CONVERGE Institutional Review Board Annotated Bibliography

This annotated bibliography includes resources focused on Institutional Review Board (IRB) procedures for hazards and disaster research. This bibliography is meant to support those interested in learning more about how to navigate the IRB process and to complement the CONVERGE Institutional Review Board and Extreme Events Research Training Module. These references were compiled through searching Web of Science and Google Scholar databases. If you identify missing references, please send them to converge@colorado.edu, and we will add them to the list.

Citation

Aarons, D. (2018). Research in epidemic and emergency situations: A model for collaboration and expediting ethics review in two Caribbean countries. *Developing World Bioethics, 18*(4), 375–384. https://doi.org/10.1111/dewb.12157

Abstract

Various forms of research are essential in emergency, disaster and disease outbreak situations, but challenges exist including the long length of time it takes to get research proposals approved. Consequently, it would be very advantageous to have an acceptable model for efficient coordination and communication between and among research ethics committees/IRBs and ministries of health, and templates for expediting (done with speed and efficiency) ethical review of research proposals in emergency and epidemic situations to be used across the Caribbean and in other low and middle income countries. This project involved a literature search and the interviewing of ministry of health officials, public health practitioners, and research ethics committee/IRB members in Jamaica and St. Lucia, to obtain suggestions for the best model for efficient coordination and communication between research ethics committees (RECs), and developed a template for expediting review of research protocols in epidemic and emergency conditions.

Citation

Aarons, D. (1995). Research ethics. *West Indian Medical Journal*, *44*(4), 115-118.

Abstract

This article reviews the ethical requirements for research. The ethics of human experimentation are informed by the basic principles of beneficence, justice and respect for persons. The principle of beneficence requires

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that a research protocol present a favorable risk/benefit ratio to subjects. Justice demands that the burden and benefits of research be equitably distributed. Respect for persons entails an obligation both to obtain informed consent from research subjects and to protect those who are unable to consent from the risks of research. The fundamental tenet of research ethics is a prior review by a panel of peers. This article argues for the establishment of Research Ethics Committees across the Caribbean to ensure that clinical research conforms to the highest scientific and ethical standards.

Citation

Bledsoe, C. H., Sherin, B., Galinsky, A. G., Headley, N. M., Heimer, C. A., Kjeldgaard, E., Lindgren, J., Miller, J. D., Roloff, M. E., & Uttal, D. H. (2007). Regulating creativity: Research and survival in the IRB iron cage. *Northwestern University Law Review*, *101*(2), 593-641.

Abstract

IRB has been generalized from the medical world to a wide range of social science and, in some cases, humanities research. The major American professional scholarly associations, in their ethics statements, tend to urge their members to obtain IRB approval as a matter of professional ethics. Although most approved FWAs are in the U.S., IRBs have inserted themselves into the research codes of one or more institutions in nearly all countries in the world. And although most educational institutions with IRBs are universities or medical research organizations, a growing number of high schools, though they do not appear to have formal FWAs, have been drawn into IRB requirements, or at least the language of IRB compliance, through an organization called Science Service, which sponsors the International Science and Engineering Fair program. Several elementary schools, in fact, have linked their science fairs to IRB rules through the same Science Service portal. IRB obligations now appear to be incumbent even on kindergartener science fair participants in one ambitious school district in Tennessee. Predictably, faculty objections to the tightening grip of IRBs on research have escalated. Recently, a serious First Amendment question has emerged as well: that of censorship. Censorship refers to the act of inspecting some form of expression-anything from a scientific finding or a political opinion to a work of art-in order to suppress or delete elements alleged to be harmful, offensive, or immoral. Given the limits of our own expertise, we cannot conclude that IRBs' rules or practices constitute censorship in the most technical constitutional sense. … Social science researchers tend to have less assistance than biomedical researchers for generating IRB protocols and keeping track of the voluminous documentation that each protocol can create. More problematically, as we will explain, social science research paradigms fit poorly into the thrust of medically-driven IRB protocol templates and language. Among them is the fact that it is often the demand for regimentation itself within a narrow bureaucratic rule corpus that allows the research to go on, especially, as we have argued, in the cracks of what practices such as consensual censorship can open up.

