Ethics and human subject research: practices and issues

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The basic idea of the "social sciences" is to use the methods of the natural sciences to examine and try to understand social and political phenomena. In many universities and other research-generating bodies, this is accompanied by the institutionalized belief that standards of ethical review are necessary for researchers using human subjects in the social sciences, and that they should be comparable to those used to protect human subjects of medical and scientific experiments.[1][2][3][4] The University of Toronto (U of T), for example, requires researchers to make use of a "risk matrix" for such research, incorporating "group vulnerability" such as "socio-economic or legal status" and "research risk" such as "stress or anxiety during data collection".[5] Research that involves more than "minimal risk" as evaluated through the matrix requires review by a full ethics board.[6] Similarly, three major funders of Canadian research have collaborated to produce a 216-page policy statement on research involving humans, covering everything from qualitative research and Canada's First Nations to human genetic research and pluripotent stem cells.[7][8][9][10]

The belief that scientific standards of ethical review should be used in the social sciences can be criticized on various grounds, including an alleged lack of historical cases in which subjects have been harmed, supposed capriciousness in the ethics review process within and between institutions, the possibility review boards will be comprised of experts from disciplines unrelated to the research being considered. Other critics highlight how committees may fail to allocate time on the basis of the ethical complexity of a project, how review boards may be overworked and understaffed, and how committee members assess proposals based on personal

[1] A 1979 report on using human subjects for medical research is controversial in the context of the ethics of social science research, with some considering it a largely inapplicable model. United States Department of Health and Human Services, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*.

[2] See: Yanow and Schwartz-Shea, "Reforming Institutional Review Board Policy: Issues in Implementation and Field Research", p. 483.

[3] Tolleson-Rinehart, "A Collision of Noble Goals: Protecting Human Subjects, Improving Health Care, and a Research Agenda for Political Science", p. 508.

[4] Related but somewhat different ethical issues may arise in relation to research that doesn't fall clearly into the domain of social sciences but which may have, for instance, policy implications. For an example, on threats to human beings from chemical flame retardants, see: Cordner and Brown, "Moments of Uncertainty: Ethical Considerations and Emerging Contaminants", p. 469–94.

[5] University of Toronto, *Humans in Research*.

[6] Sharpe, *Research Ethics in the Social Sciences & Humanities*, p. 9.

[7] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*.

[8] An online tutorial also exists: Panel on Research Ethics, *TCPS 2: CORE (Course on Research Ethics)*.

[9] See also: Sharpe, *Research Ethics in the Social Sciences & Humanities*.

[10] Compliance with ethical review processes may also be a requirement for publication in journals. See: Jordan and Hill, "Ethical Assurance Statements in Political Science Journals", p. 243–50.

experience or the quality of the proposal's language.[1112] Further criticisms include how ethical restrictions may limit the ability of researchers to reveal various kinds of wrongdoing observed in the course of their studies, how ethics reviews reduce the productivity of researchers, how requiring ethical approval in advance constrains methods like ethnography, how requirements to destroy raw data can cause problems later, and how ethical review boards may lack a history of effectively protecting research subjects.[131415] Formal processes for data protection may also have little utility in some research contexts, and may even produce false confidence that subjects have been protected effectively.[16] As Mitchell Seligson demonstrates, it is quite possible to both recognize the essential role of ethics review processes for work with human subjects and identify the major shortcomings of those approaches.[17] From the perspective of research within political science, there do seem to be some ethical issues that researchers ought to bear in mind, particularly concerning research on vulnerable individuals and populations, and it seems plausible that ethical review can encourage the due consideration of these issues in many cases. That being said, there are good reasons to question whether existing ethical review processes are well-designed to mitigate these risks, or whether they generate inconvenience for researchers without producing much protection for subjects. Furthermore, there are cases where different understandings of "risk" and "reward" in the context of research generate inconsistent or inadequate guidance about what protections are necessary and what research ought to be done. The main danger with ethics review processes may be substituting a culture of checkbox-ticking for a rigorous and sympathetic examination of the impacts of research on subjects and other relevant individuals and groups.[18] Another important criticism is that the ethics review process inappropriately front-loads methodological design and evaluation in contexts where ethical decisions are necessarily made at multiple stages, from research design to fieldwork to dissemination and

[11] See: Schrag, "The Case against Ethics Review in the Social Sciences", p. 120–131.

[12] Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 502.

