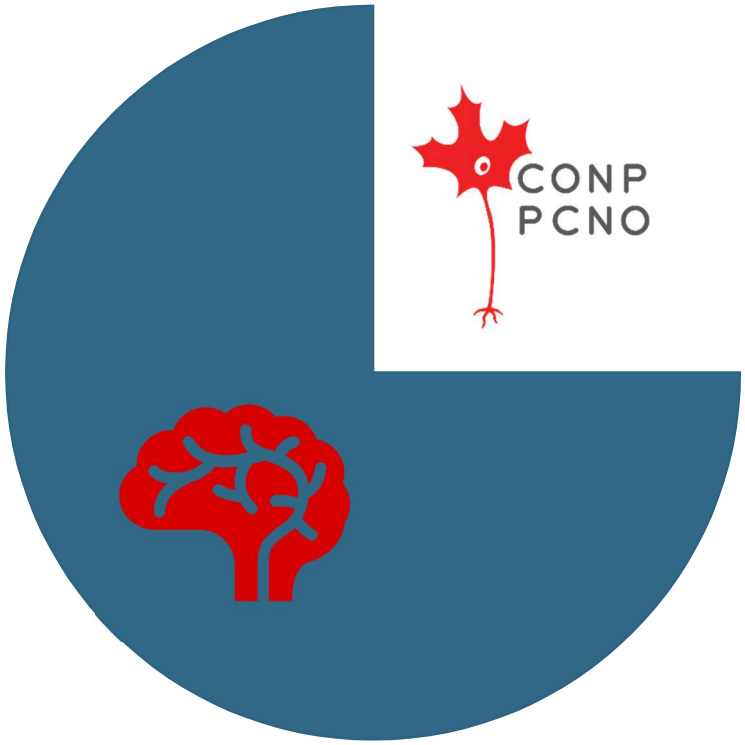
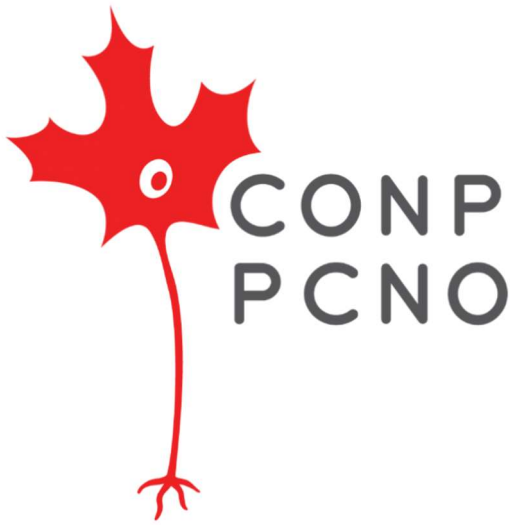


July 17, 2019

CONP Ethics and Data Governance Framework



CONP Ethics and Data Governance Framework

July 17, 2019

The CONP Ethics and Data Governance Framework has been developed by the CONP Ethics and Governance Committee.

This document is currently open for comment until August 17, 2019.

For more information or to submit comments, please contact: adrian.thorogood@mcgill.ca

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The Ethics and Governance Committee would also like to acknowledge the numerous members of the CONP and scientific community who have contributed to this policy.

Canadian Open Neuroscience Platform (CONP) Ethics and Data Governance Framework (v 1.0 17 July 2019)

Executive Summary

This Framework outlines core ethical elements, general principles, and practical guidance for the neuroscience community in Canada and internationally, as it adopts open science practices and develops supporting information and communication technology (ICT) infrastructure, namely the Canadian Open Neuroscience Platform (CONP). Open science involves the rapid and wide distribution of scientific knowledge, in order to improve scientific collaboration, integrity, and reproducibility; accelerate discovery; and improve human health. If conducted responsibly, open science can foster the human right of everyone to share in scientific advancement and its benefits.[1] This Framework focuses on safeguarding the rights and interests of data subjects in open science contexts, which include autonomy, privacy, health, and inclusion. It should be interpreted with reference to the CONP mission.[2]