Citation

Bosso, J. A. (1983). The role of the institutional review board in research involving human subjects. *Drug Intelligence and Clinical Pharmacy*, *17*(11), 828-834. https://doi.org/10.1177/106002808301701112

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Abstract

Concern with the rights and welfare of human experimental research subjects has given rise to the evolution of institutional review boards. This article describes the basic composition and purposes of these boards, as well as the federal regulations by which they are governed. Since many of these regulations are open to interpretation, the policies and procedures of one such board are included to represent an example of how these regulations are interpreted and applied.

Citation

Brown, P., Morello-Frosch, R., Brody, J. G., Altman, R. G., Rudel, R. A., Senier, L., Pérez, C., & Simpson, R. (2010). Institutional review board challenges related to community-based participatory research on human exposure to environmental toxins: A case study. *Environmental Health*, *9(*39), 1-12.

Abstract

Background: We report on the challenges of obtaining Institutional Review Board (IRB) coverage for a community-based participatory research (CBPR) environmental justice project, which involved reporting biomonitoring and household exposure results to participants, and included lay participation in research. Methods: We draw on our experiences guiding a multi-partner CBPR project through university and state Institutional Review Board reviews, and other CBPR colleagues' written accounts and conference presentations and discussions. We also interviewed academics involved in CBPR to learn of their challenges with Institutional Review Boards. Results: We found that Institutional Review Boards are generally unfamiliar with CBPR, reluctant to oversee community partners, and resistant to ongoing researcher-participant interaction. Institutional Review Boards sometimes unintentionally violate the very principles of beneficence and justice which they are supposed to uphold. For example, some Institutional Review Boards refuse to allow report-back of individual data to participants, which contradicts the CBPR principles that guide a growing number of projects. This causes significant delays and may divert research and dissemination efforts. Our extensive education of our university Institutional Review Board convinced them to provide human subjects protection coverage for two community-based organizations in our partnership. Conclusions: IRBs and funders should develop clear, routine review guidelines that respect the unique qualities of CBPR, while researchers and community partners can educate IRB staff and board members about the objectives, ethical frameworks, and research methods of CBPR. These strategies can better protect research participants from the harm of unnecessary delays and exclusion from the research process, while facilitating the ethical communication of study results to participants and communities.

Citation

Browne, K. E., & Peek, L. (2013). Beyond the IRB: An ethical toolkit for long-term disaster research. *International Journal of Mass Emergencies and Disasters, 31*(3).

Abstract

This article argues for expanding the ethical frame of concern in disaster research from the early phases of site access to longer-term issues that may arise in the field. Drawing on ethical theory, these arguments are developed in five sections. First, we identify the philosophical roots of ethical principles used in social science

research. Second, we discuss how ethical concerns span the entire lifecycle of disaster-related research projects but are not fully addressed in the initial protocols for gaining Institutional Research Board (IRB) approval. Third, we introduce the idea of the philosophically-informed "ethical toolkit," established to help build awareness of moral obligations and to provide ways to navigate ethical confusion to reach sound research decisions. Specifically, we use the work of W. D. Ross to introduce a template of moral considerations that include fidelity, reparation, gratitude, justice, beneficence, self-improvement, and non-maleficence. We suggest that in the absence of a clear framework that researchers can use to think through ethical dilemmas as they arise, Ross' pluralist approach to ethical problem solving offers flexibility and clarity, and, at the same time, leaves space to apply our own understanding of the context in question. Fourth, we draw on six examples from our respective research studies conducted following Hurricane Katrina. Using these examples, we discuss how, in retrospect, we can apply Ross' moral considerations to the ethical issues raised including: (1) shifting vulnerability among disaster survivors, (2) the expectations of participants, and (3) concerns about reciprocity in long-term fieldwork. Fifth, we consider how the ethical toolkit we are proposing may improve the quality of research and research relationships.

