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International scope of biomedical research ethics review

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APPENDIX

International Scope of Biomedical Research Ethics Review

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NOTE: The study reported in this article relies on the opinions of these leading scholars from each country with expertise in research ethics and law, but other experts in the same country might interpret the requirements of their applicable laws and regulations differently and might have different opinions about the desirability or nature of possible changes.

To facilitate comparative analyses, the lead authors (M.A.R and B.M.K.) formulated key questions for all coauthors and distributed sample answers for the United States. Coauthors from all countries were invited in late 2023, and all answers to the standard questions were received by early 2024. These standard questions, and coauthors responses, are reflected in the country reports, including references in support of the conclusions. Country reports for each country are available at the end of the supplementary materials. Tables below synthesize and summarize the findings.

Tables Based on Country Reports

Kelly Carty Zimmerer, JD, MA, University of California, Irvine

Table S1

Country	**Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering**	
	Societal implications of proposed research, such as the economic, health equity, and public health implications?	**Longer-term (beyond the research period) implications of proposed research?**
Argentina	Permit[3]	Require
Australia	Permit[1]	Permit[2]
Canada	Require	Permit[3]
China	Require	Permit[3]
France	Permit[3]	Permit[3]
Germany	Permit[4]	Require
Israel	Permit[4]	Permit[3]

Japan	Permit[1]	Permit[3]
Kenya	Permit[3]	Permit[1]
Lebanon	Permit[2]	Permit[3]
Mexico	Require	Require
Netherlands	Permit[3]	Permit[4]
Nigeria	Require	Permit[1]
Poland	Permit[1]	Permit[3]
Qatar	Permit[3]	Permit[3]
Singapore	Permit[3]	Permit[2]
South Africa	Require	Permit[1]
South Korea	Permit[4]	Permit[4]
Spain	Require	Permit[4]
Sweden	Require	Permit[3]
United Kingdom	Require	Permit[3]
United States	Prohibit	Prohibit

Permit[1]: the law or guiding documents state research ethics committees may consider societal or long-term implications.
Permit[2]: generally permitted but required in relation to specific types of research or in relation to a particular subset of a research project.
Permit[3]: the law and ethics guidelines do not provide specific information prohibiting or requiring consideration of these issues.
Permit[4]: the law and ethics guidelines do not provide specific information prohibiting or requiring consideration, but research ethics committees may be required to or already do consider these implications due to other requirements or guidelines.

Table S2

Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering							
Societal implications of proposed research, such as the economic, health equity, and public health implications?				**Longer-term (beyond the research period) implications of proposed research?**			
Require	**Permit: RECs may consider societal implications**	**Permit: there are no explicit prohibitions or requirements**	**Prohibit**	**Require**	**Permit: RECs may consider longer-term implications**	**Permit: there are no explicit prohibitions or requirements**	**Prohibit**
(8) Canada China Mexico Nigeria South Africa Spain Sweden United Kingdom	(3) Australia Lebanon Poland	(10) Argentina France Germany Israel Japan Kenya Netherlands Qatar Singapore South Korea	(1) United States	(3) Argentina Germany Mexico	(3) Kenya Nigeria South Africa	(15) Australia Canada China France Israel Japan Lebanon Netherlands Poland Qatar Singapore South Korea Spain Sweden United Kingdom	(1) United States

Table S3

Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering societal implications of proposed research, such as the economic, health equity, and public health implications?				**Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research?**			
Require	**Permit: RECs may consider societal implications**	**Permit: there are no explicit prohibitions or requirements**	**Prohibit**	**Require**	**Permit: RECs may consider longer-term implications**	**Permit: there are no explicit prohibitions or requirements**	**Prohibit**
(8) Canada China Mexico Nigeria South Africa Spain Sweden United Kingdom	(3) Australia Lebanon Poland	(10) Argentina France Germany Israel Japan Kenya Netherlands Qatar Singapore South Korea	(1) United States	(3) Argentina Germany Mexico	(3) Kenya Nigeria South Africa	(15) Australia Canada China France Israel Japan Lebanon Netherlands Poland Qatar Singapore South Korea Spain Sweden United Kingdom	(1) United States

Table S4

Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering societal implications of proposed research, such as the economic, health equity, and public health implications?			
Require	**Permit: RECs may consider societal implications**	**Permit: there are no explicit prohibitions or requirements**	**Prohibit**
(8) Canada China Mexico Nigeria South Africa Spain Sweden United Kingdom	(3) Australia Lebanon Poland	(10) Argentina France Germany Israel Japan Kenya Netherlands Qatar Singapore South Korea	(1) United States

Table S5

Do research funders require consideration of societal implications and long-term consequences?		**Would multi-disciplinary scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications?**	
No	**Yes**	**Yes**	**No**
(12) Argentina China Germany (some examples of yes) Japan Kenya Lebanon Netherlands Nigeria Poland Spain Sweden USA	(10) Australia Canada (Tri-Agencies) France (some – Horizon Europe and national funders) Israel (most applications have an ELSI section) Mexico (send a report to Ministry of Health Qatar (national research funder) Singapore (public funders) South Africa (for two main public funders) South Korea (public sector) UK (e.g. Wellcome)	(21) Argentina Australia Canada China France Germany Israel Japan Kenya Lebanon Mexico Netherlands Nigeria Poland Qatar Singapore South Africa Spain Sweden UK United States	(1) South Korea (unsure how receptive biomedical researchers would be)

Table S6

Government agency funders of research			Non-profit funders of research			Biomedical research entities		
Yes	**No**	**Unsure**	**Yes**	**No**	**Unsure**	**Yes**	**No**	**Unsure**
(16) Australia Canada Germany Israel Japan Kenya Netherlands Nigeria Mexico Poland Qatar Singapore South Africa South Korea Sweden UK (most either because already the case or because there are governmental regulations supporting)	(0)	(6) Argentina China France Lebanon Spain United States (could be seen as interference; not in the short term; substantial groundwork needed – nothing in regulations)	(17) Argentina Australia France Germany Israel Japan (probably not for large funders) Lebanon Mexico Netherlands Nigeria Poland Qatar Singapore South Africa South Korea UK United States	(0)	(5) Canada China Kenya Spain Sweden (depends on group; seen out outside interference; issues of fairness – must be applied globally)	(7) Canada Germany Kenya Mexico Singapore Sweden UK	(8) Argentina China France Lebanon Qatar South Africa South Korea US (slowing down research)	(7) Australia Israel (but they do it anyway) Japan (no one is outspoken against it but don't know what they really think) Netherlands Nigeria Poland Spain (slowing down research; concerns of cost; lack of precise regulation)

Biomedical research ethics review bodies			**Biomedical researchers**			**Bioethics, social sciences, law, humanities, and PH scholars**		
Yes	**No**	**Unsure**	**Yes**	**No**	**Unsure**	**Yes**	**No**	**Unsure**
(14) Australia Canada Germany Israel Japan Kenya Mexico Nigeria Poland (if payment) Qatar South Korea Spain Sweden UK	(5) Argentina Lebanon Singapore South Arica US (make more work)	(3) China France Netherlands (bodies don't have the tools; lack of skills and resources)	(4) Israel Kenya Mexico Netherlands	(9) Argentina China Lebanon Nigeria Poland Qatar South Africa South Korea United States (don't want non-scientists judging; concerns about implications for funding)	(9) Australia Canada (also a no) France Germany Japan Singapore Spain Sweden (varies) UK (could be seen as interference; don't want non-scientists judging)	(20) Argentina Australia China France Germany Israel Japan Kenya Lebanon Mexico Netherlands Nigeria Poland Qatar South Africa South Korea Spain Sweden UK United States	(0)	(2) Canada Singapore (some think this is toxic for social scientists by instrumentalizing their work)

Table S7

If societal and longer-term implications should be considered in ethical assessments of research, are current research ethics review bodies the most appropriate entities to undertake the assessment?		
Yes	**No**	**Unsure/ It depends.**
(13) Australia Canada France Israel Kenya Lebanon Netherlands Mexico Poland South Africa South Korea Spain UK (many say they already do this)	(6) China Japan Nigeria Qatar Singapore United States (lack of resources; there is another entity that is better suited or already does this; there is considerable variation among these bodies)	(3) Argentina Germany Sweden (may need resources; variation among these bodies)

ARGENTINA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Permit.

Broader societal issues are not prohibited. Those implications (economic, health, equity) can be addressed by ethical review bodies with a fundament and rationale to consider them.

Relevant legislation/Regulations (applies for A and B).[1]

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit.

IRB is not prohibited to consider longer term implications beyond the research project period. Its members may argue about possible effects of the research as among those research risks that fall within the purview of its responsibility.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally, these issues are not a part of scientific grant applications, but there wouldn't be obstacles to include them.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This approach is a key element of translational bioethics.

1. Argentine Civil and Commercial Code, Article 58. Law 26.994/2015
Resolution Ministry of Health 1480/2011 https://e-legis-ar.msal.gov.ar/htdocs/legisalud/migration/html/18264.html
Provincial legislation/regulations; http://leg.msal.gov.ar/atlas/comites.html

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Unsure. Probably not in the short term for most agencies, but longer-term prospects are better if initial efforts by some agencies are successful.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. They are concerned about these issues, but they are unlikely to support any measures that they think will interfere with research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They would likely be concerned about slowing down research.**

(4) biomedical research ethics review bodies – **No. It would make more work and most members do not have a background in social science, humanities, etc.**

(5) biomedical researchers (individual scientists) – **No. At least initially, it can be expected that many would be concerned about negative consequences for funding, and they would be leery of non-scientists judging their science.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, this is a challenge for translational bioethics.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

They might be, but in my country in most of the cases, they do not have the expertise, human resources, time and budgets to raise and study those implications.

AUSTRALIA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Permit.

Broader societal issues are not required to be addressed but are referenced in the National Statement for the Ethical Conduct of Research Involving Human Subjects as being something that may be taken into consideration where relevant (eg reference to 'societal goals' and considering risk implications at a societal level- see Chapter 2.1, Risk and Benefit).

In relation to research involving indigenous peoples, specific reference is made throughout the National Statement and associated guidelines (Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders) of the need to be mindful of the social implications of the research on their communities.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit.

Longer-term considerations are not required to be addressed but are in contemplation in the National Statement for the Ethical Conduct of Research Involving Human Subjects as being something that may be taken into consideration where relevant, particularly in relation to risk classification (see Chapter 2.1, Risk and Benefit).

In relation to research involving indigenous peoples, the National Statement and associated guidelines (Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders) provide a broad mandate to be mindful of the longer-term implications of the research on their communities.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Although there is some variance between major funding bodies (ARC, NHMRC, MRFF) all schemes generally require some demonstration of current and future benefits. For example, the ARC requires a statement in grant applications as to capacity to contribute to national priority areas and economic, commercial, environmental, social and/or cultural benefits for Australian and international communities.

NHMRC – the NHMRC has a list of health priorities that include consideration of the regulatory and ethical issues associated with development of health technologies. In addition, specific funding schemes/calls generally require demonstration of the social impact of research, and the projected impact of research in terms of scientific knowledge, practice or policy underpinning human health.

