REVIEW ARTICLE

A Canadian Perspective on Ethics Review and Neuroimaging: Tensions and Solutions

Eric Racine, Georg Northoff, Ravi S. Menon, Jonathan Kimmelman, Judy Illes

ABSTRACT: Neuroimaging research has raised ethical concerns such as the management of unexpected findings and the classification and assessment of risks. Research ethics boards (REBs) bear responsibility for the oversight of these challenges but neuroimagers struggle with the practical aspects of ethics review and report that administrative load and inconsistency contribute to eroding confidence and trust in ethics review. Our goal was to discuss and propose strategies for institutional and educational change to improve ethics review. We used an iterative and deliberative workshop-based writing process involving multiple disciplines. We propose recommendations in three tension areas: (1) communication between researchers and REBs; (2) collaboration and sharing of expertise between REBs; and (3) practical considerations and the needs of neuroimagers engaged in the ethics review process. Our recommendations are intended as openings rather than endpoints. Researchers and research ethics governance communities should decide on the future uptake of these recommendations.

RÉSUMÉ: Perspective canadienne sur l'évaluation éthique en neuroimagerie : tensions et solutions. La recherche en neuroimagerie a soulevé des préoccupations éthiques telles la question de découvertes fortuites et la classification et l'évaluation des risques. Les comités d'éthique ont la responsabilité de surveiller ces aspects alors que les chercheurs en neuroimagerie sont aux prises avec les aspects pratiques de l'évaluation éthique et rapportent que le fardeau administratif et les contradictions contribuent à miner la confiance et la crédibilité de l'évaluation éthique. Notre but était de discuter et de proposer des stratégies de changement institutionnel et éducatif afin d'améliorer l'évaluation éthique. Nous avons utilisé un processus itératif et délibératif d'écriture basé sur un atelier impliquant des participants provenant de plusieurs disciplines. Nous proposons des recommandations dans trois domaines où il existe des tensions : 1) la communication entre les chercheurs et les comités d'éthique ; 2) la collaboration et la mise en commun de l'expertise entre les comités d'éthique ; et 3) les considérations pratiques et les besoins des chercheurs en neuroimagerie impliqués dans le processus de révision éthique. Nous proposons ces recommandations comme des ouvertures et non des points d'aboutissement. Les chercheurs et les comités chargés de la gouvernance de l'éthique de la recherche devraient déterminer la suite à donner à ces recommandations.

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Neuroimaging studies based on methods such as functional Magnetic Resonance Imaging (fMRI) seek to understand brain function in healthy and clinical populations spanning a wide-range of age groups, experimental questions, and brain-related conditions. Participation in neuroimaging research as well as findings derived from such studies have raised concerns that fall within the context of ethics. These include, for example, questions regarding the management of unexpected findings of possible clinical significance,[1,2] the classification and assessment of risks to human subjects,[3-5] the implementation of guidance and oversight,[6] and the identification of broader social consequences that could result from neuroimaging research.[7,8] It is essential that these challenges are addressed head-on by the neuroscience community to ensure the protection of subjects as well as to preserve the ongoing dynamism of this burgeoning research.

Research ethics boards (REBs) also bear responsibility for the oversight of these challenges, but finding solutions and common ground between REBs and researchers has proven to be difficult.[1,7,9] For example, there are different views on best practices for managing incidental findings,[7] discrepancies on how risks related to fMRI are assessed,[5] and consensus is

From the Neuroethics Research Unit (ER), Institut de recherches cliniques de Montréal; Biomedical Ethics Unit (ER, JK), Division of Experimental Medicine (ER), Department of Neurology/Neurosurgery (ER), Department of Human Genetics (JK), Department of Social Studies of Medicine (JK), McGill University; Departments of Medicine and Social and Preventive Medicine (ER), Bioethics Programs, University of Montreal, Montreal, Quebec; Mind, Brain Imaging and Neuroethics (GN), Institute of Mental Health Research (GN), University of Ottawa; Royal Ottawa Healthcare Group (GN), Ottawa; Robarts Research Institute (RSM), Medical Biophysics (RSM), University of Western Ontario, London, Ontario; National Core for Neuroethics (JI), Division of Neurology, Faculty of Medicine, University of British Columbia, Vancouver, British Columbia, Canada.

