

A Competency Framework for Health Research Ethics Educational Programs:

Results from a Stakeholder-Driven Mixed-Method Process

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Appendix A.

Survey for International Listservs for Feedback on the Competency Framework

Start of Block: Default Question Block

Q1 Thank you for your willingness to provide feedback on our draft framework that can support the development of competencies for health research ethics.

Competencies are the abilities of an individual to perform specific activities or functions in particular ways. We are seeking to describe competencies for health research ethics to guide education and training programs globally, especially formalized programs such as those granting Masters degrees.

The draft framework has 7 broad domains, and each domain has subdomains (which are more specific and fit within a domain). These domains and subdomains will serve as the basis for developing specific competencies in the next step of our project. The domains and subdomains have been developed based on a review of the literature and group concept mapping with stakeholders in the health research ethics system in Malaysia.

We are interested in your feedback on the overall framework and any specific comments you have on each domain and subdomain.

While it is possible to complete this survey on a mobile device, it would be easier on a laptop or desktop computer.

Should you have any questions, please contact us at stacket1@jhmi.edu. Thanks again!

Page Break

The draft competency framework has 7 domains. Each is briefly described below. We will ask for feedback on each domain (and its subdomains) and then on the framework as a whole.

Domain 1: Foundational knowledge
Possess broad knowledge of ethical foundations of health research, health research methods, and the structures and functions of health research ethics systems
Domain 2: Laws, regulations, guidelines, and policies for research oversight
Interpret local and international health research laws, regulations, guidelines, and policies
Domain 3: Ethical issue identification, analysis, and resolution
Provide effective ethical review and analysis and propose options to optimize ethical conduct of health research
Domain 4: Engagement, communication, and advocacy
Engage with researchers, communities and other stakeholders to raise awareness about ethics in health research
Domain 5: Lifelong learning, education, research, and scholarship
Stay apprised of emerging information related to health research ethics, share knowledge with others, and contribute to related scholarly efforts
Domain 6: Coordination, stewardship, and responsiveness in health research ethics systems
Work within health research ethics systems and engage in systems-strengthening to achieve optimal functioning
Domain 7: Impartiality, honesty, responsibility
Exhibit personal and professional integrity in research ethics practice

Q22

Please provide feedback on this domain and its subdomains

Domain 1: Foundational knowledge

Possess broad knowledge of ethical foundations of health research, health research methods, and the structures and functions of health research ethics systems

Subdomains:

1. Historical, philosophical, religious, and cultural bases for health research ethics principles and practice
2. Health research ethics theories, principles, and conceptual frameworks
3. Principles and practices of human and non-human health-related research in order to be able to provide competent ethical review
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)

Q77 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

Clarity

Relevance

Priority

	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)
Domain 1: Foundational knowledge (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 1: Historical, philosophical, religious, and cultural bases for health research ethics principles and practice (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 2: Health research ethics theories, principles, and conceptual frameworks (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 3: Principles and practices of human and non-human health-related research in order to be able to provide competent ethical review (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 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) (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q91 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Q89

Please provide feedback on this domain and its subdomains

Domain 2: Laws, regulations, guidelines, and policies for research oversight

Interpret local and international health research laws, regulations, guidelines, and policies

Subdomains:

1. Interpreting health research-related laws and regulations
2. Interpreting health research-related guidelines and policies
3. Interpreting international health research ethics standards and their applicability in the local context

Q90 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

	Clarity			Relevance			Priority		
	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)

Domain 2: Laws, regulations, guidelines, and policies for research oversight (5)

Subdomain 1: Interpreting health research-related laws and regulations (1)

Subdomain 2: Interpreting health research-related guidelines and policies (2)

Subdomain 3: Interpreting international health research ethics standards and their applicability in the local context (3)

Q78 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Q95

Please provide feedback on this domain and its subdomains

Domain 3: Ethical issue identification, analysis, and resolution

Provide effective ethical review and analysis and propose options to optimize ethical conduct of health research

Subdomains:

1. Reviewing proposed health research to identify potential harms and benefits
2. Analyzing ethical issues in health research by applying appropriate ethical theories, principles, and conceptual frameworks
3. Proposing solutions or strategies to optimize ethical health research implementation
4. Basing ethics reviews or analyses on evidence
5. Showing sensitivity to local cultural norms as they relate to health research ethics

Q92 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

	Clarity			Relevance			Priority		
	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)

Domain 3: Ethical issue identification, analysis, and resolution (5)

Subdomain 1: Reviewing proposed health research to identify potential harms and benefits (1)

Subdomain 2: Analyzing ethical issues in health research by applying appropriate ethical theories, principles, and conceptual frameworks (2)

Subdomain 3: Proposing solutions or strategies to optimize ethical health research implementation (3)

Subdomain 4: Basing ethics reviews or analyses on evidence (6)

Subdomain 5: Showing sensitivity to local cultural norms as they relate to health research ethics (7)

Q93 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Q96

Please provide feedback on this domain and its subdomains

Domain 4: Engagement, communication, and advocacy

Engage with researchers, communities and other stakeholders to raise awareness about ethics in health research

Subdomains:

1. Engagement with researchers, communities and other stakeholders on health research ethics
2. Clear communication in spoken and written form on health research ethics
3. Advocacy for public awareness of health research ethics

Q97 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

	Clarity			Relevance			Priority		
	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)

Domain 4: Engagement, communication, and advocacy (5)

Subdomain 1: Engagement with researchers, communities and other stakeholders on health research ethics (3)