Citation

California State University San Marcos. (n.d.). *Consent & assent forms.* Graduate Studies & Research Home. https://www.csusm.edu/gsr/irb/consent.html

Abstract

N/A

Citation

Centers for Disease Control and Prevention. (2021, April 22). *Research implications*. https://www.cdc.gov/tuskegee/after.htm

Abstract

N/A

Citation

Children's Hospital of Philadelphia Research Institute. (n.d.). *Waiver or alteration of consent.* https://irb.research.chop.edu/waiver-or-alteration-consent

Abstract

N/A

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Citation

Chung, B., Jones, L., Campbell, L. X., Glover, H., Gelberg, L., & Chen, D. T. (2008). National recommendations for enhancing the conduct of ethical health research with human participants in post-disaster situations. *Ethnicity & Disease, 18*(3), 378-383.

Abstract

The intricacies and time- sensitivity of conducting high- quality and clinically relevant health-related human subject research in post-disaster situations challenges traditional approaches to ensuring optimal protection that study participants are protected from exploitation and harm. This article briefly reviews the ethics and guidelines for conducting research in post-disaster periods and offers recommendations to improve human subjects research conducted in situations defined by the National Response Framework as 'disasters' and 'emergencies.'

Citation

Collogan, L. K., Tuma, F. K., & Fleischman, A. R. (2004). Research with victims of disaster: Institutional review board considerations. *IRB: Ethics & Human Research*, *26*(4), 9-11. https://doi.org/10.2307/3563698

Abstract

N/A

Citation

Colt, H. G., & Mulnard, R.A. (2006). Writing an application for a human subjects institutional review board. *Chest, 130*(5), 1605-1607. https://doi.org/10.1378/chest.130.5.1605

Abstract

After reading this article, readers will be able to do the following: understand the role and responsibilities of an institutional review board (IRB); recognize the major areas that must be addressed in an IRB submission; and avoid common mistakes in writing a research application submission to an IRB.

Citation

DePrince, A. P., & Chu, A. (2008). Perceived benefits in trauma research: Examining methodological and individual difference factors in responses to research participation. *Journal of Empirical Research on Human Research Ethics*, *3*(1), 35-47. https://doi.org/10.1525/jer.2008.3.1.35

Abstract

This study examined methodological and individual difference factors in relation to perceived benefits and cost-benefit ratios among adult participants in trauma-related research. In two samples (*N*'s = 72 and 118), ethnically-diverse community participants completed trauma-related questionnaires plus an in-depth

interview. In separate community (*N* = 213) and undergraduate (*N* = 130) samples, participants completed trauma-related questionnaires, but no interviews. Participants rated their perceptions of the research process using the Response to Research Participation Questionnaire (RRPQ). Cost-benefit ratios were favorable in all samples. The research procedures (questionnaires only versus questionnaires plus interviews) explained unique variance in RRPQ scale scores and cost-benefit ratios, as did trauma-related distress. Implications of these findings for developing trauma research protocols are discussed.

Citation

Dols, J.D., Hoke, M.M., & Rauschhuber, M.L. (2017). Mock institutional review board: Promoting analytical and reasoning skills in research ethics. *Nurse Educator, 42*(6), E4-E8. https://doi.org/10.1097/NNE.0000000000000377

Abstract

Although it is critical that nurses possess ethical reasoning skills for research, there is limited information on effective strategies to develop these skills in graduate health care students. A research study analyzing educational interventions including the effect of online human subjects training followed by a mock institutional review board simulation demonstrated that knowledge acquisition is not enough to acquire the ethical reasoning skills needed to implement health care research. Situational context is also needed to envision the application of ethical principles.

Citation

Education Development Center. (2009). *Willowbrook hepatitis experiments*. https://science.education.nih.gov/supplements/webversions/bioethics/guide/pdf/master_5-4.pdf

Abstract

N/A

Citation

Ferreira, R., Buttell, F., & Ferreira, S. (2015). Ethical considerations for conducting disaster research with vulnerable populations. *Journal of Social Work Values and Ethics*, *12*(1), 29–40.

Abstract

Worldwide there has been a significant increase in disasters the past decades, particularly in the United States. Due to the increased frequency of disasters, the field of disaster research has seen a corresponding increase in empirical studies involving human subjects. A large number of these studies include vulnerable populations. Study of these populations requires additional precautionary disaster research practices in order to align with ethical standards for research. This article has a dual purpose: Part I provides a better understanding of the vulnerability of populations associated with disaster research; Part II offers a framework for best practices in conducting disaster research with vulnerable populations.