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Correspondence to: Eric Racine, Institut de recherches cliniques de Montréal (IRCM) 110 avenue des Pins Ouest, Montréal, Quebec, H2W lR7, Canada.

lacking on how best to address broader social issues that are raised by neuroimaging results.[7] Neuroimagers also struggle with the practical aspects of ethics review and report that administrative load and inconsistency contribute to eroding confidence and trust in ethics review.[7,9,10] Similar concerns have been articulated by the broader neuroscience research community,[11] and the result has been a call for greater collaboration between researchers and REBs, and better standardization between and within REBs themselves.[12] In the North American context, two recent studies have established the existence of important barriers to the development of research ethics in neuroimaging based on a survey and interview-based study of Canadian neuroimagers[7] as well as a larger-scale survey study of North American neuroscientists.[9] Our goal here is to respond to the call for greater collaboration on ethical issues related to neuroimaging research specifically, benefitting from the cross-fertilization of knowledge, ideas, collective creative thinking, and proactive ethics reflection among the author group and interactions with a larger group of interdisciplinary scholars. We focus on the relationships between researchers and research ethics boards, and on strategies for institutional and educational change to improve ethics review in neuroimaging research.

Methods And Materials

We used an iterative and deliberative writing process based on previous work involving multiple disciplines in decision- and consensus-making.[13,14] We focused on three tension areas that have been highlighted in past research[5,10,15-24] and expert opinion: (1) communication between researchers and REBs; (2) collaboration and sharing of expertise between REBs; and (3) practical considerations and the needs of neuroimagers engaged in the ethics review process. We focus on primary neuroimaging research only. We do not tackle specific issues of more general clinical research that may include imaging.

Participants selected for this initiative were identified based on their relevant expertise and leadership in research ethics, neuroimaging research, policy, and ethics governance. There were 19 participants in the workshop coming from different disciplinary backgrounds and Canadian institutions. (Please see acknowledgments for the list of participants and their institutions.) Seven participants were current or former REB members. The group met face-to-face for a one-day meeting that involved both plenary and break-out group sessions, and then worked iteratively using electronic communication. Results and recommendations were derived from the discussions and by consultation of the transcripts. Although we assert that all parties share responsibility for realizing positive change to the challenges raised, we organized our recommendations according to the party (neuroimagers, REBs, and institutions [academic and funding]) who we believe holds primary responsibility for action.

Results

We provide 26 key recommendations for neuroimagers, REBs, academic institutions, and funding bodies to consider (Table 1)

1. Communication Between Researchers and REBS

Challenges

In an effort to sustain and revamp ethics review of neuroimaging research, good communication between REBs and neuroimagers is a desirable goal. Effective communication requires respect for all involved and the use of corresponding approaches that engage all parties equally. However, we identified substantial challenges related to communication and, more profoundly, challenges associated with mutual understanding that compromise trust as follows:

- The relationship between REBs and researchers is often marked by frustration and lack of mutual confidence. This has been reported in the literature on the ethics of neuroimaging[7,9] and surfaced in our discussions. The process of independent ethics review requires REBs to make their own assessment rather than to defer to the judgment of researchers. As a result, a certain distance between the REB and the researcher needs to be maintained during the ethics review process to ensure independence. Misunderstanding of this aspect of the REB's approach and process could be interpreted as mistrust and unjustified questioning of the researcher's credentials.
- Neuroimagers misunderstand how REBs work and the purposes of ethics review.[9] Correspondingly, REBs struggle to understand neuroimaging modalities and to determine the appropriate level of risk they pose. Research ethics boards were described by neuroimagers as a "black box" while neuroimaging modalities were identified reciprocally as a "black box" for REB members. For example, the augmentation of magnetic resonance imaging (MRI) field strength is often interpreted by REBs as a straightforward increase in the risk of the procedure. These challenges in communication and mutual understanding are significant threats to the overall ethics review process.
- Practical inefficiency such as long delays for REB responses and communication and an emphasis on changes considered to be minor in scope or importance further hinder a productive relationship. Previous studies have reported that REBs focus on minor changes (e.g., word smithing), which can frustrate researchers and discredit the ethics review process.[7,8,25-27] Wording (e.g., in consent forms) may have legal or regulatory significance and research subjects may not understand what is clear to experts. Researchers also need to do their share to ensure that all relevant information required by the REB is provided explicitly and in a timely manner to avoid delays. In addition, prior biases against the ethics review process – viewing the ethics review process as a regulatory hurdle rather than as a chance to explicitly engage in ethical dimensions of protocols, and failing to appreciate the salient ethical dimensions of protocols[7,9] – can lead to unnecessary delay in spite of well-intentioned efforts of the REB.

Recommendations

Neuroimagers

Encourage early exposure of trainees to ethics: Encourage early exposure of new investigators to REBs and early interactions of researchers by increasing the familiarity of trainees with ethics requirements and the ethics review process. Mentors and graduate training programs can play an important

Table 1: Key recommendations and actions to improve ethics review of neuroimaging research

Stakeholders	Specific recommendations
Communication between researchers and REBs	
Neuroimaging researchers	Encourage early exposure of trainees to ethics
	Increase participation of researchers in ethics review
Research Ethics Boards	Foster direct, in-person, communication between REBs and neuroimagers
	Ensure clarity in the communication of changes requested
	Increase transparency about the rationale of decisions
	Prioritize efficient communication
	Foster collegiality in communication
	Experiment with community-level communication
Academic institutions and funding bodies	Implement platforms for information- and resource-sharing
Collaborations and sharing expertise between research ethics boards	
Neuroimaging researchers	Foster dialogue at national meetings and professional societies
Research Ethics Boards	Refine and reflect on processes of collaborative ethics review
	Establish collaborations among REBs
Academic institutions and funding bodies	Reflect on and develop, as appropriate, a centralized ethics review process
	Develop a clearinghouse for information on ethics review of neuroimaging
	Understand the cost of ethics review
	Recognize the contribution of REB members with appropriate currency
Practical needs of researchers in ethics review	
Neuroimaging researchers	Engage in discussions about the risks of imaging modalities and risks related to specific protocols
	Recognize that REBs need to examine scientific validity to assess risks
	Participate in research on research ethics in neuroimaging and in efforts to develop tailored guidance
Research Ethics Boards	Take into account the specific nature of protocols, including target populations
	Adopt subject-oriented and evidence-based recommendations for informed consent and research ethics practices
	Participate in research on research ethics in neuroimaging and in efforts to develop tailored guidance
Academic institutions and funding bodies	Clarify the role of REBs in examining scientific validity
	Update guidelines on the risks of neuroimaging modalities like MRI
	Develop training modules on research ethics in neuroimaging for neuroimagers and REBs
	Support the development of research on ethics in neuroimaging and support efforts to develop tailored guidance

role in carrying forward this component of training.[28] Hands-on ethics training would beneficially supplement theoretical training, which is becoming a requirement of some funding bodies.

Increase participation of researchers in ethics review: Service as an REB member will have the reciprocal benefit of exposing neuroimagers to the workings of REBs while bringing scientific expertise to the REB table.