[13] See: Schrag, "The Case against Ethics Review in the Social Sciences", p. 120–131.

[14] See also: Yanow and Schwartz-Shea, "Reforming Institutional Review Board Policy: Issues in Implementation and Field Research", p. 484–5.

[15] Porter, "Research Ethics Governance and Political Science in Canada", p. 496.

[16] See: Fujii, "Research Ethics 101: Dilemmas and Responsibilities", p. 719.

[17] Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 477–82.

[18] See: Fujii, "Research Ethics 101: Dilemmas and Responsibilities", p. 717–23.

discussion. Addressing these concerns may involve a measure of institutional process reform, but also involves more abstract elements like the creation and sustenance of a research culture in which normative issues are engaged with consistently and meaningfully.

1 | Protecting the vulnerable

For contemporary Canadian research, standards for working with human subjects have been laid out by major funding bodies which use them as a requirement for receiving funding.[19] The Tri-Council Policy Statement for Research Involving Humans, 2nd Edition (TCPS2) espouses three "core principles": respect for persons, concern for welfare, and justice.[20][21][22][23][24] Reference to the TCPS2 is included in both U of T's university-wide and graduate-student-specific guidance for research on human subjects.[25][26] For social scientists, it is notable that the 2010 update to this statement (originally from 1998) shifts away from the "biomedical model" somewhat, by adding a chapter on qualitative research.[27] Nonetheless, legitimate questions have been raised about the appropriateness of using what was originally a scientific and medical model in the context of social science research, as well as the ways in which the requirements of the policy have been implemented by research institutions.

The main purpose of restrictions on research with human subjects is to prevent exploitation. The TCPS2 draws special attention to the possibility that research subjects will have a diminished ability to exercise autonomy: "[s]ome people may be incapable of exercising autonomy because of youth, cognitive impairment, other mental health issues or illness".[28] Diminished autonomy may have a physiological, cognitive/emotional, or a

[19] Porter, "Research Ethics Governance and Political Science in Canada", p. 495.

[20] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*, p. 8.

[21] These align with the three basic ethical principles of "respect for persons, beneficence, and justice" from the Belmont Report Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 478.

[22] See also: Levine and Skedsvold, "Where the Rubber Meets the Road: Aligning IRBs and Research Practice", p. 501.

[23] Brooks, "The Ethical Treatment of Human Subjects and the Institutional Review Board Process", p. 51–9.

[24] Fujii, "Research Ethics 101: Dilemmas and Responsibilities", p. 716.

[25] University of Toronto, *Humans in Research*.

[26] University of Toronto School of Graduate Studies, *Research Involving Human Subjects: Guide on Ethical Conduct*.

[27] Sharpe, *Research Ethics in the Social Sciences & Humanities*, p. 8.

[28] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*, p. 9.

social basis.[29] It also identifies the risk that individuals will lack "capacity", defined as ability to "understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate".[30] It is probably in this domain that the greatest ethical risks for social science exist, at least in terms of research areas within political science. Decision-makers and bureaucrats occupy positions of power, maintain institutional support, and expect to be subject to questions from journalists, researchers, and the general public.[31][32] For such individuals, it seems generally unlikely that a political science research program will harm or threaten them, except in terms of scholarly criticism of policy procedures or outcomes, which Canadian ethics review bodies have recognized as legitimate.[33] By contrast, some potential research subjects face multiple forms of vulnerability: think of incarcerated First Nations young offenders, the mentally ill, illegal drug addicts, sex workers, or abused children. While working with such subjects may involve many special ethical considerations, a strong case can be made that social science research on their experiences within society could have academic and policy value. If one aim of free and democratic societies is to encourage the equal flourishing of all people and to discourage discrimination and systematic abuse, it is necessary to collect information on the life experiences of members of vulnerable groups, as well as the impacts that past and ongoing policies have had on their lives.[34] For researchers, it is necessary to develop programs of investigation whereby such answers can be found without violating important values about the protection of research subjects.

Interestingly, the TCPS2 also discusses the "inappropriate exclusion" of some groups from research. For instance, it describes how "[w]omen have historically been inappropriately excluded from participating in some research" and how this has "delayed the advancement of knowledge, denied potential benefits to women, and

[29] Sharpe, *Research Ethics in the Social Sciences & Humanities*, p. 11.

[30] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*, p. 40.

[31] The TCPS2 recognizes that "observation of individuals in contexts in which it can be expected that the participants are seeking public visibility" does not require ethical review. University of Toronto School of Graduate Studies, *Research Involving Human Subjects: Guide on Ethical Conduct*.