Citation

Fleischman, A. R., & Wood, E. B. (2002). Ethical issues in research involving victims of terror. *Journal of Urban Health, 79*(3), 315-321. https://doi.org/10.1093/jurban/79.3.315

Abstract

Although research after an episode of terror can provide important information to improve the health and well-being of present and future victims, there are unique ethical challenges that need to be addressed. Man-made disasters have profound effects on victims, rescue workers, and their families and on others in the community; this may impair their ability to provide voluntary and uncoerced decisions about research participation. Because such potential participants in research may be vulnerable and also subject to being overburdened with redundant research, they deserve special consideration. We propose specific recommendations to assist investigators, institutional review boards (IRBs), public health officials, and political leaders to help serve the interests of future participants in terror-related research.

Citation

Flicker, S., & Worthington, C. A. (2012). Public health research involving Aboriginal peoples: Research ethics board stakeholders' reflections on ethics principles and research processes. *Canadian Journal of Public Health, 103*(1), 19-22. https://doi.org/10.1007/BF03404063

Abstract

Objectives: The second edition (2010) of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (TCPS2) prescribes a set of principles and provisions for engagement with Aboriginal communities. The objective of this study was to explore research ethics board (REB) stakeholder perspectives on the principles and processes of reviewing and conducting public health research with Aboriginal populations and communities. Method: Twenty-four semi-structured qualitative interviews were conducted with REB staff, chairs, members (academic, community and student), and ethics policy key informants with knowledge of the ethics review process, including four Aboriginal participants. Interviews were professionally transcribed verbatim and thematically analyzed using NVivo 8 qualitative data management software. Results: Three dominant themes emerged specific to ethical research practices with Aboriginal communities: 1) the importance of understanding Aboriginal research as a distinct form of research; 2) the unique nature and complexity of negotiating community consent; and 3) the importance of trust and relationship-building in the research process. Conclusion: Thematic results highlight the most prominent issues that REB participants encountered in reviewing research involving Aboriginal peoples. Continued attention needs to be paid to acknowledging and respecting issues of diversity in research involving diverse First Nations, Inuit and Métis peoples. While specific to Aboriginal peoples, the TCPS2 guidelines also illustrate processes and practices that may assist in the development of respectful, collaborative public health research relationships with other historically marginalized populations.

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Citation

Flory, K., Kloos, B., Hankin, B. L., & Cheely, C. A. (2008). Clinical research after catastrophic disasters: Lessons learned from Hurricane Katrina. *Professional Psychology, Research and Practice*, *39*(1), 107-112. https://doi.org/10.1037/0735-7028.39.1.107

Abstract

When catastrophic disasters such as Hurricane Katrina strike, psychologists and other mental health professionals often wonder how to use resources and fill needed roles. We argue that conducting clinical research in response to disasters is 1 important way that these professionals can contribute. However, we recognize that designing and implementing a clinical research study can be a daunting task, particularly in the context of the personal and system-wide chaos that follows most disasters. Thus, we offer a detailed description of our own experiences with conducting clinical research as part of our response to Hurricane Katrina. We describe our study design, recruitment and data collection efforts, and summarize and synthesize the lessons we have learned from this endeavor. Our hope is that others who may wish to conduct disaster-related research will learn from our mistakes and successes.

Citation

Fothergill, A., & Peek, L. A. (2015). *Children of Katrina*. University of Texas Press.

Abstract

The vulnerability of children was starkly apparent in Hurricane Katrina, the most disruptive and destructive disaster in modern U.S. history. A dozen children and youth in Louisiana perished in the disaster. An untold number of children lost loved ones, were orphaned, or were left homeless. Over 5,000 children were reported missing, many of whom were separated from their family members for weeks or even months after the storm. Over 370,000 school-age children were displaced immediately following Katrina, while 160,000 remained dislocated for years. Children of Katrina examines what happened to children and youth in Hurricane Katrina and how their lives unfolded in the years after the catastrophe and displacement. They wanted to know: What happened to these children? What did they need during the emergency response and recovery periods? Who helped them? How did they help themselves and other children as well as adults? How did their lives unfold following the catastrophe and displacement? To answer these questions, the authors spent seven years using ethnographic methods to study and analyze the experiences of children and youth in the aftermath of Katrina.