Research ethics boards

Foster direct, in-person, communication between REBs and neuroimagers: Encourage and create opportunities for neuroimagers to explain studies in person, leading to dialogue and transparency between researchers and REB members. We believe that the benefits of this recommendation currently outweighs the downsides although a better understanding of the possible beneficial and negative effects of the attendance of investigators at REB meetings is needed.[29]

Ensure clarity in the communication of changes requested: Distinguish minor (e.g., benign terminological or language changes) from major conceptual or substantial changes in review decisions and related communications. Minor changes should be handled quickly and should not require full board re-review when this is still in practice. A reasonable option would be to leave open the possibility of granting conditional approval while waiting for minor changes to be made.

Increase transparency about the rationale of decisions: Communicate the rationale behind reviews and approval decisions concerning neuroimaging protocols, especially when decisions vary between similar protocols. Further, processes for transferring information about neuroimaging protocols across rotating REB members ("institutional learning") should be developed. Such learning could take the form of a "book of reasoned decisions" to help consolidate perspectives on decisions and share insights between REB members. This would allow REBs and neuroimagers to benefit from precedent decisions but without being bound to them, and avoid "reinventing the wheel" for each similar protocol, which can lead to delay, frustration, and misunderstandings. There are other tools REBs could develop to provide assistance to neuroimagers in high volume centers. Documents such as a Question and

Answer page or a model protocol are examples of simple tools that REBs could make available to researchers.

Prioritize efficient communication: Research ethics boards should prioritize communication efficiency using modern methods (e.g., electronic submission of protocols and electronic communication methods). This can be achieved while preserving the human face of communication by assigning protocols to an REB staff member who becomes ultimately responsible for shepherding them through the process.

Foster collegiality in communication: Researchers who take a defensive stance at the onset of the ethics review process may inadvertently fuel sentiments countering collegiality and openness. Research ethics boards may also inadvertently nourish perceptions of distrust although their independence and authority is essential. There are ways that REBs and investigators can work together to foster a productive working relationship that is non-adversarial. Researchers should endeavor to clearly justify practices within protocols that may be ethically contentious and REBs should be as transparent as possible about the rationale for major criticisms in a protocol.

Experiment with community-level communication: Develop and test communication pathways between REB networks and professional societies that could replace the time-consuming "single-researcher" and "single-REB" interactions. Community-level communication would help tackle issues common to both the community of researchers and the community of REBs involved in the review of neuroimaging research. For example, both our discussions as well as field research have highlighted a gap between the ethics literature on incidental findings and the uptake of recommendations and guidance by local researchers and local REBs.[7]

Academic institutions and funding bodies

Implement platforms for information- and resource-sharing: Both virtual and physical platforms for sharing information and resources online such as approval application forms, consent forms, protocols, and exemplar materials could potentially improve the quality and efficiency in REB submissions and thus improve the soundness of ethical review and decision-making.

2. Collaborations and Sharing Expertise Between Research Ethics Boards

Challenges

Greater collaborations between REBs will enable the sharing of expertise, tools, and resources and improve both the rigor and the practical handling of ethics review of neuroimaging research as well as ensure consistency in review between sites. Some examples to build on are the clarifications from the Department of Health and Human Services[30] on ethics review of MRI research; the Canadian Association of Research Ethics Boards (http://www.careb-accer.org/); and collaborative ethics review processes like the one developed by the Regroupement Neuroimagerie Québec based at the Université de Montréal. Ongoing sources of tension reflect a lack of collaboration or jeopardize collaboration between REBs as well as between neuroimagers and REBs. Some of these sources of tensions are:

- REBs that are understaffed, under resourced, under-valued and under-recognized by institutions and funding bodies.
- The lack of familiarity of many REBs with neuroimaging research design, neuroimaging equipment, and neuroimaging data analysis procedures as well as a lack of an identified pool of experts to draw from when needed.[5]
- Frequent rotation of REB members that create challenges for consistency and familiarity with neuroimaging research combined with lack of clear standards and practices for the training of REB members.
- The existence of multiple sources of information with conflicting answers to scientific and ethical questions (e.g., in Canada, the gaps between the detailed peer review literature on incidental findings and the limited guidance presented in the Tri-Council Policy Statement until recently).
- Outdated guidelines for MRI (e.g., Health Canada's guidelines on MRI date back to 1987[31]) and the absence of specific guidelines for newer imaging technologies (e.g., magnetoencephalography, transcranial magnetic stimulation, and near infrared spectroscopy) and the combination of technologies that imply new risks.