[32] See also: Porter, "Research Ethics Governance and Political Science in Canada", p. 496.

[33] Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, p. i9.

[34] For example, Canada's 2011 Supreme Court ruling ordering the federal government to grant Vancouver's Insite safe-injection clinic an exemption to the *Controlled Drugs and Substances Act* relied on scholarly research conducted on vulnerable drug-using populations. Supreme Court of Canada, *Canada (Attorney General) v. PHS Community Services Society, 2011 SCC 44, [2011] 3 S.C.R. 134*.

exposed women to harm when research findings from male-only research projects were generalized inappropriately to women".[35] In order to apply this principle, the statement directs researchers not to exclude women from research without a valid reason, and that the reproductive capacity of women should not be taken as such a reason in and of itself.[36][37] The statement similarly highlights the value of improving knowledge of "the unique needs of children throughout their development" as justification for including children in research, subject to appropriate ethical considerations.[38] The statement also discusses the elderly, those who lack the capacity to consent for themselves, and those "whose circumstances may make them vulnerable in the context of research".[39] These articles and the associated passages on application highlight the possibility that researchers may behave in ethically inappropriate ways by choosing to *exclude* members of groups that have sometimes been vulnerable from their research. This complicates the work of researchers seeking to be compliant, since doing so cannot be accomplished simply by excluding members of groups for which research designs may be more difficult to develop and defend. Compliance requires — among other things — developing consent and data-retention procedures that can be justified for use with vulnerable groups.

The policy further requires that researchers consider the "equitable distribution of research benefits", including "new information about social issues", "information sharing", and "improved conditions for a group".[40][41] Even in cases where research concerns subject matter that largely falls in the domain of the natural sciences, sociological issues may arise in relation to its dissemination and social scientists may be able to comment usefully on them.[42] Alissa Cordner and Phil Brown highlight some of the complex issues involved in the communication of results, including the explanation of methods to research subjects, appropriately conveying uncertain and ambiguous results, tailoring the presentation of findings to different audiences, and assessing the policy rele-

[35] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*, p. 48.

[36] Ibid., p. 49.

[37] At the same time, researchers must guard against the over-representation of vulnerable groups. See: Brooks, "The Ethical Treatment of Human Subjects and the Institutional Review Board Process", p. 58–9.

[38] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*, p. 49.

[39] Ibid., p. 52.

[40] Ibid., p. 53.

[41] See also: ibid., p. 109, 124–5.

[42] See: Cordner and Brown, "Moments of Uncertainty: Ethical Considerations and Emerging Contaminants", p. 469–94.

vance of research findings.[43] These considerations demonstrate how ethical decision-making for researchers doesn't end with initial research design, even though that is where the ethics review is generally expected to take place, but may easily extend into the communication of research findings and engagement with the public discussions they induce. As the authors discuss, in the context of these activities, "informal ideas and practices" may take on a larger role in comparison with formal ethical review procedures.[44][45] Institutions aspiring to producing socially- and policy-relevant research while meeting ethical obligations for the treatment of individuals must consider such informal phenomena, in addition to their formalized ethics review processes.

Other dimensions of ethical consideration and protection incorporated into formal policies include procedures for ascertaining free and informed consent, protocols for research methodologies that employ (temporary) deception, privacy and confidentiality, and conflicts of interest.[46] While there are doubtless many circumstances in which appropriately defining and meeting these standards is challenging, they probably involve fewer profound conceptual problems than questions about the appropriate treatment of vulnerable groups and ways of balancing the risks and benefits of human subject research.[47]

2 | Risks and benefits of ethics reviews

The TCPS2 calls for balancing between risks and potential benefits from research, with a higher level of scrutiny to be applied by ethics boards in cases where risks are elevated.[48] The intent is to: "direct the most intensive scrutiny, time and resources, and correspondingly, the most protection, to the most ethically challenging research" and to establish that each project has "a favourable balance of risks and benefits".[49] The notion of 'balance' in this context is somewhat unusual. U of T's School of Graduate Studies, for instance,

[43] See: Cordner and Brown, "Moments of Uncertainty: Ethical Considerations and Emerging Contaminants", p. 478–87.

[44] See: ibid., p. 488.

[45] Other authors discuss the role review boards themselves can play in encouraging a collegial and fair informal research climate, including through educational outreach. Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 504.