MRFF –MRFF often aligns its priorities and funding calls with national health priorities with a view to projects contributing to better health outcomes and healthcare delivery. They usually have built-in requirements for ELSI to be a specific component of a project.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This approach has been explicitly recognized by some Australian funding bodies where the embedding of multi-disciplinary scholars within scientific projects is required through inclusion of an ELSI component. This approach is consistent with the Australian Government's focus on seeking to facilitate and prioritise effective translation and impact of scientific projects.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. See comments above (Issue 1, A and B).**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes, particularly when well aligned with the objectives of the research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Unsure. Although some might be concerned about slowing down research, there are good examples where research institutes have been open to embedding multi-disciplinary scholars.**

(4) biomedical research ethics review bodies – **Yes. Australian research ethics review bodies require inter-disciplinary membership and would likely be amenable to an approach that promotes composition including multi-disciplinary scholars.**

(5) biomedical researchers (individual scientists) – **Unsure. There may be reticence on the part of some researchers, but there is increasing acceptance by biomedical researchers of the importance of ELSI considerations.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes. Such an approach would generally be welcomed by these scholars as an opportunity to enhance interdisciplinary collaboration.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes – research ethics committees are already permitted to consider societal and longer-term implications of proposed research (see response above to Issue 1, A and B). But this is not and should not be the only point in a project's development or trajectory at which these issues are considered. For example, one of the criteria on which some Australian funding bodies assess applications for funding is whether ELSI issues have been adequately considered and built into biomedical research projects.

CANADA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Require and Permit.

Require:

In Canada the Tri Council-Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2)[1] requires[2] REBs to consider the societal implications of proposed research: "Researchers shall demonstrate to their REBs that they have a reasonable understanding of the culture, values and beliefs of the population to be studied, and the likely effects of their research upon them." See: Article 2.8 B. Approach to Research Ethics Board Review – Concepts of Risks and Potential Benefits – Balancing Risks and Potential Benefits: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html. When assessing any risks and potential benefits of research involving communities, the TCPS suggests that consideration for participants, the community and individual community members is required. See: Article 2.8 B. Approach to Research Ethics Board Review – Concepts of Risks and Potential Benefits – Assessing Risks and Potential Benefits of Research Involving Communities: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html.

Further, the REB is required to adopt a proportionate approach to research ethics review. See Article 2.9: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html.

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1. The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans focuses on "ethical conduct of research involving humans" and "is a joint policy of three federal research agencies": the Canadian Tri-Agencies (Canadian Institutes of Health Research, the Social Sciences Research Council, Natural Sciences and Engineering Research Council of Canada). The policy addresses current ethical issues and guides researchers conducting research involving humans. See: Panel on Research Ethics, "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS 2" (Panel on Research Ethics, 2022) <https://ethics.gc.ca/eng/tcps2-eptc2_2022_introduction.html>

   The TCPS2 is not a legally binding policy. However, in order to receive funding from the Canadian Tri-Agencies, researchers involving human participants must be in compliance with the Policy Statement. The TCPS 2 has considerable sway in Canadian research ethics and is generally followed by private actors and private REBs as well.

2. "Mandatory provisions are signaled by the use of the term "shall." Guidance for the interpretation of the core principles is generally indicated by use of the term "should" (See: Interpreting this Policy https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter1-chapitre1.html#c).

Permit:

The TCPS2 also permits analysis of different factors to fulfill the obligation of proportionate review. For example, under Article 2.8, when trying to balance risks and potential benefits for individuals or communities, "REBs should understand the role of culture, values and beliefs of the population studied." Risk can occur in several ways, such as social, behavioural, psychological, physical or economic, and while the researcher must consider the seriousness of the harm, the risk should be assessed considering social, health, economic and cultural factors. See: Article 2.8 B. Approach to Research Ethics Board Review – Concepts of Risks and Potential Benefits – Balancing Risks and Potential Benefits: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html

Thus, if researchers should weigh social, health, economic and cultural factors when assessing risk (https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter2-chapitre2.html) then this also suggests criteria for REBs to consider. It is difficult to see how a wide range of factors like these could be mentioned without consideration of any long-term effects.

In the province of Quebec (all quotes translated from French), it would seem that societal implications should be taken into account although this is alluded to rather vaguely. First, in the Fonds de Recherche du Québec[3]- Santé - FRQS standards on the ethics of research in human health and research integrity (a non-binding but well-respected ethics policy), Section 9 specifies: "The assessment of the risk level aims to protect adequately, the integrity of persons. The risk that is concerned could be a risk for the physical, psychological, moral or social integrity of the subject." Furthermore, section 10(16) states that the benefits of the discoveries for society should be considered in the assessment.

For REBs responsible for approving research with minors, the Gazette Officielle du Québec (a binding regulation) clearly states that their mandate include: "when the circumstances afford it, [considering] the eventual consequences of such a project on the health of individuals presenting similar characteristics- age, disease or handicap- as the people submitted to the research."

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit.

There is no specific information provided on this topic in Canadian law and ethics guidelines.

3. The Fonds de recherche du Québec (FRQ) promotes an intersectoral approach to research as well as interactions between science and society. The FRQ has established partnerships with a variety of public, parapublic and private organizations in an effort to stimulate research and innovation development. https://frq.gouv.qc.ca/en/health/

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Societal implications of public research are approached in multiple ways. A condition of funding from the Tri-Agencies is adhering to the guidance in TCPS2. In addition to the above-mentioned articles, the TCPS2 has guidance regarding the responsible conduct of research, requiring research integrity by following research best practices and giving specific criteria to consider. See Responsibilities of Researchers: https://rcr.ethics.gc.ca/eng/framework-cadre-2021.html. Further, the Tri-Agencies have implemented the Tri-Agency Equity, Diversity and Inclusion Action Plan https://www.nserc-crsng.gc.ca/InterAgency-Interorganismes/EDI-EDI/Action-Plan_Plan-dAction_eng.asp with initiatives to foster a more equitable, diverse and inclusive research ecosystem in Canada. This approach inherently considers some of the societal implications and long-term consequences of research and the research environment.

In Quebec for provincial funding, criteria to consider includes balancing direct benefit for the individual as well as the group with the amount of risk stemming from the research. In this same section the FRQS addresses immediate and future benefit and that "the benefits of discoveries for society should be taken into account". While this suggests that societal implications are relevant considerations, this could still be limited to the timeframe of the project. See: Criteria 16, under chapter/section 10, p. 22: Les Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'intégrité scientifique (2008): https://frq.gouv.qc.ca/app/uploads/2021/03/standards_frsq_ethique_recherche_humain_2009.pdf

There is nothing specific written regarding long-term consequences and funding in either the public or private sector research.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. Bioethics is a quintessential multidisciplinary field of inquiry and ousting some types of ethical issues from REB mandates does not seem prudent unless other institutions are specifically equipped and mandated to evaluate these concerns. However, this assumes that REBs have the necessary expertise, time and training to properly evaluate these aspects of the research.

Fostering a multi-disciplinary approach that deals with societal implications and future consequences as part of a streamlined process throughout the research ecosystem could strengthen reforms to the system, like the one proposed in the Report of the Advisory Panel on the Federal Research Support System: https://ised-isde.canada.ca/site/panel-federal-research-support/sites/default/files/attachments/2023/Advisory-Panel-Research-2023.pdf

This report acknowledges that existing fragmented structure causes difficulties resulting in the inability to respond to societal challenges p.16 and a coordinated response and policies would help to address this challenge.

Further, the Canadian Institutes of Health Research Framework for Patient Engagement in SPOR: https://cihr-irsc.gc.ca/e/48413.html#a6 in an effort to ensure that patients are active contributors in health research, recognize the importance of including additional perspectives in the research endeavor. See Appendix 1: PE Framework Dashboard: https://cihr-irsc.gc.ca/e/48413.html#a13. Having a multi-disciplinary team to support the research process is consistent with this aim, the Tri-Agency Equity, Diversity and Inclusion Action Plan and could lead to better outcomes.

I would also speak to the longstanding successful experience of Genome Canada/ GE3LS[4] see https://genomecanada.ca/how-we-work/genomics-in-society/

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes, this would support existing policies like the TCPS2 and allow agencies to clarify, update and provide further guidance on the research/decision-making process as issues arise.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Unsure. Funding this type of research could be a problem with some NGOs. Also, unsure the NGOs culture is as receptive or convinced of the utility of this kind of research as governments are.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Public – Yes, the government has some strategic plans requiring interdisciplinary collaboration.**

Nonprofit and private – unsure. They would likely be concerned about the possibility of slowing down research and impeding commercial secrecy. However, if a case can be made that economic and reputational can flow from this the mindset may change.

(4) biomedical research ethics review bodies – **Yes. Given the complexities in the research system and the multitude of factors to consider, it would be beneficial and support the REBs in coming to the best possible decisions on complex projects. This would however necessitate reorganization of research funding to support this endeavour.**

4. The Genome Canada model consists of a multi-disciplinary approach that is about more than genomics research. "… ethical, environmental, economic, legal and social aspects…" have to be considered from the beginning stages with part of the research funding dedicated to Genetics Ethics Environment Economic Legal and Social (GE3LS) research activities. Understanding research outcomes using expertise from different disciplines allows for engagement with stakeholders, promoting genomics research, creating awareness, and tackling inequities throughout the research process. See: Genome Canada, "How We Work – Genomics in Society – GE3LS" (Genome Canada, 2022) <https://genomecanada.ca/how-we-work/genomics-in-society/>

(5) biomedical researchers (individual scientists) – **Unsure/No. At least initially, it can be expected that many researchers would be concerned about negative consequences for funding, and they would be leery of non-scientists judging their science. However, it would increase awareness and accountability to have ongoing discussions with individuals who have extensive expertise with ethical issues and ultimately make the research stronger. The younger generation of Canadian biomedical researchers is more familiar and welcoming of this type of multidisciplinary approach than the older generation as they have received more training in bioethics and have seen for themselves the benefit of this type of approach in past successful research projects. If it was aligned with the EDI Action Plan and there was funding to support researcher training or offset their time commitment to this integration, then there would likely be more support.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Unsure. The opinion on this seems quite polarized between two positions:**

1) Such arrangements are toxic for social scientists as they instrumentalize their work, limit their purview and ultimately bring them into situations of conflict of interests.

2) These arrangements are win-win for social science and biomedical researchers. Social scientists can benefit from additional source of funding, provide more grounded advice based on 'real' scenarios rather than hypothetical ones and have a concrete beneficial influence on the conduct of research.

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes, see previous comments on this above.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. However, this depends on the level of support/expertise REBs can access and the incentives available. The TCPS 2 Article 6.4 prescribes the composition of the REB such that two members must have relevant research expertise, with one ethicist, and one lawyer in disciplines, fields and methodologies covered by the REB along with one community member not affiliated with the institution. Thus, to some extent existing REBs are multi-disciplinary. However, this assumes that REBs have the necessary expertise, time, training and resources to properly evaluate these aspects of the research.

