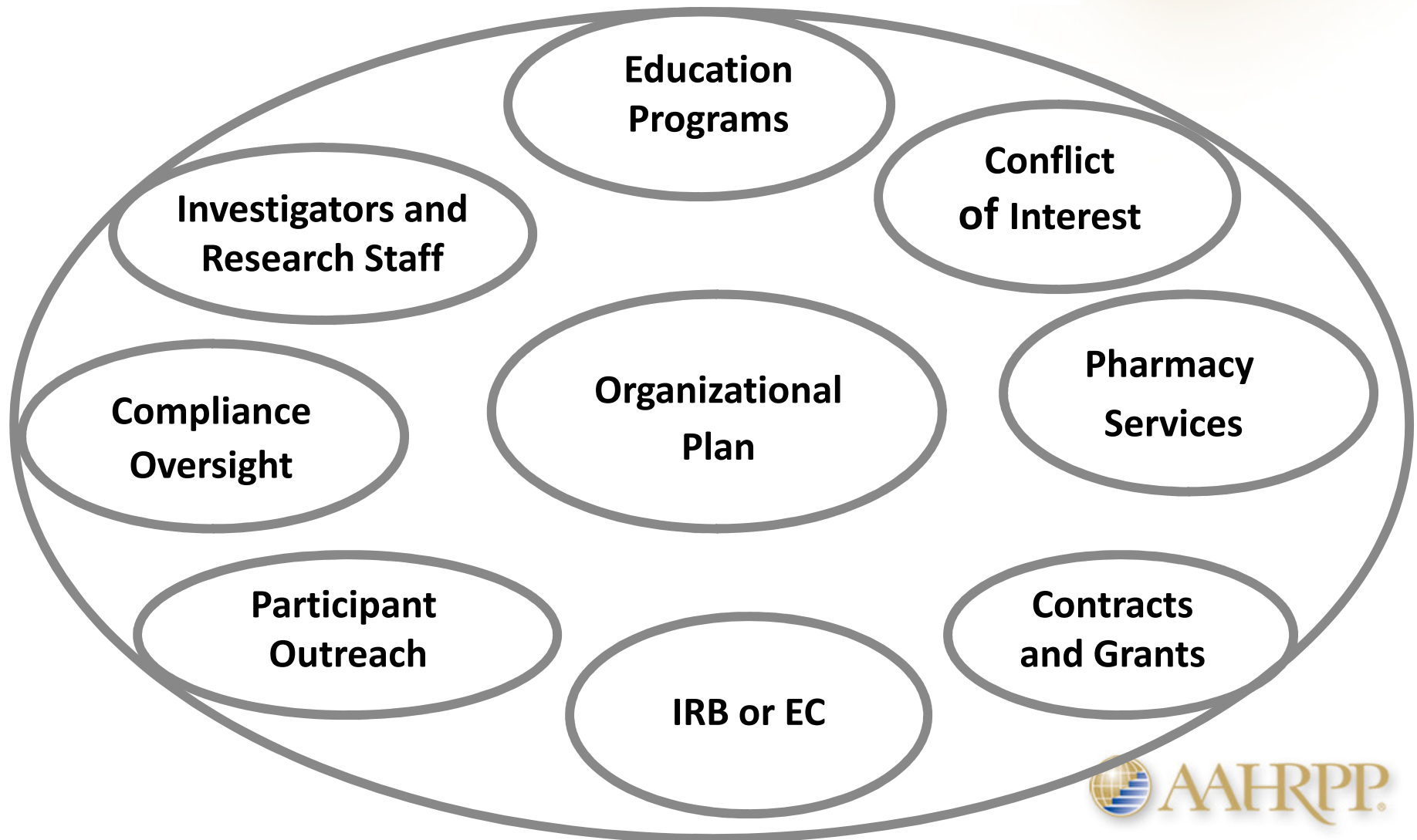
- As of September 2011, 234 organizations representing over 1,100 entities:
 - Contract research organizations, hospitals, independent IRBs, research institutes, universities and government agencies
 - Small (fewer than 20 protocols) and large (greater than 6,000 protocols) institutions
 - Clinical and non-clinical research programs
 - Accredited organizations in Canada, China, Singapore, Korea, and United States