Core Elements

1. *Researcher Integrity.* Pursue open science with a commitment to excellence, honesty, and the quality of research outputs.
2. *Autonomy.* Respect the voluntary and informed consent – or refusal – of individuals to share their data openly.
3. *Privacy, Confidentiality, and Security.* Protect the privacy, confidentiality, and security of data while maximizing their scientific utility and availability.
4. *Scope of Data Access and Use.* Make data available to any qualified researcher for any legitimate research purpose.
5. *Capacity to Consent.* Strive to include data subjects who lack the capacity to consent in open neuroscience, while ensuring their appropriate involvement in decision-making and protection from harm.
6. *Participant Health.* Ensure data subjects receive information relevant to their health in a timely fashion.
7. *Community Engagement.* Engage communities meaningfully in all aspects of the governance of open neuroscience.
8. *Trust and Accountability.* Ensure and demonstrate open neuroscience networks are able to fulfill their obligations and commitments to data subjects, communities, and society.

[1] United Nations, Universal Declaration of Human Rights (1948), art 27.
[2] Canadian Open Neuroscience Platform (CONP), "Our Mission" https://conp.ca/

Introduction

This Framework outlines core ethical elements, general principles, and practical guidance for the neuroscience community in Canada and internationally, as it adopts open science practices and develops supporting information and communication technology (ICT) infrastructure, namely the Canadian Open Neuroscience Platform (CONP). Open science involves the rapid and wide distribution of scientific knowledge, in order to improve scientific collaboration, integrity, and reproducibility; accelerate discovery; and improve human health. If conducted responsibly, open science can foster the human right of everyone to share in scientific advancement and its benefits.[3] This Framework focuses on safeguarding the rights and interests of data subjects (individuals who participate in or contribute their samples and data to neuroscience research) in open science contexts. These rights and interests include but are not limited to autonomy, privacy, health, and inclusion. It should be interpreted with reference to the CONP mission.[4]

This Framework encourages a shift in perspective from a focus on open science versus ethics, to a focus on open science with ethics.[5] Where the aims of open science and the interests of data subjects do come into conflict, this Framework provides guidance for striking a proportionate balance between them. Such a balance should be evidence-based, regularly assessed, and informed by processes of democratic deliberation.[6] This Framework should be read together with the ***CONP Publication and Commercialization Policies (draft)***, which address aspects of data governance relating to the rights and interests of data producers and data users in open neuroscience.

This Framework aims to help the neuroscience community in Canada and beyond maximize the openness of research, while respecting Canadian regulatory requirements and international norms spanning medical law and ethics, research ethics, and personal (health) information protection laws.[7] It additionally aims to enhance sensitivity to ethical and social issues beyond

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[3] United Nations, Universal Declaration of Human Rights (1948), art 27; Global Alliance for Genomics and Health, "Framework for Responsible Sharing of Genomic and Health-Related Data", (10 September 2014), online: <https://genomicsandhealth.org/about-the-global-alliance/key-documents/framework-responsible-sharing-genomic-and-health-related-data>.

[4] Canadian Open Neuroscience Platform (CONP), "Our Mission" https://conp.ca/

[5] European Union Agency for Network and Information Security, *Privacy by design in big data — ENISA*, Report/Study (2015).

[6] Democratic deliberation is "an approach to collaborative decision making that embraces respectful debate of opposing views and active participation by citizens." (Presidential Commission for the Study of Bioethical Issues, *Gray Matters: Integrative Approaches for Neuroscience, Ethics and Society (Vol 1).* (2014) at 15. See also *International ethical guidelines for health-related research involving humans*, Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (CIOMS/WHO), 2016 [*CIOMS/WHO Guidelines*] at Guideline 7 "Community Engagement".