In some Canadian research schemes, there is a push for multidisciplinary/ interdisciplinary groups to collaborate necessitating multi-perspective research from the outset. This approach and the research proposals could benefit from additional support and funding.

Regardless of the approach strengthening existing infrastructure and building capacity in these ways could procure long-term benefits and more socially responsible science.

CHINA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

The Measures for Ethical Review of Life Sciences and Medical Research Involving Human Beings, jointly released by the National Health Commission, Ministry of Education, Ministry of Science and Technology and National Administration of Traditional Chinese Medicine in February 2023, require that the ethics review committees focus on examining "whether the research involves socially sensitive ethical issues" and "Whether the research results are published, whether they are done in the right way and at the right time."(Article 19)

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

There are no biomedical research ethics regulations or policies in China that require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research. However, some ethics review committees will consider longer-term implications of proposed research.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally, these issues are not a part of scientific grant applications in the public or private sectors. Inspired by the Ethical, Legal, and Social Implications program of the National Human Genome Research Institute of the NIH, the Ministry of Science and Technology funded ELSI research projects in its two key projects, Precision Medicine and Synthetic Biology. However, there is no funding for other related projects.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. Studying the societal and long-term implications of biomedical research requires interdisciplinary research collaboration, especially among biomedical researchers and scholars in the fields of humanities and social sciences. I strongly support the translational bioethics approach recently proposed by bioethics scholars.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Unsure. Currently most of them have not thought about it. Maybe in the future some of them will realize the importance of these efforts.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Unsure. I guess only part of them may be concerned about these issues.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They would likely be concerned about slowing down research.**

(4) biomedical research ethics review bodies – **Unsure. Some biomedical research ethics review bodies would feel it is important and worth trying, while others may feel they do not have a background in social science and humanities.**

(5) biomedical researchers (individual scientists) – **No. They would more likely be concerned about negative consequences. For example, this will cause trouble for their research, and occupy their research time without producing publishable results. In addition, most biomedical researchers do not know how to collaborate with scholars in the fields of humanities and social sciences, and some are also unwilling to cooperate with them.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, but some might be concerned that their ongoing efforts will not be recognized, and that some biomedical researchers may complain ethics assessment would hinder their research.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

No. Although some research ethics review bodies may consider societal or longer-term implications, few IRBs in China have the expertise, time, or budgets to effectively support these activities.

FRANCE

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Permit by a *contrario* analysis or not applicable.

In the different systems for evaluating biomedical research in France (Comité de Protection des Personnes, CPP, and IRB), there are no legal provisions prohibiting the social evaluation of protocols, so it could be allowed. However, the criteria mentioned in Article L1123-7 of the Public Health Code on the tasks of the CPP focus the evaluation on the impact of the protocol. It is therefore not common practice. For IRBs, there is no specific law to frame their activities, it seems that they have the same positions, see for example the Règlement intérieur of the Inserm IRB where nothing is mentioned in this regard.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit by a *contrario* analysis or not applicable.

Nothing is mentioned in this regards in the law see above.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Some funders may require these issues to be addressed as part of the application, in particular to assess the impact of future results (see Horizon Europe grants or national funders such as ANR).

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. From a theoretical point of view, it is necessary to go beyond the mere evaluation of research protocols and to ensure the societal and long-term implications of the results. However, this has not been discussed or institutionalised in France, except perhaps for the environmental impact of research. It would therefore require awareness of the various stakeholders and resources/evaluation procedures to be set up and tested.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Unsure. Procedures are already very complicated to set up because of the interaction between EU and national law (there are currently several pieces of legislation applicable to research). It will add to the complexity if it is not thought through and regulated in advance, given the current legal landscape. However, this could be seen as beneficial to society as a whole and could therefore be considered in the future.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. They could support these issues that they feel are important.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They would likely be concerned about slowing down research.**

(4) biomedical research ethics review bodies – **Unsure. They could consider these issues as they are likely to be affected, but lack of resources and skills may make it difficult to include these aspects in their assessment activities.**

(5) biomedical researchers (individual scientists) – **An increasing number of scientists are concerned about the long-term impact of their research on society at large and on the environment. However, it will require them to have access to adequate tools to make this assessment and will also add to the burden of preparing their proposal.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, It is the role of these sciences to look beyond the immediate risks/benefits of research activities and to help provide a long-term vision of the impact of these activities.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes. But several conditions must be met to ensure it will work!

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. Each protocol should have an individual impact assessment, and the Comité de Protection des Personnes or the IRBs are best placed to make this assessment. However, as there is currently no competence among the current members of these committees to carry out this assessment, it will be necessary to add a new mission to these committees, with adequate resources (human, financial) and enough time to carry it out, as they are requested (in particular the CPP) to give their opinion within a time constraint.

GERMANY

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Permit/Require.

The ethics review bodies in the Federal Republic of Germany are generally not explicitly obliged, permitted or prohibited to take into account the social implications of the research they assess. The explicit focus of their evaluation is on the specifics of the research project, its effects on the persons involved, and compliance with the applicable legal framework and relevant regulations (statutes investigated: 7). Of course, the societal implications mentioned above can be inherently part of a research project, such as aspects of public health in epidemiological research.

In a broader view, however, ethics review bodies can be obliged to take such implications into account, as they are subordinate to the guidelines of good scientific practice: In their work as institutions of the universities, the ethics review committees of the university hospitals are committed to the standards of good scientific practice addressed to both researchers and institutions and also recognize them in their statutes (Statutes of the REC University Hospital Heidelberg §2 I; Statutes of the REC University Hospital Bonn §1 II; Statutes of Charité Berlin §2 I-II; Statutes of University Hospital Munich §10 I-VI). These standards make it clear, for example, that with regard to research projects, the possible consequences of research should be evaluated in detail and the ethical aspects evaluated [cf. Guideline 10 (Legal and ethical frameworks, rights of usage) of the Guidelines Safeguarding Good Research Practice of the German Research Foundation].

Furthermore, the Guidelines Safeguarding Good Research Practice point out the need for risk management by researchers. Scientists are not only responsible for their research, but must also always consider the consequences that could lead to misuse (cf. Explanation to Guideline 10, id.). Accordingly, these provisions requiring researchers to consider the societal implications of research may be subject to compliance assessment by ethics review bodies.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit/Require.

Biomedical research ethics regulations or policies in Germany do not explicitly require, permit or prohibit that ethics review bodies consider the longer-term implications of proposed research. Regardless of these circumstances, there are indications that the bodies should broaden their focus to make the longer-term implications of the proposed research part of their assessment (cf. answer to Issue 1.A). Additionally, Statements by the German Ethics Council, which advocated that further awareness-raising and responsibility-promoting measures as well as legal regulations are necessary for an appropriate risk prevention strategy to minimize the potential for misuse of biomedical research, were generally discussed controversially and were not taken up by the legislature.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally, these issues are not explicitly part of scientific grant applications, unless they are subsumed under the ethics assessment or are subject to specific study by separate research undertakings. However, indirect connections can be made.

According to the Horizon Europe funding program, recital 71 (Regulation (EU) 2021/695 establishing Horizon Europe), the measures covered by the scope of the program should, among others, take into account the opinions of the European Group on Ethics in Science and New Technologies, where appropriate.

In the standard EU-Horizon application form, the applicant must certify the proposal`s compliance with ethical principles, including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, which among its principles defines accountability for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider societal impacts (Horizon-Europe Application Form: p. 5).

The application form also contains a detailed section on the topic of "Ethics and Security", which checks whether the research project affects sensitive areas or groups. If this is the case, an "ethic self-assessment" or a "security assessment" must be completed in which the consequences of the research project are presented in detail. In this context, a wide range of possible impacts of the research project are discussed, such as damage to the environment, stigmatization of social groups, misuse of research results as well as political and economic consequences (Horizon-Europe Application Form: p. 17-24).

The Federal Government's Framework Programme for Health Research formulates the aim of ensuring that ethical, legal and social aspects are taken into account in the context of research in the life sciences from the outset. Research is to be more closely supported in sensitive research projects in order to maintain ethical and legal

standards (Federal Ministry of Education and Research, 2018: p. 24-25). To navigate the development of biomedical research by the Federal Ministry of Education and Research, the ELSA program was set up to assess the opportunities and risks associated with the findings of modern life sciences. The program has published several funding guidelines for the promotion of projects that deal with methods of genome editing (Federal Ministry of Education and Research, 2015: online) or the effects of Artificial Intelligence (Federal Ministry of Education and Research, 2018: online).

With regard to the German Research Foundation, cf. answer to Issue 1.A and Issue 1.B.

Some non-governmental organizations and commercial entities study these issues.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. It can be noted that there is some consensus that this approach is a key element of translational bioethics and there are already roots for its implementation in certain research programs of funders and for biomedical research in general (cf. answers to Issue 1.A and 1.B).

There are efforts to enact and institutionalize the analysis of such implications and make it an explicit norm in the context of translational bioethics. For example, part of the review by the Central Ethics Committee for Stem Cell Research is whether the projects serve overarching research goals to acquire scientific knowledge in the context of basic research or to expand medical knowledge in the development of diagnostic, preventive or therapeutic procedures for use in humans [§ 9 in conjunction with § 5 Nr. 1 StZG (Act ensuring protection of embryos in connection with the importation and utilization of human embryonic stem cells – Stem Cell Act – of 28 June 2002)]. The statutes of the Central Commission for the Safeguarding of Ethical Principles in Medicine and its Border Areas at the German Medical Association stipulate in § 2 that the Commission sees its task as issuing statements on ethical questions that arise from progress and technical developments in medicine and their border areas and require a joint response from the Federal Republic of Germany. In any case, this at least indicates that the assessment can also take possible longer-term and social consequences into account. (NB: The ethics committee is more diverse and interdisciplinary than, for example, the ethics committees of university hospitals (§3 para. 2 of the Statutes).

A crucial question would be to investigate in more detail not only the "if" but also the "how", i.e. which methods would be suitable for such an assessment? Technology assessment and models of specific risk assessment, for example established in data protection laws, could potentially serve as a model and starting point.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. Cf. answers to Issue 1 and Issue 2.B. Additionally, by ensuring a social and long-term assessment of the projects, it can be argued that tax money spent on research will be used more appropriately.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes, although dealing with these questions is sometimes perceived as an obstacle to research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Yes. Nonprofit, and private sector funders often receive donations. In order to issue these justifiably, an extended ethical assessment could be used. [Re: public funders, cf. answer to (1).]**

(4) biomedical research ethics review bodies – **Yes, cf. their binding to good scientific practice, Issue 1.**

(5) biomedical researchers (individual scientists) – **Unsure. The US assessment can be agreed to. Nevertheless, it will be important for them to ensure comprehensive ethical justification for their research, both in communication with patients and with the public.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, but it will be important to provide guidance so that the scope for discretion and assessment can be used appropriately and in a proportionate manner.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Assuming that the additional regulation and bureaucracy do not outweigh the positive effects of such an analysis of societal and longer-term implications, the question can be answered positively. Furthermore, the margin of appreciation and discretion of the bodies would have to be captured accordingly.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Some are appropriate, some are not. In their current form, the ethics review bodies are mainly based on the voluntary cooperation of those involved. In order to take on the outlined task, it would require an increase in professionalization and the associated expansion of resources. The involvement of representatives of all relevant disciplines with regard to the assessment of longer-term and societal implications of the research projects would be indispensable. With a greater amount of work comes a greater time requirement for decision-making, which would have to be taken into account or counteracted.