Recommendations

Neuroimagers

Foster dialogue at national meetings and professional societies: Foster discussion on challenges of ethics review of neuroimaging research at national meetings like meetings and associations of REBs (e.g., Canadian Association of Research Ethics Boards). Likewise, develop discussion on the challenges of ethics review at neuroimaging and neuroscience meetings such as the Canadian Association for Neuroscience and the Society for Neuroscience. Sharing of the outcomes of these discussions between the REB and neuroscience communities and professional meetings and associations should also be enhanced.

Research ethics boards

Refine and reflect on processes of collaborative ethics review: The momentum and experience gained from collaborative ethics review of neuroimaging in Québec and Ontario[24] are examples of collaborations between REBs that can serve to fill an intermediate-level policy gap between REBs and general ethics policies.

Establish collaborations among REBs: Collaborations between REBs may improve both the rigor and the practical handling of ethics review of neuroimaging research while the possible pitfalls of group dynamics need to be acknowledged.[32] REBs can leverage prior scholarship and research networks to achieve this goal.

Academic institutions and funding bodies

Reflect on and develop, as appropriate, a centralized ethics review process: A centralized body for ethics review of neuroimaging is one solution to streamlining review and improving efficiency. The centralized review of stem cell research at the Canadian Institutes of Health Research (CIHR), for example, is a model that can be further examined and tested for neuroimaging research.[33]

Develop a clearinghouse for information on ethics review of neuroimaging: In addition to a dedicated centralized review body, we recommend a clearinghouse for information on ethics review of neuroimaging. This could be put in place by neuroimagers and REBs in partnership with national research associations or national funding bodies (e.g., Canadian Association for Neuroscience, CIHR) and international societies (e.g., Society for Neuroscience). For example, templates such as for risk and benefit statements,[5] consent forms, lists of experts in ethics and neuroimaging for REBs to consult, neuroimaging service centers, and potentially standard operation procedures could all be shared amongst and between institutions. Educational material developed for REBs should include any available up to date consensus guidelines. This clearinghouse would work in close connection with the central body for ethics review as well as with research centers and funding bodies.

Understand the cost of ethics review: The cost of ethics review, including multi-site review, should be investigated by funding bodies in partnership with academic institutions. Both the real and hidden cost of volunteered time must be taken into account and better assessed. Depending on the results of such an investigation, better tailored support and resources of ethics review could be established.

Recognize the contribution of REB members with appropriate currency: Volunteerism and professionalism should not go unrecognized. When financial remuneration is not the mechanism of compensation for REB members, then acknowledgment, teaching relief, and academic credit are appropriate and necessary alternatives for valuing explicitly REB service. Research ethics board service is still under-appreciated and clear signals should be sent to the research community about the importance of REB service.

3. Practical Needs of Researchers in Ethics Review

Challenges

Beyond communication and collaboration, practical challenges for neuroimagers are:

- The skewed perception of MRI as a uniformly high-risk procedure: The technological profile of MRI fosters perceptions of risk while some of the most important risks and burdens may actually be related to the paradigms used in experiments (e.g., fear, deception, pain, traumatic memories).
- Duplication of peer review: Charged with the responsibility of assessing the risk-benefit ratio of protocols, review by REB members for ethics consideration can be perceived by researchers to be redundant with scientific peer review. If the former challenges or contradicts the latter, frustration is likely to ensue, especially against the backdrop of a funded proposal. This calls for greater clarification of the goals of assessing scientific validity in ethics review.
- Law and liability: Legal and liability concerns are related to, but different from, ethics issues. Researchers perceive that lengthy consent forms are solely the result of the need for risk management driven by the law, rather than a means to ensure subject welfare, which is underscored by ethics.[25] Law is also a mechanism to promote subject welfare but uses a different means of encouraging those outcomes than ethics processes.
- Guidance on substantial issues such as incidental findings: There is a need for evidence-based research on ethics practices in matters, for example, of informed consent for incidental findings.[2,34,35]