[7] *Ethical Conduct for Research Involving Humans*, Canada, Tri-Council Policy Statement (TCPS), 2014 [*TCPS2*]. For personal (health) information protection laws, see e.g., Personal Information Protection and Electronic Documents Act (S.C. 2000, c. 5); Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A. See also the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the

the law, and to develop the capacity of the neuroscience community to anticipate emerging issues.[8]

The Framework complements neuroethics policies and literature, which address issues emerging from advances in our ability to understand, monitor, and influence the brain and the resulting implications for human agency.[9] Where data governance concerns research platforms (such as the CONP), it must be flexible enough to support a wide diversity of neuroscience research areas, methodologies, species, populations, data types and normative contexts. Regulatory approaches and ethical issues can differ across jurisdictions (e.g., from province to province), sectors (e.g., academic, health-care, or commercial), and stage of the open science data trajectory (e.g., collection, generation, aggregation, storage, linkage, sharing, and use). Open neuroscience also involves networks of data producers, research platforms, and data users, each with overlapping ethical responsibilities towards data subjects and future patients. While this Framework is limited in scope to applied ethics and data governance issues in open neuroscience involving human participants, it recognizes the need for extensive integration of ethics and neuroscience in all aspects of research governance and education.[10]

Open neuroscience is also closely linked to international collaboration. This Framework promotes interoperability of data governance across jurisdictions, sectors, and projects. It builds on and aligns with best practices developed by CONP partner institutions[11] and platforms supporting open, data-intensive biomedical research in Canada and around the world, including the Ontario Brain Institute[12], Montreal Neurological Institute[13], US BRAIN Initiative[14], the EU Human Brain Project[15], International Brain Initiative[16], and the Global Alliance for Genomics and Health.[17]

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protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[8] "Ethics is more than regulatory compliance or risk mitigation." Presidential Commission for the Study of Bioethical Issues, *supra* note 4 at 12.

[9] Adina Roskies, "Neuroethics" in Edward N Zalta, ed, *Stanf Encycl Philos*, spring 2016 ed (Metaphysics Research Lab, Stanford University, 2016); Judy Illes et al, "A Neuroethics Backbone for the Evolving Canadian Brain Research Strategy" (2019) 101:3 Neuron 370; Jordan Amadio et al, "Neuroethics Questions to Guide Ethical Research in the International Brain Initiatives" (2018) 100:1 Neuron 19.

[10] For the US BRAIN Initiative, there is an effort to integrate ethical, legal, and social issues across neuroscience education, training, funding, etc. Presidential Commission for the Study of Bioethical Issues, *supra* note 4. In the EU, the Human Brain Project approach has split ethics infrastructure into four pillars (ethics support, foresight and researcher awareness, engagement, and neuroethics and philosophy). https://www.humanbrainproject.eu/en/social-ethical-reflective/

[11] http://conp.ca/about-us/national-partners/

[12] Ontario Brain Institute, Brain-Code Informatics Governance Policy (Feb 3, 2016) v 2.0 https://www.braincode.ca/sites/default/files/about/OBI-Governance-v2-2016-02-03.pdf .

[13] Montreal Neurological Institute, Framework for Open Science at the MNI, Guiding Principles (v 2.0 Dec 2018).

[14] https://www.braininitiative.nih.gov/

[15] https://www.humanbrainproject.eu/en/

[16] http://www.internationalbraininitiative.org/

[17] https://www.ga4gh.org/

ETHICS PRINCIPLES AND GUIDANCE FOR OPEN SCIENCE

1. ***Researcher Integrity.*** **Pursue open science with a commitment to excellence, honesty, and the quality of research outputs.**

    1.1. Researcher integrity includes values of research excellence, as well as honesty about actions, intentions, and conflicts of interest; showing care and respect for data subjects, and being accountable for commitments made to funders, data subjects, fellow researchers and other stakeholders.[18]

    1.2. Researchers should respect their commitments to funders, the research community, journals, and data subjects to make research data openly available.