ISRAEL

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

PERMIT.

Broader societal issues are not specified in the language of biomedical research ethics regulation or policies (notably, Public Health Regulations (Medical Experiments Involving Human Subjects) (1999)). However, the composition of all IRBs (both local and national) in Israel reflects a multi-dimensional/disciplinary review, including theology, law, ethics, social sciences and psychology. Such composition lends itself to rich and extra-scientific inputs into the review process.

No prohibition on considering "long-range effects" is in place, and IRBs are given much latitude on the items to be reviewed.

The only required items are those appearing in the Geneva convention (with its subsequent amendments).

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit (as it is not prohibited)

No prohibition on considering "long-range effects" is in place, and IRBs are given much latitude on the items to be reviewed.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Most applications will include an ELSI section, conforming with common place requirements such as the European standards for grant proposals such as in the HORIZON research platform. (https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm)

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This approach is already part and parcel of current IRB processes in Israel.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. The current state of affairs embedding multi-disciplinary scholars with biomedical researchers reflects such a positive stance.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. They are concerned about these issues, and do not hold it will interfere with good and ethical research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Mixed response if asked in the abstract. Since this is currently the modus operandi in Israel, all such parties accept, with the private sector being the less-enthusiastic.**

(4) biomedical research ethics review bodies – **Yes. This is currently the modus operandi in Israel**

(5) biomedical researchers (individual scientists) – **Yes. This is currently the modus operandi in Israel**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes. Scholars from such disciplines are expecting to be heard and to have direct influence on the review process and on the actual research protocols.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes.

The current practice attempts this goal, by introducing scholars from various disciplines into the review process, granting all equal voting powers.

On a side note – from 2001-2010 the Israeli Parliament enacted and established the Commission of Future Generations, to represent the longer-term interests of society. After one decade, it was abolished, mostly due to insurmountable frictions with the executive and legislator branches. (https://www.fdsd.org/ideas/knesset-commission-future-generations/)

JAPAN

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

The extent to which IRBs and other review bodies take into account the social and other impacts of biomedical research is left to the discretion of the review body.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

There is no clear regulations or policies.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

In general, it is desirable to consider ELSI in conducting science and technology research, although it is not necessarily required to assess social impacts. For example, in the 6th Basic Plan for Science, Technology and Innovation of the Ministry of Education, Culture, Sports, Science and Technology (MEXT), it is stated as follows

In order to design a new society and promote the creation of new value in that society, a variety of "knowledge" is necessary. In particular, in the transition to Society 5.0, it will be necessary to take a bird's-eye view of things in order to respond to the ELSI that will arise when new technologies are utilized in society, and a system that can utilize "comprehensive knowledge" including not only natural sciences but also humanities and social sciences is required.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. In Japan, it is considered necessary to consider social impact assessment and ELSI not only in biomedical research but also in science and technology research. Some universities have established research institutes specializing in ELSI, and there is a research budget for ELSI research. However, in terms of long-term forecasting, it is up to researchers to decide how long to forecast and what kind of ripple effects to consider, and there seem to be no specific standards.

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C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes, however, the inclusion of multidisciplinary scholars is not an absolute requirement for research evaluation, as the independence and discretion of the researcher regarding the content of the research is important.**

(2) Non-profit funders of research (e.g., philanthropies, disease advocacy groups) - **Yes. Not very large funds, but many interested research groups.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Unsure. In Japan, ethical review and social impact assessment of scientific research is considered necessary in the wake of several biomedical research scandals. No one is outspokenly against it, but it is not clear to what extent they actually think it is necessary.**

(4) biomedical research ethics review bodies – **Yes. However, while there is interest in ethics review, there are no rules on how to do it, and the methods are left to the review boards, so there is a lot of variability.**

(5) biomedical researchers (individual scientists) – **Unsure. Some researchers are interested, and there are such sessions at the conference. However, it is not clear if this is the overall interest.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, although the community of bioethics and medical law scholars is not very large and only a few serves on government committees.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

No. IRBs in Japan are located at different institutions, and the quality of IRBs varies considerably. Some IRBs may be able to assess social impact and long-term effects, but with small IRBs scattered throughout the country, ensuring quality is a challenge.

REPUBLIC OF KENYA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Biomedical Research Ethics Regulations do not explicitly require Institutional Scientific and Ethical Research Committees (ISERCs)[1] to consider societal implications of proposed research. The National Guidelines for Ethical Conduct of Biomedical Research Involving Human Participants, 2020[2] are silent as regards this matter. However, the Guidelines highlight the key common morality principles in the Belmont Report and classify them as the General Ethical Principles. These principles are *respect for people*, *beneficence*, and *justice*.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Biomedical Research Ethics Regulations do not require ISERCs to consider long-term implications of proposed research. However, it can be implied that the National Guidelines envisioned this principle through a provision like the one requiring the result of Clinical Trials done in Kenya to be accessible to the community from which participants were drawn.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally, consideration of societal implications and long-term consequences are not part of scientific grant applications, but the Guidelines direct all sponsors to ensure - among other obligations - that the research they sponsor or collaborate in be in line with the guidelines through clearance by ISERCs.

1. The new name for Research Ethics Committees.

2. https://www.nacosti.go.ke/nacosti/Docs/QUICK%20DOWNLOADS/National%20Guidelines%20for%20Ethical%20Conduct%20of%20Biomedical%20Research%20Involving%20Human%20Participants%20in%20Kenya.pdf

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. The approach of translational bioethics is implicitly encompassed in the National Guidelines that require ISERCs to be multi-disciplinary. It is a feasible way to analyze these implications, which can be emphasized further through regular training and sensitization of ISERC members. Context-specific issues should be identified and addressed.

Although the simpler way to assure multidisciplinary perspectives is by having various disciplines represented in the ISERCs, a further way to ensure that all relevant perspectives are factored in is to co-opt experts - when deemed necessary -and / or be required to defer to an expert body, preferably by law. Depending on the nature of the research, other regulators are already required to intervene, such as Pharmacy & Poisons Board (PPB) and National Environmental Management Authority (NEMA). With sufficient justification, other authorities could be required to weigh in on a given matter.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. Where national values and constitutional rights (see Constitution of Kenya Article 10 and Chapter 4[3]) are at stake, government agency funders will have the duty to ensure that research undertaken does not contradict or infringe on them.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes, but preferably if the scholars in question are already part of an ISERC. If not, delayed responses or "unfair" denial of permission to conduct research may make this approach unpopular. However, it would help if this approach is applied globally so there is no unfair advantage to those with more stringent regulations.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **It would be more efficient if the scholars are part of the ISERC, or else can be co-opted without excessive delay or bureaucracy, and hopefully with tangible benefits.**

(4) biomedical research ethics review bodies – **Multi/interdisciplinary perspectives and collaboration are more common nowadays. Stakeholder engagement – including consulting community gatekeepers - is also better understood today. If the community will suffer because of the research, or if permission to conduct the research could be denied at the ISERC or NACOSTI level, the best is to be open to expert input even at the stage of *designing* the research.**

3. kenyalaw.org

(5) biomedical researchers (individual scientists) – **Yes, if this is incorporated in their research (ethics) training and criteria for approval of protocols. Additional input should, however, not cause avoidable delays or unduly increase the hurdles to be overcome; rather it should highlight the benefits of that way of proceeding.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes. This would mean that their concerns are given due importance in the context of clinical research if professionalism and scientific rigor are maintained.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes. Benefit sharing means having a community that can enjoy the outcomes of the research. *Sustainable development* (national value in Kenya and basis of SDGs) requires long-term perspectives regarding current human activities. Ethical outlook cannot ignore societal implications and long-term implications of biomedical research.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. Given that Ethics Review Bodies in Kenya are required to be multi-disciplinary, they are potentially qualified to undertake Translational Bioethics Reviews that consider societal and long-term implications. Some of the challenges that they face in this regard can be addressed through ensuring appropriate composition of ISERCs, training of members and strengthening the capacity of the National Scientific and Ethics Committee (NSEC) to effectively oversee the ISERCs.

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5 February 2024

LEBANON

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Yes, permitted. And depending on the study, they might even be required. Note however that this might not apply to all IRBs/RECs in Lebanon have the same training and abide by the same requirements (at least international regulations).

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Prohibit.

"The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy as among those research risks that fall within the purview of its responsibility." 45 C.F.R. § 46.111(a)(2) (2018).

Lebanese regulations do not tackle that, so the above applies only to centers that also abide by the CFR, Common Rule, etc.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally this is done by other committees like the scientific committee prior to reaching the IRB but it depends on the IRB/REC. No official policy on that issue.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Absolutely. They bring input and viewpoints that are eye opening and relevant.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Not sure. Nothing in the regulations.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. They are concerned about these issues, but they are unlikely to support any measures that they think will interfere with research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They would likely be concerned about slowing down research.**

(4) biomedical research ethics review bodies – **No. It would make more work and most members do not have a background in social science, humanities, etc. However, depending on who is giving them training, this might be possible.**

(5) biomedical researchers (individual scientists) – **No. At least initially, it can be expected that many would be concerned about negative consequences for funding, and they would be leery of non-scientists judging their science.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, they would welcome it actually.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Even if they are trained to do so, I would argue that having experts would allow room for better discussions, feedback and indirect training that widens the horizon of a committee governed by members the majority of whom come from biomedical background.

These days, the long term implications of research can no longer be ignored. There is a shift in the nature of the studies and their implications.

MÉXICO

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

In Mexico, the Regulation of the General Health Law on research for health in its article 33 stipulates that in any community research, the ethical considerations applicable to research on individuals must be extrapolated to the communal context in the pertinent aspects.

The National Bioethics Commission has generated a National Guide for the integration of Research Ethics Committees. The ethical principles of research are considered: Respect for autonomy, Beneficence and non-maleficence and justice. According to autonomy, research procedures, purpose, risks and benefits are considered. In accordance with beneficence and non-maleficence, the aim is to maximize possible benefits and minimize potential harms or risks.

Research Ethics Committees must consider the scientific or social value when evaluating a protocol, and consequently, help improve the health or well-being of the population.

Among the applicable legislation are:
a) The General Health Law, in its articles 41 bis and 98;
b) The Regulations of the General Health Law regarding health research; and
c) The General Provisions for the Integration and Operation of the Research Ethics Committees.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

In Mexico, article 14 of the Regulations of the General Health Law on health research, in section IV, states that the probabilities of the expected beneficiaries must always prevail over the predictable risks.

