

## Appendix B.

### Item Statements That Were Sorted and the Corresponding Domains and Subdomains

Domains	Subdomains	#	Item statement
<p>1. Foundational knowledge</p> <p>Description: Possess broad knowledge of ethical foundations of health research, health research methods, and the structures and functions of health research ethics systems</p>	1.1 Historical, philosophical, religious, and cultural bases for health research ethics principles and practice	6	Recognize the relevance of ethics in health research
		58	Describe the role and function of research ethics committees
	1.2 Health research ethics theories, principles, and conceptual frameworks	68	Demonstrate an awareness of accepted standards for ethical health research
		69	Apply accepted standards for ethical health research
	1.3 Principles and practices of human and non-human health-related research in order to be able to provide competent ethical review	14	Understand principles of research integrity
		53	Understand philosophical basis of health research ethics
		54	Understand theories and principles relevant to health research ethics
		55	Understand historical development of health research ethics policies
		59	Describe the basic principles underlying informed consent
		62	Understand principles of clinical trials
		63	Understand principles of sociobehavioral research
		65	Understand principles of pre-clinical or bench research
		70	Understand principles related to privacy
		11	Understand science underlying advances in medical treatments
	1.4 Structures and functions that seek to ensure ethical health research (such as how research relates to the health system, roles and responsibilities of stakeholders in the health research ethics system, and research ethics committee review policies and procedures)	20	Understand roles and responsibilities of stakeholders in health research ethics system
		49	Understand the health system
		61	Describe relevant regulations for non-human animal health research ethics
		48	Understand principles related to human rights
51		Understand principles of health research methods	
60		Describe principles for ethical conduct of non-human animal health research	
	64	Understand principles of database or registry-based research	
	66	Understand religious foundations of health research ethics*	
	2. Laws, regulations, guidelines, and policies for research oversight	18	Interpret legal regulations related to health research ethics
		19	Interpret guidelines or other non-legal policies related to health research ethics
		52	Follow global/international landscape of health research ethics
	2.2 Interpreting health research-related guidelines and policies		
2.3 Interpreting international health research ethics standards and their applicability in the local context			
<p>3. Ethical issue identification, analysis, and resolution</p> <p>Description: Provide effective ethical review and analysis and propose options to optimize ethical conduct of health research</p>	3.1 Reviewing proposed health research to identify potential harms and benefits	12	Consider how scientific advances could disadvantage some populations
		13	Analyze the harms that could be associated with health research conduct
	3.2 Analyzing ethical issues in health research by applying appropriate ethical theories, principles, and conceptual frameworks	16	Analyze problems related to ethical health research
		17	Propose solutions to problems in health research ethics
		15	Identify ethical problems in health research conduct*
	3.3 Proposing solutions or strategies to optimize ethical health research implementation	43	Cite evidence that supports a decision or action
		34	Show sensitivity to local cultures and norms as they relate to health research ethics*
	3.4 Basing ethics reviews or analyses on evidence		
		3.5 Showing sensitivity to local cultural norms as they relate to health research ethics	
		4.1 Engagement with researchers, communities	1
2			Promote awareness of health research ethics to the public

<p>4. Engagement, communication, and advocacy</p> <p>Description: Engage with researchers, communities and other stakeholders to raise awareness about ethics in health research</p>	<p>4.2 Clear communication in spoken and written form on health research ethics</p> <p>4.3 Advocacy for public awareness of health research ethics</p>	3	Advocate for policy creation for more ethical health research ethics
		4	Advocate for ethics as a way to increase value of health research
		5	Advocate for the protection of human subjects in health research
		35	Encourage community participation in ethical health research
		36	Educate communities about health research ethics topics
		37	Solicit feedback from communities about ethical health research conduct
		38	Educate researchers about ethical health research
		24	Communicate clearly on health research ethics topics when speaking with other stakeholders
		25	Argue for an opinion on health research ethics topics in written form
		26	Argue for an opinion on health research ethics topics when speaking with other stakeholders
<p>5. Lifelong learning, education, research, and scholarship</p> <p>Description: Stay apprised of emerging information related to health research ethics, share knowledge with others, and contribute to related scholarly efforts</p>	<p>5.1 Engagement in lifelong learning</p> <p>5.2 Education of those with formal roles in health research ethics oversight or training (e.g. IRB members)</p> <p>5.3 Contribution to scholarly efforts that advance health research ethics practice</p>	39	Educate others who have formal roles in health research ethics oversight
		40	Educate health research ethics trainers
		56	Engage in lifelong learning on health research ethics topics
		57	Perform research on ethics topics
		23	Communicate clearly on health research ethics topics in written form*
<p>6. Coordination, stewardship, and responsiveness in health research ethics systems</p> <p>Description: Work within health research ethics systems and engage in systems-strengthening to achieve optimal functioning</p>	<p>6.1 Coordination with others in the health research ethics system to address ethical issues</p> <p>6.2 Identification of resources required for optimal health research ethics system function</p> <p>6.3 Efficient use of resources</p> <p>6.4 Identification of gaps in the health research ethics system</p> <p>6.5 Engagement in health research ethics system quality improvement efforts</p> <p>6.6 Recognition of and response to emerging issues relevant to health research ethics</p>	7	Follow emerging ethical challenges in health research ethics
		21	Collaborate with research ethics committees
		74	Engage in quality improvement activities to enhance health research ethics
		42	Use available resources efficiently
		71	Assess what resources are needed for proper health research ethics system function
		8	Respond to emerging challenges in health research ethics
		9	Analyze ethical challenges presented by new technologies
		10	Analyze ethical challenges presented by big data
		31	Challenge norms or current practices
		41	Access resources or expertise to address ethical challenges
		50	Identify gaps in the health research ethics system
		22	Develop structures that facilitate coordination of research ethics committees*
		67	Describe roles and functions of data and safety monitoring boards (DMSBs)*
<p>7. Impartiality, honesty, and responsibility</p> <p>Description: Exhibit personal and professional integrity in research ethics practice</p>	<p>7.1 Impartiality and openness to diverse perspectives</p> <p>7.2 Conflicts of interest identification and management</p> <p>7.3 Honesty, accountability, and transparency</p>	27	Identify one's own potential conflicts of interest
		44	Demonstrate honesty
		46	Demonstrate perseverance in resolving ethical issues
		47	Demonstrate passion for health research ethics subjects
		72	Demonstrate accountability
		73	Demonstrate a commitment to transparency
		28	Manage one's own conflicts of interest
		29	Identify conflicts of interest among others in research
		32	Critique one's own views
		33	Consider others' views with an open mind
		45	Demonstrate impartiality
		30	Identify what is required for others to manage their conflicts of interest*

\* Items with an asterisk were moved from the original cluster to the domain shown.