    1.3. Research should assure the quality and integrity of research data and other outputs through continuous validation.

2. ***Autonomy.*** **Respect the voluntary and informed consent – or refusal – of individuals to share their data openly.[19]**

    2.1. Data producers are responsible for having a data sharing plan when designing a research protocol, so they can seek corresponding ethics approval and participant consent at the outset. Research institutions should provide researchers with support in designing and implementing these plans.

    2.2. Where open science involves the public release or wide distribution of data, data subjects should be informed of any limits on their ability to withdraw their consent. Research platforms should be designed to enhance the ability of data subjects to withdraw their data from future research studies.

    2.3. Open science informational materials (e.g., consent forms, pamphlets, and websites) should clearly address the:

        2.3.1. aims and potential individual and/or societal benefits of open science approaches,

        2.3.2. types of health research that may be conducted using the data,

        2.3.3. likelihood of privacy breaches and risk of harm,

        2.3.4. privacy and security protections in place to prevent or mitigate breaches – while clarifying that open science can never be risk-free, and

        2.3.5. access policies and processes (see s 4).

    2.4. Efforts should be made upon recruitment to ascertain and respect the wishes of data subjects concerning re-contact over time for the purposes of additional data collection or recruitment.

    2.5. Legacy data are previously collected data where the original consent does not fully address new data sharing practices. Sharing or re-using these data may still be justified

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[18] Human Brain Project, Researcher Integrity SOP (19 July 2016).

[19] Montreal Neurological Institute, Open Science Principles, *supra* art 5.3; Global Alliance for Genomics and Health, *Consent Policy*, 27 May 2015 https://www.ga4gh.org/wp-content/uploads/Consent-Policy-Final-27-May-2015.pdf.

where the data are anonymized, or where a research ethics board determines that sharing is in the public interest, re-consent is impracticable, confidentiality and security will be maintained, the privacy risks to data subjects are minimal, known wishes of data subjects are respected, and the research is unlikely to adversely affect data subject welfare.[20]

3. *Privacy, Confidentiality, and Security.* Protect the privacy, confidentiality, and security of data while maximizing their scientific utility and availability.

Privacy

3.1. Open neuroscience should adopt a privacy model that strikes a proportionate balance between protecting data subject anonymity and maintaining data utility, considering the context of data release (a privacy model statistically demonstrates a target level of data subject anonymity in a given context).

3.2. Identifiable data should generally be removed from datasets before release (information that is reasonably likely to directly, or indirectly in combination with other information, identify an individual).

3.3. Coded data may be preferable to anonymized data. Coded data are separated from identifiers, which are replaced with a random code and can only be re-identified with access to additional information kept securely. Anonymized data are irreversibly separated from identifiers. This offers greater privacy protection but may decrease the scientific utility and value of data (e.g., precludes follow-up or linkage), and affect the interests of data subjects (e.g., the ability to withdraw data, or to receive individual research results and incidental findings). Research ethics board review is generally required for secondary use of coded or anonymized data (see s 2.4).

3.4. Special attention should be paid to protecting sensitive data generated in certain neuroscience contexts, e.g., data relating to stigmatized conditions or behaviours, or potentially revealing data subjects' intimate thoughts and memories.

3.5. Privacy by design emphasizes embedding privacy as a priority in all aspects of organizational governance. Processes should be in place to protect privacy, including education and training of technical staff, privacy impact assessments, identifying personnel responsible for privacy, audits, and breach handling/reporting. Such processes are compatible with the goals of open science to maximize the availability and scientific utility of neuroscience data.

3.6. De-identifying data is an important safeguard even where the resulting dataset remains identifiable.[21] Best practices for different data types should be followed (e.g., de-facing for MRI data).[22]

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[20] *TCPS2*, *supra* note 5, arts 3.7A, 5.5.
[21] Mark Phillips & Bartha M Knoppers, "The discombobulation of de-identification" (2016) 34 Nat Biotechnol 1102.
[22] Amanda Bischoff-Grethe et al, "A Technique for the Deidentification of Structural Brain MR Images" (2007) 28:9 Hum Brain Mapp 892.