Meanwhile, Article 17 of the aforementioned Regulation considers research risk to be the probability that the research subject will suffer some harm as an immediate or delayed

consequence of the study. It contemplates research without risk, research with minimal risk and research with greater than minimal risk.

The National Bioethics Commission in the National Guide for the integration of Research Ethics Committees indicates that research Ethics Committees must consider proportionality in risks and benefits when evaluating a protocol. The monitoring of protocols is also contemplated, from the moment the decision was made, until the completion of the investigation and reporting of the results. Adverse events are considered to be a sign, symptom or illness associated with the use of a medicinal product.

Among the applicable legislation are:
a) The General Health Law, in its articles 41 bis and 98;
b) The Regulations of the General Health Law regarding health research; and
c) The General Provisions for the Integration and Operation of the Research Ethics Committees.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

In Mexico, article 11 of the Regulations of the General Health Law on health research, states that a report will be sent to the Ministry of Health regarding international agreements and treaties on research, which must include, among other points, the origin and destination of the financial resources involved, including those of sponsored research that is related to the development of inputs, technologies and other application processes, susceptible to patents or commercial development, among others, that are carried out on human beings.

From reading the Ethical Principles of Research and the Regulations of the General Health Law on research for health, it can be concluded that consideration the risks and community effects of the research.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. In accordance with the Regulations of the General Health Law on health research and other regulations, multidisciplinary research must comply with the regulations that address both the social and long-term implications, mainly in terms of risk.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Yes.**

(4) biomedical research ethics review bodies – **Yes.**

(5) biomedical researchers (individual scientists) – **Yes.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. In Mexico, the Research Ethics Committees in accordance with the Regulations of the General Health Law on research for health and the National Guide for the integration of Research Ethics Committees must address the risks and community effects of the research.

THE NETHERLANDS

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

In the Netherlands there are various research ethics committees. The two relevant acts are the Medical Research Involving Human Subjects Act (Wet medisch-wetenschappelijk onderzoek met mensen or WMO[2]) and Embryo Act (Embryowet[3]). Both Acts foresee in the institution of the Central Committee on Research Involving Human Subjects (CCMO). The CCMO is an official law-based body, with its 32 members being appointed by the government. It was constituted to review research proposals falling within the scope of either one of these acts concerning research with human beings. A positive opinion is required to start these research proposals. In addition, the CCMO is empowered to recognise other committees ('accredited committees' or Medical Ethics Review Committees, MRECs), that have the power to review research proposals falling within the scope of both acts and give an opinion – with researcher given the opportunity to appeal to the CCMO in case their proposal was not approved by one of the 14 MRECs and to get thus a final opinion.

For proposed research falling outside the realm of the WMO or Embryo Act there is no legal obligation for a prior positive opinion by the CCMO, a MREC or other ethics review committee. These research proposals may include research with human tissue, file research, non-interventional safety studies after the authorisation of a medicinal product and non-WMO research with a medicinal product not subject to the (EU based) Clinical Trials Regulation.

Many institutions that carry out research with human beings not covered by the WMO or Embyo Act require the research proposal to be reviewed prior to its initiation. As a result a great number of privacy committees, ethical review committees, biobank review committees and other non-WMO regulation committees have been created.

The MRECs and CCMO can only give a positive opinion on a research proposal as long as the proposal meets the following criteria (Article 3 WMO):

1. Aart Hendriks is professor in health law, Leiden University, and Martine de Vries is Martine de Vries is professor of normative aspects of medicine, Leiden University Medical Centre, the Netherlands.

2. https://wetten.overheid.nl/BWBR0009408/2022-07-01.

3. https://wetten.overheid.nl/BWBR0013797/2021-07-01.

- **It is likely that the proposed research leads to new insights in the area of medical research;**

- **It is likely that the new insights cannot be achieved by other ways of scientific research with research subjects or less intrusive scientific research;**

- **It is likely that the proposed study is in the interest of research subjects and other present and future patients and is in balance with the disadvantages and risks for research subjects, taking into account the circumstances in which research subjects find themselves;**

- **The proposed research entails a minimal risk and a minimal disadvantage in comparison with a standard treatment of the disease a patient is suffering from in case of research that is not therapeutic for the research subject, with research subject that are younger than 16 years or that are unable to assess their interests at stake;**

- **The proposed research meets the criteria of a proper research methodology;**

- **The proposed research is carried out by appropriate research institutions that are leaded by persons who are knowledgeable with respect to the area of scientific research, including at least one person who is knowledgeable with respect to interventions focussed on research subjects;**

- **It is likely that the financial compensation offered to research subjects does not influence the consent given by research subjects younger than 18 years;**

- **It is likely that the financial compensation offered to research subjects does not disproportionately influence the consent given by research subjects of 18 years and older;**

- **The researcher and the research institution shall not receive a financial compensation that is disproportionately higher than needed given the nature, scope and goal of the scientific research;**

- **The research protocol clearly indicates the degree of intrusiveness for research subjects and the amount in which the proposed research can benefit the research subjects;**

- **The research protocol contains criteria focussed on the scientific criteria for the recruitment of research subjects;**

- **The results of the research will be made available to the public by the CCMO, unless the institution carrying out the research objects to this;**

- **The proposed research <u>also otherwise meets the criteria that reasonably should be met</u>.**

The above criteria do not explicitly refer to the societal implications of proposed research, even though there is an independent review of the research proposal and the requirement of informed consent.

Since there are no legal requirements for the review of research proposals falling outside the scope of the WMO or Embryo Act, there are no assessment criteria for privacy committees and other bodies reviewing these proposals.

Thus the law and general practice permit a prior assessments of research proposals on societal implications, but there is no requirement of doing so.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

See also our answers under A (above).

The law and general practice permit research ethics review committees to consider longer-term (beyond the research period) implications of proposed research. There are no relevant legal or other texts on this issue.

Of importance in this context is the fact that the CCMO sees the Declaration of Helsinki as an important document to which researchers should always refer in research protocols. Reference must always be made to the latest version of the Declaration. In the case of 'longer term implications' article 34 in the Declaration about Post-Trial Provisions (compassionate use or access to medication after termination of the trial) is relevant. The CCMO and MRECs should discuss post trial access with the sponsor of a trial.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

See our answers under A and B.

Such requirements for the public and private sectors to consider these issues are part of de Declaration of Helsinki.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

In these times where societal and long-term implications become increasingly important, such initiatives would be welcomed. We also think it is feasible, for example by using a Guidance Ethics Approach[4], or value based design in the case of technological innovations. A Guidance Ethics Approach[4] is well-suited for investigating what is

4. Verbeek, P.-P., Tijink, D., Guidance Ethics Approach : An ethical dialogue about technology with perspective on actions. The Hague : ECP | Platform voor de Informatie Samenleving, 2020.

of moral significance according to directly affected stakeholders in developing new medicines or technology. A Guidance Ethics Approach recognizes that biomedical research can have a large impact on society and individuals, and therefore seeks to ensure that its development is guided by ethical considerations and is aligned with stakeholders' values as much as possible.

At the same time, there is more and more resistance from groups and political parties to touch on these issues since they resist new forms of these regulations. Thus, such initiatives are objectively necessary, but its achievement depends on various factors, including the political will to do so. Up until now, in The Netherlands there are no formal obligations to do parallel ethics research, only institutional recommendations.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. The largest funder in the Netherlands (The Netherlands Organisation for Health Research and Development, or ZonMw) for some years now has in many of its calls the condition that there should be a paragraph in the protocol about responsible innovation, and that there are ethicists embedded in the research (including the budget). This may change due to the outcome of the November 2023 elections in the Netherlands with right wing political parties gaining a majority of the seats in Parliament. These parties do not want political 'interferences' with respect to – amongst others - research.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes, these organisations are generally very concerned about the lack of importance attached to these goals. They also follow the conditions of The Netherlands Organisation for Health Research and Development (ZonMw) – see under (1).**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Unsure. The agenda of these entities varies. Some want more research with less regulatory or ethical obstacles. Others promote research that complies with all kind of guarantees.**

(4) biomedical research ethics review bodies – **Unsure. Review bodies in the Netherlands now struggle with the fact that there is no legal obligation to analyse societal and long-term implications of research proposals. They don't have the tools yet to look at these implications. On the other hand, within the law there is room to look at these implications. The review bodies do, however, not use these possibilities even though they could have done so if they wanted to. The sheer fact that they did not do so up until now shows a lack of importance attached to this, apart from the fact that the constituency of an biomedical research review committee will have to undergo changes to have qualified experts on board.**

(5) biomedical researchers (individual scientists) – **Unsure. Same reasons as biomedical research ethics committees, apart from the fact that more (administrative) obligations implies more work and less chances of funding.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, probably very willing. Yet, there is no guidance on how to achieve this.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes, no doubt about that, provided that the assessment criteria could be formulated as clearly as possible.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. In the Netherlands research ethics review bodies are, under the WMO and Embryo Act, used to reviewing a proposal from various perspectives which has added value for all. Have a proposal reviewed by two different committees implies more work for the research proposals and entails the risk of two opposing opinions, and thus a delay on the decision whether the research can start or not.

NIGERIA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Require.

Societal implications of proposed research are required to be considered, such as sharing of benefit of the research.

"Intellectual property, indigenous knowledge and contributions of all parties must be taken into consideration, adequately protected and compensated particularly where research leads to tangible or intangible benefits. Satisfactory parameter(s) that shall determine sharing of commercial and other benefits should be clearly articulated and where indicated, benefit sharing agreements, materials transfer agreements, patent rights, intellectual property and royalties' distribution agreements should be signed before initiation of research." National Code of Health Research Ethics 41 – 42, § F(i) (2007)

Moreover, the research architecture of the country includes an entity known as the "Oversight by Community Advisory Committees (CAC) "whose primary role . . . is to assist investigators understand and incorporate community concerns into their research activities," which must necessarily include broader societal issues. National Code of Health Research Ethics 52, § M(c)(4)(2007).

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Require.

Extant regulations lack clear language on this, but a reading of some provisions (see below) would suggest that an obligation to consider long term implications of proposed research does exist. Aside from the mandate of the CAC (see response to Question A), further evidence is provided by strong emphasis on consideration of social value of the research, community involvement, mechanism to ensure that the research has long term impact and sharing of the benefits of the result of the research. Moreover, some of the stipulated actions such as making a determination as to the "lasting impact" of the research or whether the result "transfers technology" [National Code of Health Research

Ethics 41, § F(i) (2007)] cannot be taken until the research has been completed.

"It is also necessary to determine the social value of the research and engage in creative approaches for effective representations and involvement of researchers and communities in the entire enterprise." National Code of Health Research Ethics 41, § F(h) (2007)

"The requirement to respect both enrolled and potential participants means that researchers should engage with communities where research is being conducted whenever this is appropriate. In certain instances, community consultation or assent may have to precede research activities in order to engender community buy-in and to respect the socio-cultural values of the community and its institutions. It may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and well being, and the outcome of the research." National Code of Health Research Ethics 41, § F(g) (2007)

"For research to be ethical, the interest of participants, researchers, sponsors and communities must be protected. This will ensure that the research has lasting impact, transfers technology where appropriate, contributes to capacity building and demonstrates respect for socio-cultural and other differences." National Code of Health Research Ethics 41, § F(i) (2007)

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Unsure. But to be compliant with extant regulations, it seems the approval process must be subjected to the provisions discussed in response to Issue 1(B).