Recommendations

Neuroimagers

Engage in discussions about the risks of imaging modalities and risks related to specific protocols: Imaging modalities like fMRI typically pose minimal risk but depending on study designs and the measures in place to deal with risk management, the risk profile of fMRI studies can be significant. Neuroimagers need to engage in peer discussion to better characterize the risks of neuroimaging tools like MRI and fMRI and publish up-to-date systematic reviews and consensus statements. For example, a review of risks in pediatric MRI has identified corresponding strategies to mitigate risks.[4]

Recognize that REBs need to examine scientific validity to assess risks: Neuroimagers must value the task of REBs to identify and assess risk; scrutiny of the scientific merits of a protocol is needed to satisfy the mandate of determining acceptable risk. However redundant it may appear to some, REBs are acting within their mandates of subject protection and subject information and their scrutiny of scientific validity is not entirely redundant. At the same time, the goals and standards for assessing scientific value to determine the eligibility for funding a protocol (e.g., by an expert peer-review committee of a funding body) may overlap but is distinct from the assessment of an REB, which focuses on the risk-benefit trade-off. Research ethics boards may be qualified to engage in the latter but not the former and therefore, as described above, their role in examining scientific validity needs to be focused.

Participate in research on research ethics in neuroimaging and in efforts to develop tailored guidance: Researchers can solicit the collaboration of ethicists to engage in research to better develop evidence-based practices in the area of informed consent and the practical handling of research ethics challenges. For example, criteria for writing good consent forms should be identified in order to guide practice.

Research Ethics Boards

Take into account the specific nature of protocols, including target populations to assess risks: Adjust risk and benefit assessment to take into account specific features of protocols. Research involving participants from historically vulnerable populations may change the threshold of acceptable risk or minimal risk but other factors such as task demands are also critical in this decision and can augment risks related to a specific protocol.

Adopt subject-oriented and evidence-based recommendations for informed consent and research ethics practices: Successful uptake of evidence-based research ethics should be a shared responsibility of researchers, REBs, and institutional bodies. Research ethics boards are well positioned to promote evidence in research ethics even though they would need dedicated resources and support to fully play this role.

Participate in research on research ethics in neuroimaging and in efforts to develop tailored guidance: Studies have reported challenges in understanding how REBs deal with ethics review of neuroimaging,[5,7] and there is little REB participation

in this research. Lack of time and a sense of external evaluation, among other factors, might account for this phenomenon. Further understanding of impediments to research participation of REB members is crucial to develop evidenced-based research ethics. Once the causes are better understood, funding bodies and academic institutions should provide the required support to ensure that ethics review is part of a knowledge cycle that includes empirical research on REB practices per se.

Academic institutions and funding bodies

Clarify the role of REBs in examining scientific validity: As stated above, REBs are responsible for assessing the risk-benefit ratio of protocols and this task includes, logically, consideration of the scientific validity of protocols. Research ethics board members need to be instructed and trained to understand and interpret their specific role with respect to established policies.

Update guidelines on the risks of neuroimaging modalities like MRI: A key tension point in current ethics review concerns the risks of new neuroimaging modalities such as MRI. The MRI has been used in clinical practice and in research studies for three decades, but in REBs, research uses have brought several questions about their risks. The Health Canada guidelines on MRI are dated[31] and need revisions to bring them up to modern international standards such as the American Food and Drug Administration.[36-39] While we await revised Health Canada guidelines (which, to our knowledge, is not underway), the revised Food and Drug Administration guidelines could be used. Funding bodies like the Institute of Neuroscience, Mental Health, and Addiction of the CIHR and agencies like Health Canada should collaborate to develop guidelines for Canadian neuroimaging researchers.