3.7. Individual-level data linkage enriches the scientific utility of data but can also increase the privacy risks of datasets, and affect the contextual integrity under which data subjects agreed to participate in open neuroscience.[23] Privacy safeguards should be in place when conducting individual-level linkage (e.g., privacy impact assessments, contractual restrictions on unauthorized linkage).
3.8. Researchers using open science data should not attempt to re-identify data subjects from coded or anonymized data without appropriate authorization.[24]
3.9. Privacy must be considered across the entire data life cycle, including the eventual destruction or permanent archiving of data.

Confidentiality

3.10. By default, open neuroscience data should be released as openly as possible. Data not bound by confidentiality requirements (e.g., anonymized data) should not be treated as confidential.
3.11. When sharing scientifically useful data that are confidential by default (e.g., identifiable information), data subjects' voluntary and informed consent to public release or wide sharing of data should be taken at the time of recruitment. It should be made clear that confidentiality and security are not guaranteed.
3.12. Confidential data can be made available across a trusted network of researchers, by ensuring appropriate standards of oversight, confidentiality, and security across the network.

Security

3.13. Trust in open neuroscience depends on establishing proportionate security standards (including administrative, technical, and organizational safeguards) at research institutions and across distributed, open science networks.
3.14. Important aspects of security in open science environments include identity management and authentication, access authorization, and ongoing auditing.[25]
3.15. Security safeguards should be resilient (e.g., technical protections can be backed up by contractual safeguards and breach reporting obligations).[26]
3.16. Technologies that facilitate secure sharing should be explored, such as encryption for data at rest and in flight, secure cloud computing environments, and networks of secure datasets made available for federated search queries or analyses.

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[23] Helen Nissenbaum, "Privacy as contextual integrity" (2004) 79 Wash Law Rev 119.
[24] Global Alliance for Genomics and Health, *Data Privacy and Security Policy (draft)* (2019) https://www.ga4gh.org/wp-content/uploads/Privacy-and-Security-Policy.pdf.
[25] Global Alliance for Genomics and Health, *Security Technology Infrastructure: Standards and implementation practices for protecting the privacy of shared genomic and clinical data*, v 3.0 (2019).
[26] *Ibid*.

3.17. Risk assessments should be performed at regular intervals or whenever major changes are made to data sharing plans or platforms, and should consider risks to both the institution and the open science ecosystem.[27]

4. *Scope of Data Access and Use.* Make data available to any qualified researcher for any legitimate research purpose.

4.1. One focus of open science is to encourage the creativity and freedom of researchers to use data in innovative ways, as long as they can demonstrate they are contributing to improving general knowledge of health and disease.

4.2. Open neuroscience data should generally be made publicly available, subject to appropriate processes of de-identification, consents and approvals. Even for publicly available data, user identification, training, and terms of use may still be desirable to track impact and encourage ethical behavior.

4.3. A broad characterization of scope of use should be incorporated into open neuroscience protocols and consent documents when seeking permissions from research ethics boards and data subjects.

4.4. Limits on the scope of access and use may exceptionally be needed to prevent misuse and to respect the rights, interests, and reasonable expectations of data subjects. Any limits on use should be clearly communicated and respected across open science networks.

4.5. Misuse of open neuroscience data should be clearly defined, and to the extent feasible monitored and sanctioned.[28] Common characterizations of data misuse may include undesirable military purposes, nefarious or criminal activities, marketing or intelligence gathering, or direct sale of data for commercial gain.

4.6. Where restrictions must be placed on access for legal or ethical reasons, access policies and processes should be transparently defined.

4.6.1. This includes defining what data are available, who can access data (e.g., qualified researchers), for what purposes, what body makes access decisions (e.g., a research ethics board or data access committee), what processes the body follows, what terms and conditions apply to data users, and how compliance with those conditions will be monitored and enforced.