[46] Sharpe, *Research Ethics in the Social Sciences & Humanities*, p. 14–.

[47] This being said, some especially important discussion about the nature and limits of consent can be found in: Fujii, "Research Ethics 101: Dilemmas and Responsibilities", p. 717–23.

[48] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition*, p. 24.

[49] Ibid., p. 24–5.

stresses that: "The scientific value of the research does not in any way trump the rights of the participants".[50] A tension seems to exist between the general idea that research that may carry greater rewards (by curing a serious illness or ameliorating a severe social problem, for instance) might legitimately incorporate more risk than research without such rewards and the idea that the benefits of research should not be weighed against the risks to individuals. The drafters of ethical review standards often explicitly deny that scientific information can ever take precedence over the safety of research participants, which arguably runs against what is implied in the 'balance' argument. There may also be tensions between the idea that research subjects can appropriately give informed consent for research that involves risks and the idea that their safety must always be paramount, as well as with the requirement that various vulnerable groups not be excluded from research solely on the basis of that vulnerability. Finally, there can also be a conflict between making data available for the purpose of replicating research and providing appropriate protection to the original research subjects.[51][52][53] Analysis for which the supporting data has been anonymized or destroyed may be questioned in terms of credibility, as well as challenging and resource-intensive to replicate. Such analysis also cannot contribute to the general accumulation of primary-source data, and the comparative research that facilitates.[54]

Sue Tolleson-Rinehart discusses related "collisions of noble goals" in the context of medical research.[55] She cites the example of checklists developed to reduce the number of line infections introduced into patients by intravenous lines, and the subsequent determination that the testing of these checklists violated requirements for human subject research.[56] Specifically, the Office for Human Research Protections (OHRP) within the U.S. Department of Health and Human Services found that the checklist research was "designed to develop or contribute to generalizable knowledge" and thus required review board approval. Interpreted broadly, virtually any activity carried out with the intention of improving patient outcomes could fall under this definition. Tolleson-Rinehart suggests that political scientists could play a role in improving ethics review processes by

[50] University of Toronto School of Graduate Studies, *Research Involving Human Subjects: Guide on Ethical Conduct*.

[51] See: Jordan and Hill, "Ethical Assurance Statements in Political Science Journals", p. 248.

[52] Brooks, "The Ethical Treatment of Human Subjects and the Institutional Review Board Process", p. 66.

[53] Elman, Kapiszewski, and Vinuela, "Qualitative Data Archiving: Rewards and Challenges", p. 23–7.

[54] Ibid., p. 24.

[55] Tolleson-Rinehart, "A Collision of Noble Goals: Protecting Human Subjects, Improving Health Care, and a Research Agenda for Political Science", p. 507–11.

[56] Ibid., p. 507.

applying familiarity and expertise to "enduring questions of power, the allocation of resources, the regulation of conflict, and interest in human society".[57] While it is hard to see a reason why political scientists cannot comment on such issues, there do seem to be reasons to ask how seriously they are likely to be taken in the context of medical ethics. Given the historical examples of abuse of human subjects, the general assumption that doctors are best-placed to adjudicate on issues of medical ethics, and the risk that any ethical violations could have serious financial and legal repercussions for institutions where they occur, it may be overly generous to think that whatever insights political scientists may generate will have a tangible impact on the practice of medical research.[58] Nonetheless, there are good reasons for ethical review boards and those defining ethical review processes to consider "conflicts" of the sort Tolleson-Rinehart identifies and ways through which they may be mitigated. The conclusion of the checklist example further highlights the ambiguities and apparent contradictions in the ethics review process; where previously the OHRP saw fit to order the discontinuation of experiments with checklists, they decided after publicity in the media that the use of the checklists had progressed beyond the experimental stage and into "clinical purposes", and could therefore continue.[59] The message that unauthorized research that such a body has ordered to stop can become approved clinical practice without an ethical review or research redesign in between seems paradoxical and potentially perverse for researchers and practitioners.[60]

The complexity of balancing research risks with rewards is acknowledged by ethics review bodies and in the related literature, with an acknowledgment that "principles cannot always be applied so as to resolve beyond despite particular ethical problems".[61] This complexity increases when the balance of risks and rewards for researchers — as well as for subjects — is taken into account. For instance, the balance between risk and reward can be considered from the perspective of the relationship between the amount of bureaucracy to which

[57] Tolleson-Rinehart, "A Collision of Noble Goals: Protecting Human Subjects, Improving Health Care, and a Research Agenda for Political Science", p. 509.