The focus of accreditation

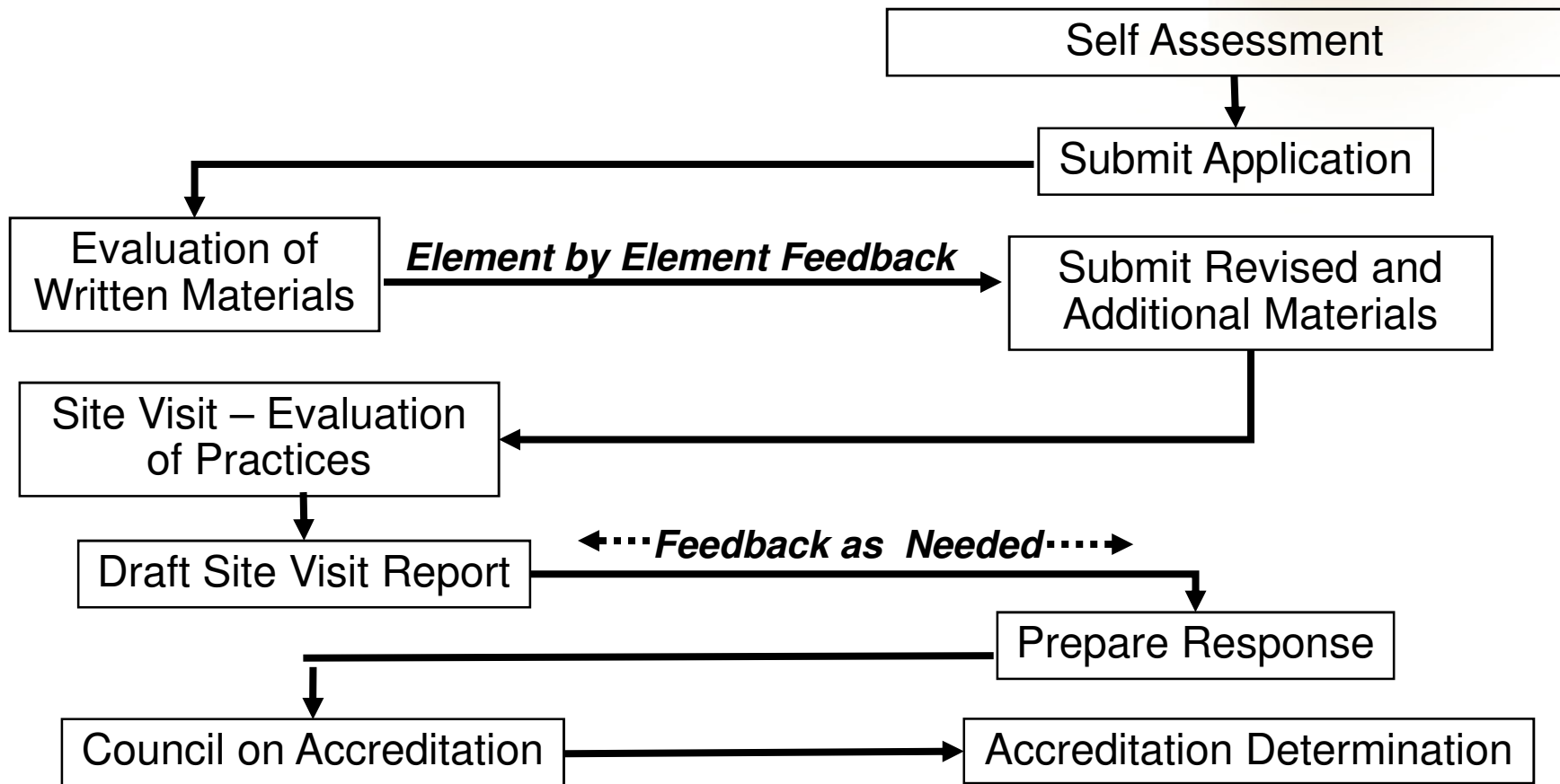
- Organization
 - IRB or EC
 - Researchers and Research staff
- } Human Research Protection Program

Protecting research participants is a shared responsibility

Human Research Protection Program



The accreditation process



Organizing the work

Element	REGS	SOP(s)	GAPS	RESPONSIBLE PARTIES	SOP Due Date	Forms to create	Other Resources
Element I.1.A							
Element I.1.B							

Analyzing your SOPs and practices

- Do they address the standard?
- Are they adequate?
- Are they up-to-date?
- Are they internally consistent?