4.6.2. Access policies and processes should ensure standards of research oversight, scope of use, and privacy and security protection are upheld, while also coordinating between access bodies to avoid duplicative regulation.[29]

4.6.3. Access processes should respect principles of independence, non-discrimination, and procedural fairness (e.g., by providing reasoned decisions for access refusals).

4.6.4. Transparent information should be made available about access (e.g., list of users and lay abstracts).

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[27] *Ibid*.

[28] Luciano Floridi et al, "Key Ethical Challenges in the European Medical Information Framework" (2018) Minds Mach, online: <https://doi.org/10.1007/s11023-018-9467-4>.

[29] Global Alliance for Genomics and Health, *Ethics Review Equivalency Policy* (13 February 2017). https://www.ga4gh.org/docs/ga4ghtoolkit/regulatoryandethics/GA4GH-Ethics-Review-Recognition-Policy.pdf

4.7. To ensure data are as open as possible, data can be divided into tiers according to sensitivity. Some research data can be made publicly available (which can support discovery of data), while access to more sensitive research data can be limited to qualified researchers (e.g., through registered or controlled access models).[30]
4.8. Access policies and processes should be harmonized, or even centralized, where possible, to streamline access to multiple data sets.

5. *Capacity to Consent.* Strive to include data subjects who lack the capacity to consent in open neuroscience, while ensuring their appropriate involvement in decision-making and protection from harm.

5.1. Neuroscience often involves the study of children and individuals with conditions that may affect decision-making capacity (e.g., neurological or psychiatric conditions).
5.2. Safeguards for their inclusion, involvement, and protection in decisions may include:
  5.2.1. risk-benefit assessments to ensure research or data release are likely to benefit a similar age or disease group;
  5.2.2. informed consent from a parent or legally authorized representative (LAR);
  5.2.3. duties of researchers and parents/LARs to consult the individual, and processes to obtain the individual's assent to participation or to respect a refusal where appropriate.
  5.2.4. criteria to guide proxy decision making (e.g., respect for the individual's immediate and long-term interests; current wishes; and previously expressed wishes, values and beliefs).
5.3. Guidelines should be developed that clarify who may act as an LAR for open neuroscience across Canadian jurisdictions, and under what conditions.
5.4. Data sharing plans should anticipate changes in legal status that could affect the future availability of data (e.g., when a minor reaches majority or when an adult loses capacity or passes away).
5.5. Future efforts are needed to develop and validate the concept of capacity, capacity assessment tools, and tailored communication tools, for open neuroscience contexts.[31]

6. *Participant Health.* Ensure data subjects receive information relevant to their health in a timely fashion.

6.1. Baseline health assessments, brain imaging, and molecular sequencing, among other research methods, may reveal individual-level findings useful to the health of data subjects (variously referred to as individual research results, incidental findings, and secondary findings).

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[30] Stephanie OM Dyke et al, "Registered access: a 'Triple-A'approach" (2016) 24:12 Eur J Hum Genet 1676.
[31] Presidential Commission for the Study of Bioethical Issues, *Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (Vol 2)* (2015) at recs 6,7.

6.2. The neuroscience community should establish standard definitions, responsibilities, processes, and procedures to ensure individual-level findings with significant welfare implications for data subjects (or potentially also their family members) are effectively identified, assessed, validated, and communicated to those who consent to receive them.[32] Standards should be flexible enough to be applied across different contexts (e.g., population, technology platform, data type, and institutional setting). Areas for standardization include:
    - definitions (type of finding, significance, usefulness),
    - data quality,
    - elements of return plans,
    - informed consent descriptions of the nature/likelihood of findings and return plan (and opportunity for opt-out),
    - the appropriateness and feasibility of routine screening, assessment, and validation (considering potential risks and benefits),
    - communication processes,
    - special considerations for family members or children (e.g., return of adult onset conditions), and
    - ultimate responsibility for clinical follow-up.[33]

6.3. Researchers who collect, produce, and initially analyze data are primarily responsible for anticipating and handling such findings. Where it is foreseeable that individual-level findings may be identified by other researchers after data are released, data producers and research platforms should clearly inform data users of their respective responsibilities for handling incidental findings, and the policy and process for reporting them.[34]

6.4. Evidence about the incidence of individual findings, and the utility versus risks of returning them should be collected on an ongoing basis.[35]

7. *Community Engagement.* Engage communities meaningfully in all aspects of the governance of open neuroscience.