Subdomain 2: Clear communication in spoken and written form on health research ethics (2)

Subdomain 3: Advocacy for public awareness of health research ethics (1)

Q98 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Q101

Please provide feedback on this domain and its subdomains

Domain 5: Lifelong learning, education, research, and scholarship

Stay apprised of emerging information related to health research ethics, share knowledge with others, and contribute to related scholarly efforts

Subdomains:

1. Engagement in lifelong learning
2. Education of those with formal roles in health research ethics oversight or training (e.g. IRB members)
3. Contribution to scholarly efforts that advance health research ethics practice

Q102 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

	Clarity			Relevance			Priority		
	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)
Domain 5: Lifelong learning, education, research, and scholarship (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 1: Engagement in lifelong learning (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 2: Education of those with formal roles in health research ethics oversight or training (e.g. IRB members) (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Subdomain 3: Contribution to scholarly efforts that advance health research ethics practice (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q103 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Q105

Please provide feedback on this domain and its subdomains

Domain 6: Coordination, stewardship, and responsiveness in health research ethics systems

Work within health research ethics systems and engage in systems-strengthening to achieve optimal functioning

Subdomains:

1. Coordination with others in the health research ethics system to address ethical issues
2. Identification of resources required for optimal health research ethics system function
3. Efficient use of resources
4. Identification of gaps in the health research ethics system
5. Engagement in health research ethics system quality improvement efforts
6. Recognition of and response to emerging issues relevant to health research ethics

Q106 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

	Clarity				Relevance			Priority	
	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)

Domain 6: Coordination, stewardship, and responsiveness in health research ethics systems (5)

Subdomain 1: Coordination with others in the health research ethics system to address ethical issues (1)

Subdomain 2: Identification of resources required for optimal health research ethics system function (2)

Subdomain 3: Efficient use of resources (3)

Subdomain 4: Identification of gaps in the health research ethics system (8)

Subdomain 5: Engagement in health research ethics system quality improvement efforts (9)

Subdomain 6: Recognition of and response to emerging issues relevant to health research ethics (10)

Q107 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Q109

Please provide feedback on this domain and its subdomains

Domain 7: Impartiality, honesty, responsibility

Exhibit personal and professional integrity in research ethics practice

Subdomains:

1. Impartiality and openness to diverse perspectives
2. Conflicts of interest identification and management
3. Honesty, accountability, and transparency

Q110 Please rate this domain and its subdomains based on clarity as written, relevance to health research ethics, and priority for inclusion in educational programs.

	Clarity			Relevance			Priority		
	Not clear (1)	Somewhat clear (2)	Very clear (3)	Not relevant (1)	Somewhat relevant (2)	Highly relevant (3)	Not a priority (1)	Intermediate priority (2)	High priority (3)

Domain 7: Impartiality, honesty, responsibility (5)

Subdomain 1: Impartiality and openness to diverse perspectives (1)

Subdomain 2: Conflicts of interest identification and management (3)

Subdomain 3: Honesty, accountability, and transparency (2)

Q111 Please share any comments you have on this domain and its subdomains related to clarity, relevance, and priority for education in health research ethics. Feel free to share any other comments you have here too.

Page Break

Q83 Please review the domains again and respond to following prompts about these competency domains for health research ethics.

Domain 1: Foundational knowledge
Possess broad knowledge of ethical foundations of health research, health research methods, and the structures and functions of health research ethics systems
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Q84 How comprehensive is this framework overall? To what extent does it include all elements of competency relevant for health research ethics?

- Not at all comprehensive, very few elements included (1)
- Some elements included, many missing (2)
- Most elements included, a fair number missing (3)
- Almost all elements included, a few missing (4)
- Comprehensive, all elements included (5)

Q85 Please suggest any additional elements of competency that should be included in the framework.

Q86 To what extent is the framework internally coherent?

- Not at all coherent (1)
- A little coherent (2)
- Somewhat coherent (3)
- Very coherent (4)
- Completely coherent (5)

Q87 Please share any other suggestions about how we can improve this framework or any other thoughts about it.

Q112 How might this framework be useful in your work?

Page Break

Q71 How old are you?

▼ Under 18 (31) ... 85 or older (39)

Q73 With which gender do you identify?

- Female (1)
- Male (2)
- Other (please specify) (3) _____
-

Q75 Approximately how many years of experience do you have in health research ethics?

- <1 year (1)
- 1-5 years (2)
- 6-10 years (3)
- 11-15 years (4)
- 16-20 years (5)
- > 20 years (6)
-

Q113 In which country is your primary residence? (195 response options – single choice)

Q115 In which country do you primarily do your health research ethics work currently? (195 response options – single choice)

Q114 In which other countries have you done health research ethics work (195 response options - Please select all that apply)?

Q74 Please indicate which health research ethics experiences you have had.

	Yes, currently do (1)	Yes, have done, but not currently (2)	Never done (3)
Teaching research ethics (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Research and scholarship in research ethics topics (2)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Research ethics review committee service (3)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Formulate institutional policies related to health research ethics (4)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advise funder/sponsors on research ethics (5)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advise professional society policies on health research ethics (6)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advise government policymakers (and/or create policy) on health research ethics (7)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advise international policy-making bodies on health research ethics (8)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Participate in regulatory activity on health research ethics (9)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Participate in accreditation on health research ethics (13)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Advise research consortia or networks on health research ethics (10)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Engage with media on health research ethics issues (11)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other (please specify) (12)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Q76 Thank you so much for your time and thoughtful feedback. You may share any final thoughts here or click through to complete the survey.