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. Multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant backgrounds bring different sets of knowledge, skills and concerns, and which biomedical researchers may not have but which are necessary for a deeper and more robust analysis of societal and long-term implications of the research.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. Since the Trovan clinical trial debacle of 1996, the government and its agencies are committed to taking any measure that would prevent similar occurrence in the country. Embedding multi-disciplinary scholars with biomedical researchers in research projects is consistent with this approach. See Jeanne Lenze, Secret Report Surfaces Showing that Pfizer was at Fault in Nigerian Drug Tests, 332(7552) BMJ 1233 (2006) stating that "A secret Nigerian government report concluded that the drug manufacturer Pfizer undertook an "illegal trial of an unregistered drug" when the company enrolled nearly 100 Nigerian children with meningitis in a trial testing its antibiotic trovafloxacin (Trovan) against ceftriaxone during a 1996 meningitis epidemic."**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. Given that non-profit funders are aware, I assume, about the Trovan experience and resulting distrust of biomedical research in the country, they are or ought to be inclined toward permitting any process, including embedment multi-disciplinary scholars with biomedical researchers, that would gain the trust of the people concerned.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Not sure. They might be concerned about cost implications and slowing down research but since they would not wish to attract community distrust, which is a big issue in Nigeria, they might be open to allowing the impediments.**

(4) biomedical research ethics review bodies – **Yes. Although it might mean more work but the contribution of participants from different disciplines would, it seems, strengthen their conclusions and recommendation regarding the societal and long-term implications of the research.**

(5) biomedical researchers (individual scientists) – **Not sure. They might not be receptive to having non-scientists sit in judgment over their work but in countries with widespread suspicion of research intentions, involving others whose backgrounds could enhance reception by the host community might make them more accepting of the involvement of non-scientists.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, since they understand their involvement as predicated on pushing the imperatives of beneficence and justice beyond the frontiers of traditional bioethics to include broader societal concerns.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

No. They lack requisite capacity to undertake such an assessment.

POLAND

Dorota Krekora-Zając
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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

There is no express prohibition or requirement in Polish law for bioethics committees to check the implications of conducted research for society. In accordance with the provisions art 29 of the Act on the Professions of Physician and Dentist, the bioethics committee takes into account ,, the conditions of conducting the experiment and ethical criteria relating to conducting experiments involving humans and the purposefulness and feasibility of the project."

The criterion of the purposefulness of the project indicated in the footnote assumes that the bioethics committee may, but does not have to, investigate the societal implications of proposed research, such as the economic, health equity, and public health implications.

Because these criteria are quite general, bioethics committees can analyze all the effects of research as long as it does not fall within the concept of ethical principles of conducting research on humans. This means that if, during the analysis, the commission finds that the experiment has, for example, a eugenic purpose, it should not consent to it.

Bioethics committees may also be established by medical universities and then operate on the basis of their regulations. However, the regulations I analyzed did not indicate the need to examine the societal implications of proposed research, such as the economic, health equity, and public health implications.

Moreover, non-medical universities establish ethics committees. They provide opinions on biomedical research conducted by university employees. The regulations of these committees do not specify the project evaluation criteria. Therefore, especially in the case of controversial research, the committee may also analyze.

Separate Supreme bioethics committee reviews clinical trials in accordance with the European regulation.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

There is no express prohibition or requirement in Polish law for bioethics committees to check the longer-term implications of conducted research. In accordance with the provisions art 29 of the Act on the Professions of Physician and Dentist, the bioethics committee takes into account "the conditions of conducting the experiment and ethical criteria relating to conducting experiments involving humans and the purposefulness and feasibility of the project."

The criterion of the purposefulness of the project indicated in the footnote assumes that the bioethics committee may, but does not have to, the longer-term implications.

Bioethics committees may also express opinions on scientific projects that are not medical experiments. In practice, however, there are no specific laws that would require obtaining such consent for other research.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally, these issues are not a part of scientific grant applications. In the Code of the National Science Center (it is the largest public entity financing biomedical research) regarding research reliability research and applying for funds for

The study does not provide specific criteria in this regard. Similarly, such requirements do not appear in financial projects by The National Center for Research and Development.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This approach is a key element of all Polish ethics and bioethics committee. These committees are always multidisciplinary and include scientists from various fields, lawyers and bioethicists, and sometimes clergy. Article 29(4) of the Act on the medical and dental professions indicates that the composition of the bioethics commission includes persons with high moral authority, high specialist qualifications and significant experience in matters related to medical experiments.
For example, it can be pointed out that in accordance with art 15 Act on Clinical Tests of Medicinal Products for Human Use, The Supreme Bioethics Committee consists of no more than:

1) 15 representatives of scientific disciplines: medical sciences, pharmaceutical sciences or health sciences, with at least 10 years of professional experience in the field of:

a) practicing as a doctor, dentist, nurse, midwife, laboratory diagnostician, pharmacist or
b) conducting scientific research in the field of medical and health sciences, in particular clinical research;

2) 6 representatives of the scientific disciplines: philosophy or theological sciences, with at least 5 years of professional experience in the field of bioethics;

3) 6 representatives of the scientific discipline of legal science, with at least 3 years of professional experience in performing activities requiring legal knowledge directly related to the application of medical law or to the creation of draft normative acts related to medical law and pharmaceutical law;

4) 3 representatives of patient organizations entered in the list of patient organizations referred to in Art. 55a section 1 of the Act of November 6, 2008 on patient rights and the Patient Ombudsman"

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. New regulations regarding clinical trials enable the involvement of many specialists.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes, if there were financial resources to pay experts**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Unsure. For them, the biggest problem is the lack of precise legal regulation. Maybe if the law specified clear criteria, they would be interested.**

(4) biomedical research ethics review bodies – **Yes, if there were financial resources to pay experts**

(5) biomedical researchers (individual scientists) – **No. At least initially, it can be expected that many would be concerned about negative consequences for funding, and they would be leery of non-scientists judging their science.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, if there were financial resources to pay experts.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

I think it depends on the type of research conduct. It seems that initially it would be advisable to create a list of studies that required such an extended justification

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes, I think that ethics and bioethics committees have the most experience in this area. Pursuant to Polish law, the bioethics committee may request the opinion of an additional expert. It is possible to postulate their composition to be determined in this respect

QATAR

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Permit.

I'm not aware of any specific regulatory or legal frameworks implemented by biomedical research institutions or governmental bodies that either prohibit or require this. Therefore, I believe that the principle of original permissibility would be applicable in this case. Drawing from my personal experience serving on various IRBs and ethics committees in Qatar, where I provide expertise in Islamic bioethics, I don't recall encountering issues in raising such long-term religious or societal concerns.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit.
I would contend that the situation here doesn't substantially deviate from what I previously elaborated on in my response to the preceding question.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

One of the primary national research funding agencies in Qatar is the Qatar Research Development and Innovation (QRDI) Council. Within their grant application process, researchers are required to complete the "Data Management Plan" form. Within this form, there exists a specific section titled "long-term preservation." Beyond that, I do not observe stringent requirements regarding the evaluation of societal implications or long-term consequences beyond this.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

I strongly support this approach. Since their beginnings in the 1980s, contemporary discussions on bioethical matters in the Muslim world have predominantly taken an interdisciplinary character. Nevertheless, the primary contributors have consistently hailed from two domains: Islamic Studies and Biomedical Sciences. Recent appeals advocate for an expansion of this interdisciplinary approach by engaging specialists from various other fields, such as the humanities, social sciences, psychology, ecology, and more.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **I am leaning towards a yes-response, as I anticipate minimal objections from the stakeholders who would be involved. However, it's essential to acknowledge that there is still substantial groundwork to be accomplished to ensure the feasibility of this initiative.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes, this would be even more likely.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No, I do not anticipate them showing enthusiasm for this. Nevertheless, external pressures from the public or governments might eventually compel them to reconsider their stance, especially in the long run.**

(4) biomedical research ethics review bodies – **In theory, I would say yes, this is doable. The primary challenge, however, lies in translating this theoretical readiness into practical application. This entails tasks like recruiting experts from diverse fields and effectively incorporating their perspectives into the ethics committees, all while maintaining a streamlined review process.**

(5) biomedical researchers (individual scientists) – **I believe they might not readily embrace this concept, particularly in the initial stages. It's common for them to voice concerns about the existing Institutional Review Boards (IRBs), let alone considering the expansion of their responsibilities and oversight.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **In principle, yes, but there would also be some hurdles to overcome. For example, the time and effort invested by these researchers and scholars in these new responsibilities must be acknowledged and valued by their respective institutions. They would also need to see that their perspectives are given due consideration and that they can ultimately influence research projects.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

From an ethical standpoint, yes. However, this should be complemented with a certain degree of enforcement, such as through legal mechanisms.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Not necessarily. I would argue that the current influential transnational Islamic institutions dedicated to addressing bioethical issues would serve as a more fitting initial point for discussion. The resolutions and recommendations put forth by these institutions significantly influence the bioethical landscape, particularly among the general population in Muslim-majority countries.

SINGAPORE

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Permitted, but only in manner specified by legislation or regulation, or otherwise as recommended by the Bioethics Advisory Committee of Singapore, which is an independent body constituted by the Government of Singapore to provide it with advice on ethical, legal and social issues that pertains to human biomedical research.

Under Section 13(1), Section 17(1)(f), Section 62(1) and the Fifth Schedule of the Human Biomedical Research Act 2015, appropriate consent may be waived under certain specified condition, including emergency research. Paragraph 7 of the Fifth Schedule defines "emergency research" as:

"…human biomedical research where life threatening emergency situations may arise such that appropriate consent may not be obtained before the research subject is subjected to any intervention or after any individually identifiable biological material is obtained from his or her body, or any of his or her individually identifiable health information is used."

Emergency research includes research conducted during a public health emergency.

See also 2019 regulations on consent exemption for research.

In the 2015 ethical guidelines of the BAC, it reads the principle of respect for persons as also requiring a proper regard for religious and cultural diversity (paragraph 2.4 on page 16). Additionally, it observes that an individual's autonomy can be curtailed under certain circumstances, for the public good, such as when quarantined during disease epidemics (paragraph 2.5 on page 16). The principles of solidarity (paragraphs 2.8 and 2.9) and sustainability (paragraphs 2.11 and 2.12) similarly suggests that an IRB may take into account societal implications when warranted (i.e. relating to safety and welfare of research participants).

As far as I am aware, there is no requirement for IRBs to consider broad societal implications of the research, but there is also no explicit prohibition of this.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permissible if such consideration pertains to the review of consent-taking and documentation, risk evaluation and access to novel interventions. See for instance the BAC's elucidation of the principle of justice (paragraphs 2.8 and 2.9 on page 17) in its 2015 guidelines.