[58] For a discussion of the risks faced by institutions that fail to meet the ethics standards of funding bodies, see: Brooks, "The Ethical Treatment of Human Subjects and the Institutional Review Board Process", p. 48.

[59] Tolleson-Rinehart, "A Collision of Noble Goals: Protecting Human Subjects, Improving Health Care, and a Research Agenda for Political Science", p. 510.

[60] Seligson identifies another perverse consequence which can arise from ethics review restrictions, in that they may encourage people to reclassify their activities as something other than 'research'. Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 479.

[61] Levine and Skedsvold, "Where the Rubber Meets the Road: Aligning IRBs and Research Practice", p. 501.

researchers are subjected to the amount of harm prevented through its use. The criticism that ethical reviews can occupy inordinate amounts of time and impede useful research may be especially applicable to particular methods that pose few risks to subjects, such as surveys. On the matter of the ethics process suppressing the productivity of researchers, Seligson asserts that what is required of political scientists is akin to real drivers having to certify their intent to obey traffic laws before every journey, noting that drivers failing to do so cause many more deaths than researchers using surveys could cause.[62] That being said, shifting the balance from 'benefit of research versus risks to subjects' to 'level of inconvenience for researchers versus ethical violations avoided' involves a considerable jump in the standards of ethics being applied. The convenience versus benefit form of argument represents an inversion of the absolutist position that no harm to a subject is ever permissible, regardless of benefit. Under this calculus, the ratio between harm prevented and researcher time wasted is the yardstick by which the suitability of ethical review processes is measured, as least when certain methods are being applied. Arguably, such an approach takes the possibility of harm as inherent to the practice of research, and interprets it as capable of being mitigated to a greater or lesser degree by different institutional procedures. In this perspective, at least occasional harm to subjects is taken as a 'cost of doing business', in stark contrast with the perspective that even the most valuable research is unethical if it puts subjects at risk.

3 | Conclusions

Issues identified in ethics review processes for human subjects vary by tractability. Various proposals have been made to protect what is valuable about ethics review processes while mitigating their downsides. These include directing review committees to focus on what is ethically pertinent as opposed to general questions of methodology, providing templates for low-risk research that allow automatic approval, shifting ethics review from the university to the discipline level, shifting review from pre-research to pre-publication in some cases, moving toward a model where aggrieved parties file complaints after the fact, or focusing on other risks like the danger that research data will be subpoenaed by prosecutors.[63] They also include protocols for producing

[62] Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 481.

[63] See: Schrag, "The Case against Ethics Review in the Social Sciences", p. 127–8.

data that has been consistently and reliably stripped of identifying information on research subjects, so that it can be used for secondary analysis by other researchers without imposing risks on those who were originally studied.[64][65][66] To some degree, these suggestions have been implemented at U of T, notably through the existence of a Research Ethics Board specifically for 'Social Sciences & Humanities', as well as through a framework for subjecting potential research to more or less rigorous levels of ethical review depending on pre-defined criteria.[67][68]

When research bodies design their ethics review processes for human subjects, and when researchers engage with those processes, they ought to bear in mind the applicable criticisms and limitations, particularly those that cannot be easily moderated through institutional reforms. They should recognize that having an ethics board provide approval in advance for a research method doesn't eliminate the possibility of further ethical issues arising later in the research process, including in the dissemination and discussion of results. Both researchers and research institutions should also be wary of the reduction of the review process into a formalized ritual, rather than a sympathetic undertaking in which the particularities of each research circumstance are considered. Such thinking cannot guarantee an appropriate balance between protecting human subjects and achieving valuable research results, but they may suffice to encourage that outcome.

[64] Seligson, "Human Subjects Protection and Large-N Research: When Exempt is Non-Exempt and Research is Non-Research", p. 503.

[65] Journals may also impose their own requirement for a data sharing plan, when research employing particular methods is published. Jordan and Hill, "Ethical Assurance Statements in Political Science Journals", p. 246–7.

[66] On challenges in qualitative data sharing, see also: Elman, Kapiszewski, and Vinuela, "Qualitative Data Archiving: Rewards and Challenges", p. 23–7.

[67] University of Toronto School of Graduate Studies, *Research Involving Human Subjects: Guide on Ethical Conduct*.

[68] University of Toronto, *Research Ethics Boards (REBs)*.

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