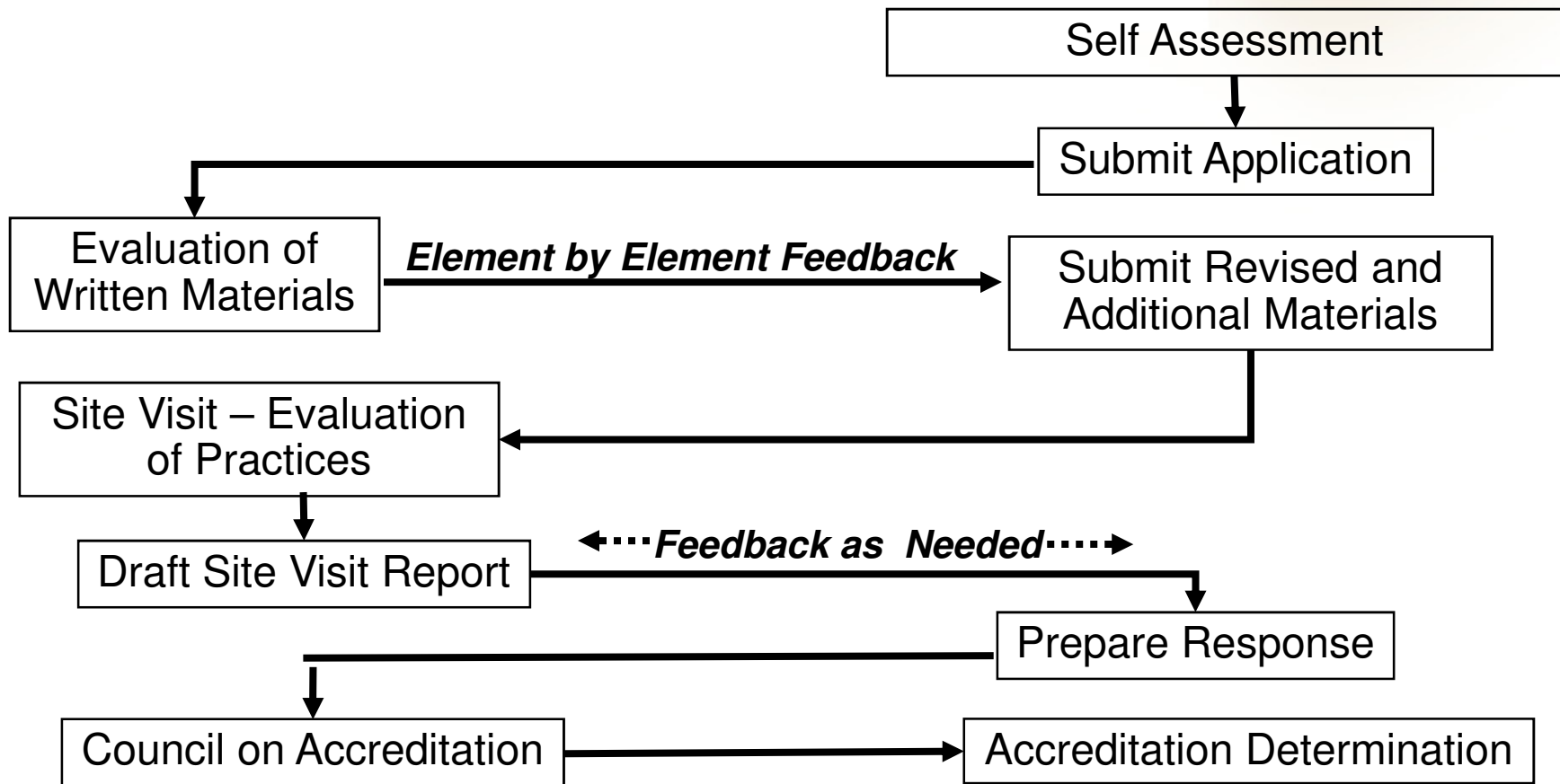
Identifying the gaps

- What more do you need?
- Who will create the new SOPs, practice or FTE ?
- Who must approve?
- How will you implement?