Where these implications have wider (e.g. policy) implications that extend beyond the scope of the protection of human participants, the BAC tends to be the body that will consider these implications. Its recommendations may be taken up by the government in the form of legislation or regulation. This has been the case with 'sensitive' research like human embryonic stem cell research, research involving human-animal combinations and human germline genetic modification.

As far as I am aware, there is no explicit prohibition of the sort set out in 45 C.F.R. § 46.111(a)(2) (2018).

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Key public funders like the National Research Foundation and the Biomedical Research Council of the Agency for Science, Technology & Research (BMRC) do consider societal implications (from a national interest standpoint), and have collaborated with the BAC in the past. Societal implications and long-term consequences that are of an ethical and legal nature have generally been entrusted with the BAC, which has collaborated with the Singapore Academy of Law on a few occasions. As for the private sector, the Economic Development Board and the BMRC have strong links to pharmaceutical and biotech companies, and have different funding and policy initiatives to encourage translational research perceived to have public benefit.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes, there are such multi-disciplinary units linked to large scale human biomedical research initiatives like Precise and to a number of research institutes and centres (such as those at the National University of Singapore). However, the pool of bioethics scholars is relatively small and many of them may not be well-versed with policy evaluation and development.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes, the BAC and its secretariat has this role, and ad hoc support is provided by bioethics scholars in academic institutions from time to time.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. although these funders are more likely to collaborate with bioethicists in academic institutions.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Yes, this is already the case for some major research initiatives as noted above. However, there is no clear policy or consistent practice relating to this.**

(4) biomedical research ethics review bodies – **No, the current regulatory landscape does not support this.**

(5) biomedical researchers (individual scientists) – **Unsure as this depends on the type of human biomedical research and how particular the findings / outputs of the multidisciplinary group are likely to be.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Unsure, as this also depends on the extent of overlapping interests and expertise. There are also some collaborative platforms in place, although it is unclear how inclusive these platforms are, and if individual scholars are incentivised to engage.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes, it is already implicit in the two key roles of IRBs: (1) Safeguarding the safety and welfare of research participants; and (2) Enabling ethical research to progress. Please see paragraphs 2.1 and 2.2 of the 2015 BAC guidelines.

Additionally, the BAC states (paragraph 2.24 on page 20): "An IRB review is a means to ethical governance of biomedical research. It follows that an IRB is not merely implementing procedural rules in which contingencies are specified in advance, but is intended to be a forum in which the ethics of a research proposal can be discussed and an independent decision made, in accordance with the principles of ethical research and in light of the facts and expert opinions available to the IRB."

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

No, if taking on consideration of societal and longer-term implications extends beyond the key roles attributed to IRBs. However, IRBs provide feedback to the BAC or relevant government departments (particularly the Ministry of Health) so that such implications may then be taken up by (where these issues pertain to human biomedical research) the BAC for deliberation at a policy level. In other words, IRBs have a participatory role in surfacing concerns over societal and longer-term implications, as well as contributing to policy development in consultation with the BAC. This is practicable in the context of Singapore, where there is strong communicative links between IRBs (as well as their host institutes) with BAC and the Ministry of Health, which provides secretariat support to the BAC.

SOUTH AFRICA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Require.

The department of Health's regulations require health research, which involve humans to 'be responsive to health needs or priorities of the population, participating community or proposed participants' (DOH 2014, para 2b). Distributive justice is one of the broad ethical principles in decision-making in ethics review. To ensure equality, the national department of health's guidelines require 'a fair balance of risks and benefits amongst all role-players involved in research, including participants, participating communities and the broader South African society' NHREC-DOH 2015, para 2.1). The guidelines also require Research Ethics Committees (RECS), in weighing risk of harm against likelihood of benefits, to consider not only 'current participants or research animals themselves but also… societal interests and future hypothetical beneficiaries' (NHREC-DOH 2015, para 1.6.8). The South African Medical Research Council's (SAMRC) ethics policy and Guidelines on the responsible conduct of research also require the Human Research Ethics Committee to ensure that the submitted proposals follow the broad ethical principles of equity.

Regarding genetic research, the guidelines explicitly state that 'RECs must pay particular attention to multiple considerations, including the proposed social value of the research… as well as the potential effect of the research on families, communities and other groups' (NHREC-DOH 2015, para 3.3.8). Social value is also a general requirement in reviewing qualitative research (NHREC-DOH 2015, para 6.5; see also para 3.1.6).

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permit.

As stated above (A), the benefits of research to future hypothetical beneficiaries is a consideration under the NHREC-DOH guidelines (2015, para 1.6.8).
The SAMRC Guidelines on the responsible conduct of research also recognise the long-term value of research data.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

The two main public funders of biomedical research in South Africa require consideration of societal implications and long-term consequences in line with the Department of Science and Technology's White Paper on Science, Technology and Innovation 2019.

For example, the National research Foundation (NRF) Strategy 2025, seeks to support research that generates societal impact and one of the outcome indicators under its strategy are social impact in excellent research, which it funds. The South African Medical Research Council also aims to produce "ethically acceptable, sustainable and socially desirable research and innovations outcomes which are responsive to a wide range of stakeholders and societal grand challenges, and be sensitive to the values, needs and expectations of South Africans", (SAMRC strategic plan p.14).

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This approach has been adopted by South African institutions since it is important for assessing the ethical implications of multidisciplinary biomedical research. For example, the SAMRC's Bioethics Advisory Panel consists of members with multidisciplinary backgrounds.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes. Since the National Health Act prescribes occupational diversity of members who serve on the National health research ethics committee, this is a clear indication that the government supports embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed research. For example, the NHREC-DOH guidelines require research ethics committees to 'review different methodologies appropriately and in accordance with accepted methodological standards of different research and academic disciplines'(2015, para 6.1).**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. If they are operating in South Africa, they are bound to follow the national strategies for promoting multidisciplinary research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They tend to work in silos.**

(4) biomedical research ethics review bodies – **No. Most bodies and institutions tend to have separate review committees for medical and non-medical studies to speed up the review process.**

(5) biomedical researchers (individual scientists) – **No. Most researchers prefer to deal with discipline-specific review committees that are established by their institutions, and the response in item (4) above dictates how they operate. They also tend to operate in silos.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, but they tend not to understand each other's perspectives due to the prevailing trend of scholars working mostly within their disciplines. Some exceptions are scholars within the medical humanities or global health who tend to be more open to embrace multi-disciplinary scholarship and review process.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. Since South Africa faces complex societal problems, these can be addressed by ensuring that research is responsive to societal needs and that research does not contribute to prevailing inequalities in the society. The necessary policies are already in place to support this approach as indicated in issue no.2A above.

SOUTH KOREA

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Require

Although the Bioethics and Safety Act of Korea does not explicitly require an IRB to consider societal implications of proposed research, such can be assumed from the composition of IRBs under law.

"Article 11 (Composition and Operation of Institutional Committees)

> **(1) An institutional committee shall be comprised of at least five members, including one chairperson, with mixed gender; and shall include at least one person who has sufficient experience and knowledge to evaluate social and ethical validity and at least one person from outside of the relevant institution."[1]**

But in practice, societal implications of research proposals are not routinely examined by IRBs.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Require

Although consideration of longer-term implications of proposed research is not explicitly required, it is arguably subsumed under the societal implications above.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

1. This translation is provided by a Korean government organization. (https://elaw.klri.re.kr/kor_service/lawView.do?hseq=52559&lang=ENG) The term "사회적(社會的)" in the statute would be closer to "societal" than "social" in meaning here.

No for the private sector.

For the public sector, it is not part of scientific grant application per se. However, The Korea Institute of Science and Technology Evaluation and Planning (KISTEP), which plays an important role in the general direction of research funding in the public sector, considers societal implications and long-term consequences of government-funded research projects. It regularly publishes "technology impact reports" on breakthrough scientific discoveries and technologies – which included topics such as gene editing, synthetic biology, and precision medicine in the past –, along with public meetings. Thus, the KISTEP can be said to consider societal and long-term implications of biomedical research funding in a roundabout way in selected cases.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Not sure.

Such a scheme will only work if researchers are genuinely open to the idea of closely working with non-biomedical scholars on a regular basis. I am agnostic as to how receptive Korean biomedical researchers will be to that idea.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) Government agency funders of research – **Probably yes. Government agency funders should welcome the idea of possible societal or long-term implications being "vetted" by outside experts.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) –**Probably yes. For the same reason as above.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They would consider it another red tape.**

(4) biomedical research ethics review bodies – **Yes, but reluctantly. They will consider it extra work, but they will realize that it is supposed to be part of their job under law anyways.**

(5) biomedical researchers (individual scientists) – **No. For the same reason as (3) above.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, they will probably consider it an opportunity to expand their role in biomedical research.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes, but selectively.

With some types of biomedical research, it will be difficult to assess societal or long-term implications, especially for research of basic or upstream nature. If assessment becomes mandatory, however, the members of the review body may be reluctant to give an unqualified green-light, due to various concerns, however remote, and instead will likely start looking hard for even remote, theoretical societal or long-term implications.

I think assessment of societal and long-term implications should be reserved for those research proposals that realistically bear societal or long-term implications.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes, from a practical perspective.

As it is, the IRB review and approval process is not known for speed in Korea, which frustrates many researchers. The intervention by a whole new body to review societal or long-term implications may significantly slow down the whole review process, and, on balance, may not be in the best interests of society.

Notwithstanding the statutory requirement mentioned above, not all IRBs operating in Korea have a true expert on board to analyze societal or long-term effects of biomedical research. Thus, inviting a truly qualified member with expertise to assess societal and long-term implications to the IRB and making the assessment a part of the IRB review process, as Korean law already assumes, can be the practical solution.

SPAIN

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Societal implications of research are considered by ethics committees as an ethical issue.

Evaluation of "psychosocial issues" is required expressly by Royal Decree 1090/2015, which regulates clinical trials with medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Registry of Clinical Studies:

Article 5: Clinical Trials with minors. "2. The Research Ethics Committee that is responsible for assessing Part II of the assessment report of a clinical trial involving minors must have experts in paediatrics among its members or have sought advice on the clinical, ethical and psychosocial issues in the field of paediatrics". Article 6. Clinical trials involving persons with modified capacity to consent "2. The protocol must be approved by a Research Ethics Committee that has experts in the disease in question or has sought advice from such experts on the clinical, ethical and psychosocial issues in the field of the disease and the group of patients concerned".