Develop training modules on research ethics in neuroimaging for neuroimagers and REBs: Training modules for REBs and neuroimagers on basic ethical and legal concepts should be developed by funding bodies. Alternatively, those already in place at academic institutions should be recognized and shared. Training should also be developed for good ethics practices for both investigators and trainees. Such training would integrate ethics in actual experimental procedures and go beyond the ethics review process and decision, ideally being reflected in the culture of research groups. Legal representatives of institutions can also play a key role on REBs to clarify the mandate of REBs, as can the offices of legal counsel, and risk-management. These concerns are heightened in the cases of multi-center initiatives because applicable law can differ between states, provinces, and countries. Centers with high volumes of ethics review in neuroimaging may be most concerned with these recommendations.

Support the development of research on ethics in neuroimaging and support efforts to develop tailored guidance: The support of academic institutions and funding bodies will be a vital force in improving ethics review by enabling the acquisition of data about research ethics practices, uptake of guidance, and sufficient time and resources to further integrate evidence-based practices in ethics review.

Table 1 provides a full summary of our findings and recommendations.

Limitations

The problems and solutions for ethics review of neuroimaging reported in this paper are based on the views of a group of neuroscientists, legal and policy scholars, and ethicists. Although they represent diverse interests and institutions and our findings are consistent with and expand on previous work on this topic,[25-27] we do not know the generalizability of the views of these Canadian scholars to others. Given the range and depth of issues tackled, we focused on the Canadian setting to ensure sufficient expertise and familiarity. We provide specific recommendations to important prevailing questions, but have certainly not addressed all. Also, we acknowledge that many of

Table 2: : Standing questions

No consensus reached
• Causes underlying the perception that neuroimaging is risky in spite of a general low risk profile in comparison to standard clinical trials.
• Value of jurisprudence or casuistry as model approaches to establishing precedent-based or case-based research ethics reviews in order to diminish variability and foster consistency in decisions.
• Acceptability of setting limits on lengths of consent forms to strike a balance between subject protection and practicality.
• Role of REBs in issues of public communication of neuroscience, knowledge transfer, and public engagement.
Beyond the scope of work
• Overall cost and efficacy of REB review to institutions, REB members, researchers, and society.
• Overlap between legal counsel within an institution and the role of REBs in addressing legal issues surfacing in research ethics.
• Conflicts of interest in research and industry pressure on research agendas.
• Inadvertent challenges to researchers' sense of responsibility and ownership of research ethics.

the issues tackled in this paper connect to issues faced in other fields. Neuroimaging constitutes one specific context where knowledge and expertise generated in research ethics builds on or extends to other fields of research. Table 2 captures some key questions for which there was no consensus or that fell outside the scope of this initiative. Both sets of questions lend themselves to further research and discussions.

Conclusions

We have identified and presented some significant problems in ethics review that directly concern neuroimagers, REBs, academic institutions, and funding bodies based on a deliberative approach. We tackled three major areas where attention is needed and presented a range of strategies that may be adopted to address the problems identified. Overall, these strategies represent a pragmatic approach to the ethics review process. They are consistent with our view that, like most discussions in the realm of ethics, few solutions are clearly right. Rather, finding solutions in matters of ethics is a creative process based on a continuum of knowledge created through gap identification, discussion, and convergence on action. Our interdisciplinary contribution, therefore, is intended to promote further dialogue, open communication and experimentation, and reflection while rebuilding trust to strenghten relationships among key stakeholders in research. Our recommendations are intended as openings rather than endpoints. As researchers and research ethics governance communities decide on the future uptake of these recommendations, rigorous evaluation for impact and outcome is imperative.

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