Tips

- Study the applicable laws, regulations, codes, and guidance
- Browse Web sites of accredited organizations
- Use the AAHRPP Evaluation Instrument and Accreditation and Tip Sheets
- Ask AAHRPP
- Consult with your task force or working group
- Test it with research personnel

The accreditation process



Council determinations

- New applicants
 - Full Accreditation
 - Qualified Accreditation
 - Accreditation - Pending
 - Accreditation Withheld
- Renewing applicants
 - Full Accreditation
 - Accreditation - Pending
 - Probation
 - Accreditation Revoked

Accreditation status

- New applicants
 - Valid for three years
- Renewing applicants
 - Valid for five years

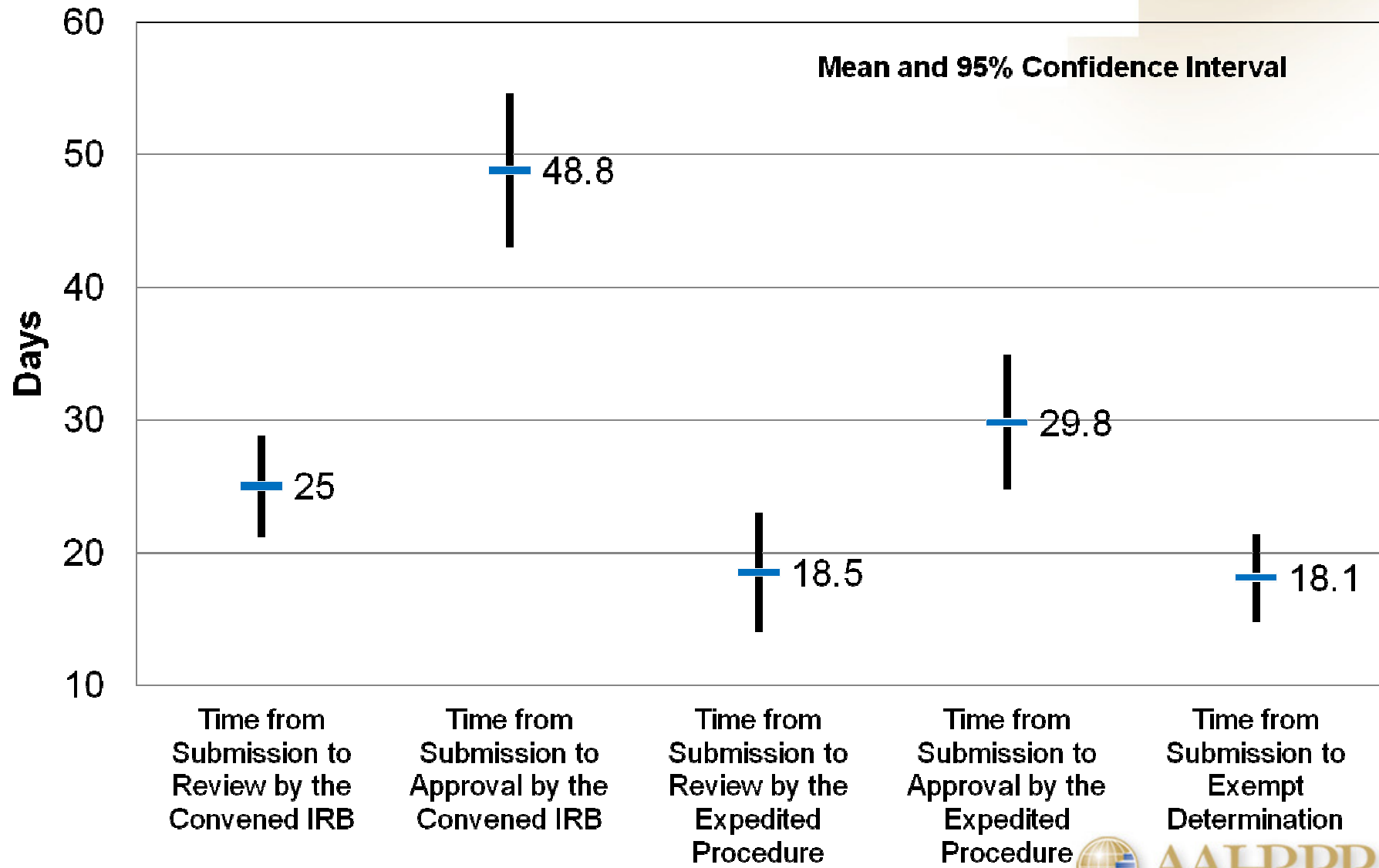
Accountability while accredited

- Annual reports
 - Notify AAHRPP of sentinel changes
- Status reports
 - Used to document practice, including education and monitoring
- Limited site visits
 - Used to verify practice
- Mandatory site visits
 - Used to investigate wrongdoing

Is accreditation making a difference?