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permitted (in my view, as part of general "ethical issues")

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Benefits and risks of the research, in general, are part of the grant applications. Applicants could include societal implications and long-term consequences. In the evaluation process, this could be taken into account.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. The evaluation of these aspects is important for the planning of progress objectives. In order to be rigorous, it is essential that it is carried out in an interdisciplinary way.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Unsure, it could be perceived as an external interference in decision making in relation to the research and development policy, but at the same time it could have a positive social impact in the perception of this policy.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Unsure, this could be perceived as an external criteria influencing their own decisions concerning research and development support, but at the same time it could have a positive social impact in the perception of this support.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Unsure, it could be perceived as an extra scientific interference in the design of their projects, but at the same time it could have a positive effect in the name of the entity.**

(4) biomedical research ethics review bodies – **Yes, in fact they evaluate some of these aspects but without a specific recognition, beyond being able to understand that they fall into the general category of "ethical aspects".**

(5) biomedical researchers (individual scientists) – **Unsure, it could be perceived as an interference outside strict scientific criteria in relation to project design, but at the same time scientists concerned about these issues would be interested in this perspective of their own research**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, it could mean giving more relevance and recognition to a specific area of research**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes, because they have experience in research evaluation methodology and are conceived, regulated and organized for this task. However, they should add new expert profiles and have sufficient means to extend their evaluations.

SWEDEN

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A brief introduction to this field in Sweden

The Ethical Review Authority (Etikprövningsmyndigheten) is the authority responsible for reviewing and granting ethical approval for research studies in Sweden. The authority has 525 appointed members who, on behalf of the Ethical Review Authority, conduct the ethical examination of submitted applications. The members have different backgrounds and roles in the operation.

Introduction for context on The Act (2003:460) on Ethical Review of Research Involving Humans.[1]

A summary of sections 7-11 of the above-mentioned legal act. The basic principle for ethical review is that research can only be approved if it can be conducted with respect for human dignity and human rights, and fundamental freedom must always be considered in the ethical review.

The well-being of individuals should always take precedence over the needs of society and science. Research can only be approved if the risks it may pose to health, safety and personal integrity of research participants are outweighed by its scientific value.

If the expected result can be achieved through another method that involves less risk to the health, safety, and personal integrity of research participants, the research must not be approved.

The processing of sensitive personal data or data on criminal offenses may only be approved if it is necessary for the research to be conducted.

Finally, the research may only be approved if it is to be conducted by or under the supervision of a researcher who possesses the scientific competence required.[2]

Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

1. Lag (2003:460) om etikprövning av forskning som avser människor.
2. https://etikprovningsmyndigheten.se/om-myndigheten/

The Swedish regulation requires ethics review broadly (including legal research and social sciences research on issues concerning biomedicine broadly defined).

According to section 8 of Lag (SFS 2003:460) om etikprövning av forskning som avser människor (Legislative Act (2003:460) on Ethical Review of Research Involving Humans), the wellbeing of individuals must always take precedence over the needs of society and science. According to section 9 of the same law, research can only be approved if the risks it may pose to the health, safety and personal integrity of research subjects are outweighed by its scientific value.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

The Act on Ethical Review of Research Involving Humans (SFS 2003:460) permits taking into account long-term consequences as well as consequences during the duration of the study.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

It is no general such obligation for the private sector (for the public it most often is, including EU-funding) but it is generally accepted among research funders to follow the ethical and societal considerations of the public funders.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Absolutely yes. Having many years of experience in international and interdisciplinary research projects and programs, I see this all the time nowadays (but not ten years ago at all. Thus, it is becoming more and more frequent to have this types of research groups/collaborations for biomedical research.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **YES, INCREASINGLY**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **UNSURE – DEPENDS ON WHICH GROUP**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **YES, INCREASINGLY**

(4) biomedical research ethics review bodies – **YES**

(5) biomedical researchers (individual scientists) – **UNSURE/VARIES**

(6) bioethics, social sciences, law, humanities, and public health scholars – **YES**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes, I think that is increasingly important.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

I think it depends from country to country how the system is designed and practiced. In Sweden, for example, the system opens up for societal and longer-terms implications, but to what extent that is practiced may differ from body to body. I also think that one reason for that is the background of the people that are assessing the applications. They need more and broader knowledge of these types of implications.

UNITED KINGDOM

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Required, via policy. No regulatory or legal requirement per se.

There appears to be a policy requirement for NHS/HRA research ethics committees (RECs) (which are charged with reviewing health research involving any NHS patients and staff, which is likely to be almost all biomedical research in the UK) to consider the societal implications of proposed research. Whether any given REC actually does so, and how well, is unknown and would require some empirical investigation.

The document, Governance arrangements for Research Ethics Committees (last updated 2021), is the key policy document for NHS/HRA RECs.

It stipulates at para 1.2.2 that RECs must "[…] be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the *expected benefits* for the participants or for science and society" (emphasis added).

Further, it states the following at paragraphs 3.2.3 and 3.3.3:

"[…] RECs take into account the interests and safety of the researchers, *as well as the public interest in reliable evidence affecting health and social care and enable ethical and worthwhile research of benefit to participants or to science and society*."

"The benefits and risks of taking part in research, *and the benefits of research evidence for improved health and social care, should be distributed fairly among all social groups and classes*. Selection criteria in research protocols should not unjustifiably exclude potential participants, for instance on the basis of economic status, culture, age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation. RECs should take these considerations into account in reviewing the ethics of research proposals, particularly those involving under-researched groups."

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Permitted, via policy. No regulatory or legal requirement or prohibition per se.

There is no prohibition per se on NHS/HRA research ethics committees (RECs) (which are charged with reviewing health research involving any NHS patients and staff, which is likely to be almost all biomedical research in the UK) from considering longer-term (beyond the research period) implications of proposed research. Whether any given REC actually does so is unknown and would require some empirical investigation.

The document, *Governance arrangements for Research Ethics Committees* (last updated 2021) does not address whether RECs should or should not consider longer-term (beyond the research period) implications of proposed research. However, the absence of any statement of this affect should be interpreted to mean that RECs could consider this in their review, if they think it appropriate.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Yes. Funders such as Wellcome have a number of policies that may be said to 'require' applicants to consider societal implications and longer-term consequences of proposed research projects. Wellcome also advocates a an "engaged research approach", which means "engaging with stakeholders, from the public to policymakers, opens your research to new perspectives."

Likewise, UKRI (the main public funder in the UK) looks for applications that consider "research impact", which they define as "the demonstrable contribution that excellent research makes to society and the economy. This includes both academic and economic and societal impact."

The ESRC's guidance document Risk and Benefit, it is stated that "Researchers should consider how to balance potential risk to research participants, including immediate, short-term risks and longer term risks (for example, reputational damage), against the benefits and longer-term gains to future beneficiaries. It is the responsibility of the researchers to make such a case in detail to a research ethics committee. In making a decision, research ethics committees (RECs) should weigh up the benefits of the research and consider safety issues and participants' protection" (emphasis added).

The MRC's recently published (January 2024) Guidance on Ethics and Approvals states that applicants should "Ensure research outputs reflect diversity in society: to ensure that research brings fair benefits to all in society, it is important that the participants, proposed analysis and outputs from your research reflect the diversity of the population that you are studying."

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This would likely be welcomed.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Yes.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **Yes.**

(4) biomedical research ethics review bodies – **Yes.**

(5) biomedical researchers (individual scientists) – **Unsure. Some researchers are likely to be supportive, but others may be concerned about 'outside' critics or observers, these scholars 'not understanding' the science, and a potentially slowing down of research and innovation.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

Yes. The NHS/HRA RECs are well regarded and comprised already of multi-disciplinary experts. They should have both the capacity and competence to undertake such an assessment. It is worth noting, however, that some forms of biomedical research may be reviewed by other RECs, such as University RECs, in case the biomedical research does not involve any NHS patients or staff (although this is probably uncommon). University RECs are much more under-regulated and diverse in composition, and there may be more impediments or complexity in relying on them to undertaking such an assessment, or at least with appropriate skill and consistency.

UNITED STATES

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Issue 1: Biomedical Research Ethics Reviews

A. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies (e.g., research ethics committees, institutional review boards) from considering the societal implications of proposed research, such as the economic, health equity, and public health implications? Please attach any relevant regulations or policies.

Prohibit.

Broader societal issues are not required to be addressed and, arguably, are covered by the prohibition on considering "long-range effects" in the next question.

B. Do biomedical research ethics regulations or policies require, permit, or prohibit research ethics review bodies from considering longer-term (beyond the research period) implications of proposed research? Please attach any relevant regulations or policies.

Prohibit.

"The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility." 45 C.F.R. § 46.111(a)(2) (2018). This language links possible long-range effects with risks and generally is interpreted as not wanting possible negative societal consequences from preventing beneficial research. It also could be interpreted as prohibiting potential beneficial effects of the research from overwhelming the individual interests of research participants.

Issue 2: Biomedical Research Funders

A. Do biomedical research funders in the public or private sectors require consideration of societal implications and long-term consequences?

Generally, these issues are not a part of scientific grant applications, but they may be considered by NIH study sections in grant applications. In addition, there are separate research programs, such as the Ethical, Legal, and Social Implications (ELSI) program of the National Human Genome Research Institute of the NIH. Some non-governmental organizations and commercial entities study these issues, but there is no requirement or consistent policy.

B. In your view, would multi-disciplinary bioethics, social science, law, humanities, public health, or other relevant scholars embedded and working with biomedical researchers be a feasible way to analyze societal and long-term implications? Please briefly explain your rationale.

Yes. This approach is a key element of translational bioethics, which has been proposed recently by bioethics scholars for all research funded by the National Center for Advancing Translational Sciences at the NIH, as well as more broadly.

C. In your view, would embedding multi-disciplinary scholars with biomedical researchers or other models of ethics assessments of proposed or ongoing research likely have the support of the following groups? Please answer yes, no, or unsure (including any additional comments) for each of the following:

(1) government agency funders of research – **Unsure. Probably not in the short term for most agencies, but longer-term prospects are better if initial efforts by some agencies are successful.**

(2) non-profit funders of research (e.g., philanthropies, disease advocacy groups) – **Yes. They are concerned about these issues, but they are unlikely to support any measures that they think will interfere with research.**

(3) biomedical research entities in the public, nonprofit, and private sectors (including biotechnology and pharmaceutical companies) – **No. They would likely be concerned about slowing down research.**

(4) biomedical research ethics review bodies – **No. It would make more work and most members do not have a background in social science, humanities, etc.**

(5) biomedical researchers (individual scientists) – **No. At least initially, it can be expected that many would be concerned about negative consequences for funding, and they would be leery of non-scientists passing judgments on their science or ethics. They also would likely object to including a range of other issues (many of which are beyond their areas of expertise) in their protocols submitted for approval by IRBs or funders.**

(6) bioethics, social sciences, law, humanities, and public health scholars – **Yes, but some might be concerned that their ongoing, "traditional" efforts will be preempted or devalued. This is a challenge for translational bioethics.**

Issue 3: Biomedical Ethics Assessments Generally

A. In your view, should societal and longer-term implications of proposed biomedical research be considered in an ethics assessment regardless of the funding source or regulatory requirements?

Yes.

B. In your view, if societal and longer-term implications should be considered in an ethics assessment of proposed biomedical research, are current research ethics review bodies the most appropriate entities to undertake such an assessment? Please briefly explain your rationale.

No. In the U.S., by regulation and tradition IRBs consider the welfare of individual human research participants, but not societal implications or long-term effects. Currently, few IRBs have the expertise, time, or budgets to support these additional activities. There is also no mechanism for resolving conflicts among IRB decisions.