7.1. Engaging communities from which data subjects are recruited can improve the quality of and support for open neuroscience.[36]

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[32] National Academies of Sciences & Medicine, *Returning individual research results to participants: Guidance for a new research paradigm* (National Academies Press, 2018).
[33] Eline M Bunnik et al, "Ethical framework for the detection, management and communication of incidental findings in imaging studies, building on an interview study of researchers' practices and perspectives" (2017) 18:1 BMC Med Ethics 10; Roel HP Wouters et al, "Scanning the body, sequencing the genome: Dealing with unsolicited findings" (2017) 31:9 Bioethics 648; Judy Illes & Vivian Nora Chin, "Bridging philosophical and practical implications of incidental findings in brain research" (2008) 36:2 J Law Med Ethics 298.
[34] Susan M Wolf, "Return of results in genomic biobank research: ethics matters" (2013) 15:2 Genet Med 157.
[35] Nadia A Scott, Timothy H Murphy & Judy Illes, "Incidental findings in neuroimaging research: a framework for anticipating the next frontier" (2012) 7:1 J Empir Res Hum Res Ethics 53.
[36] *CIOMS/WHO Guidelines*, *supra* note 4 at Guideline 7.

7.2. Engagement modalities may include community review, approval, joint development of governance, or involvement in oversight bodies (e.g., data access committees).
7.3. Concerted efforts are needed to engage communities about the aims and anticipated benefits of open neuroscience, as well as to demonstrate its actual benefits over time.
7.4. Engagement may address topics including research priorities, benefit-sharing, community values, privacy risks, access policies, and the design of governance processes and tools (e.g., consent forms).
7.5. Care should be taken to identify appropriate communities and representatives, handle conflicts of interests, manage existing community power dynamics, and address time and cost barriers to participation in engagement.[37]
7.6. Community engagement is especially important for open neuroscience involving Aboriginal communities in Canada, to restore and maintain their trust in research.[38]

8. *Trust and Accountability.* Ensure and demonstrate open neuroscience networks are able to fulfill their obligations and commitments to data subjects, communities, and society.

8.1. Trust in open science depends on the ability of networks of researchers and research institutions to demonstrate they respect their commitments to openness, scientific excellence, and respecting the rights and interests of data subjects.
8.2. It should always be clear who is ultimately accountable to data subjects for ensuring appropriate levels of openness, privacy protection, and security (e.g., the data producer, research platform, and/or data user).
8.3. Research platforms should progressively develop infrastructure to improve the monitoring of data sharing practices to ensure legal and ethical breaches are identified and addressed.[39]
8.4. Research platforms should work to establish categories and criteria to define breaches, and appropriate community responses (e.g., reporting breaches to the researcher's institution; withdrawal of data access permissions).
8.5. Harmonization of ethical governance across institutions can increase the trustworthiness of research networks.
8.6. Breaches are not limited to breaches of data subject privacy. They may equally include breaches of commitments to share data openly.

[37] Canadian Institutes of Health Research Government of Canada, "Draft Ethics Guidance for Developing Research Partnerships with Patients - For public consultation - CIHR", (7 November 2018), online: <http://www.cihr-irsc.gc.ca/e/51226.html>.
[38] *TCPS2*, *supra* note 5 art 9.1.
[39] Global Alliance for Genomics and Health, *Accountability Policy* (2016).