- Quality
 - Improve protection for research participants
 - Competency of researchers and research staff
 - Competency of IRB staff and members
 - Better relationships between IRB and researchers
- Compliance

IRB Review Times



Note: Data include organizations with an IRB.



IRB Staffing and Funding

Protocol Category	Average Number of Staff	Average Number of Protocols	Average Protocols per FTE	Annual Dollars Budgeted for IRB
All	7.4	727	139.8	\$ 873,208
1-100	2.6	42	25.4	\$ 268,618
101-500	4.1	258	87.9	\$ 921,903
501-1,000	8.0	706	162.0	\$ 743,954
1,001-2,000	10.6	1449	149.5	\$ 936,701
2,001-4,000	14.8	2885	352.5	\$ 1,283,307
4,001-6,000	30.0	5028	180.9	\$ 3,519,323

Complaints

Protocol Category	Average Number of Complaints	Average Number of Complaints per 1,000
All	3.4	6.2
1-100	0.6	11.9
101-500	0.8	3.5
501-1,000	3.9	5.6
1,001-2,000	6.1	4.0
2,001-4,000	13.6	4.8
4,001-6,000	15.5	3.4

Note: Does not include independent IRBs



Non-Compliance

Protocol Category	Average Number of Determinations of Serious Non-Compliance	Average Number of Determinations of Serious Non-Compliance Per 1,000	Average Number of Determinations of Continuing Non-Compliance	Average Number of Determinations of Continuing Non-Compliance Per 1,000
All	2.2	14.1	1.1	4.1
1-100	0.8	34.4	0.3	7.5
101-500	2.0	10.3	1.0	4.9
501-1,000	3.9	5.9	0.4	0.7
1,001-2,000	2.4	1.8	2.2	1.6
2,001-4,000	4.0	1.4	2.3	0.9
4,001-6,000	5.0	1.1	1.5	0.3

Note: Does not include independent IRBs



How has the Following Changed in the Last Year?

#	Topic	Improved	No Change	Worse
1	Documentation of Records	82.2%	17.1%	0.8%
2	Quality of protocol review	79.1%	20.9	0.0%
3	Efficiency of meetings	69.8%	29.4%	0.8%
4	Use of flexibility in the regulations	48.4%	46.9%	4.7%
5	Conformance with the regulations	63.6%	36.4%	0.0%
6	Communication among administrative units of the HRPP within the organization	76.0%	23.3%	0.8%
7	Relationship between the IRB and Investigators	58.7%	37.3%	4.0%
8	Visibility of the HRPP in the organization	76.7%	23.3%	0.0%
9	Post approval monitoring of research	74.8%	22.8%	2.4%
10	Quality improvement activities of your HRPP	78.9%	21.1%	0.0%
11	HRP education programs	74.4%	22.5%	3.1%
12	Community / Participant outreach	59.1%	40.9%	0.0%
13	Management of Investigator Conflict of Interest	54.7%	43.8%	1.6%
14	Collaboration with other institutions	62.0%	38.0%	0.0%
15	Protection of human participants in research at your organization	71.3%	28.7%	0.0%
		Increased	No Change	Decreased
16	Workload of HRPP staff	87.6%	7.0%	5.4%
17	HRPP resources required	76.4%	19.7%	3.9%

Benefits to your organization

- Benefits of self-assessment and peer review
- Raises participant protection to an organizational priority
- More visible leadership from organizational official and IRB
- Improved resources
- Greater awareness of the HRPP
- Better efficiency and streamlining
- Improved communication
- Better compliant with regulations, laws, codes, and guidance
- More “transparent” operation
- Accreditation demonstrates an organization’s commitment to quality and accountability

Benefits to India

- Uniform standards across institutions that conduct research
- Signals high standards to sponsors
- Facilitates collaborations across institutions
 - Use of central IRB
 - Ethical discussions
- Demonstrates India's leadership in research protection