Citation

Gaillard, J. C., & Gomez, C. (2015). Post-disaster research: Is there gold worth the rush. *Jàmbá: Journal of Disaster Risk Studies*, *7*(1), 1-6. https://doi.org/10.4102/jamba.v7i1.120

Abstract

A quick analysis of academic peer-reviewed articles related to the foregoing events (which have stimulated the highest academic attention over the past 15 years) available from Scopus shows that the number of publications peaked immediately or a year after the disasters. This is particularly evident for Hurricane Katrina,

which has been the focus of more than 3500 peer-reviewed publications, including 382 before the end of 2005. Rushing to affected areas immediately after the event is very tempting for researchers interested in disasters. Although the collection of perishable data is often essential, both for the sake of the local affected and the international community, the multiplication of initiatives from different countries and research groups sends a very large number of individuals to the impacted areas. Even in the face of intense competition amongst academics, mostly fuelled by the international education business, the authors recognize that such research has emerged from a real desire to 'do good'.

Citation

Gaillard, J. C., & Peek, L. (2019). Disaster-zone research needs a code of conduct. *Nature*, *575*(7783), 440-442. https://doi.org/10.1038/d41586-019-03534-z

Abstract

This article calls for a code of conduct in large scale disasters that affect large numbers of researchers. It highlights several ethical dilemmas and power imbalances that have emerged in the context of recent major events.

Citation

Henderson, T. L., Sirois, M., Chen, A. C.-C., Airriess, C., Swanson, D. A., & Banks, D. (2009). After a disaster: Lessons in survey methodology from Hurricane Katrina. *Population Research and Policy Review, 28*(1), 67-92. https://doi.org/10.1007/s11113-008-9114-5

Abstract

In 2005, the National Science Foundation funded a number of projects to study the impact of Hurricane Katrina. The current article provides an overview of several research approaches used to conduct post-Katrina research. Each method had some advantages and disadvantages. The post-disaster context meant that experience from traditional survey methods often did not apply. Comparisons of advantages and disadvantages associated with each sampling method serve to inform future post-disaster research and illuminate the limits of classical research methods.

Citation

Jester, P. M., Tilden, S. J., Li, Y., Whitley, R. J., & Sullender, W. M. (2006). Regulatory challenges: Lessons from recent West Nile virus trials in the United States. *Contemporary Clinical Trials, 27*(3), 254-259. https://doi.org/10.1016/j.cct.2006.02.004

Abstract

Delays in research on emerging infections could deprive the public of appropriate therapies. This report describes challenges encountered in implementing two multicenter protocols of West Nile virus (WNV) infections in the United States during 2003. Protocol development times, federal regulatory approvals, and local Institutional Review Boards (IRB) approvals were compiled. Twenty-eight institutions participated in a

natural history study and 27 in a therapeutic trial of WNV developed through the National Institute of Allergy and Infectious Disease Collaborative Antiviral Study Group (CASG). The CASG compiled protocol development times, federal regulatory approvals, and local IRB approvals. Additional information on the local IRB process was obtained by survey of the investigators. Because of the lengthy development and approval process, protocols were distributed after the start of the epidemic season, most sites were unable to enroll subjects at the peak of the season, and a number of sites lacked IRB approval at the end of the season.

Citation

Kendra, J., & Gregory, S. (2019). Ethics in disaster research: A new declaration. In J. Kendra, S. G. Knowles, & T. Wachtendorf (Eds.), *Disaster research and the second environmental crisis* (pp. 319-341). Springer. https://doi.org/10.1007/978-3-030-04691-0_16

Abstract

The opening chapter in this volume portrayed the growing urgency of disaster research, as the nature and scope of hazards shift. People already familiar with their local environment may find that a changing climate changes their risk for certain kinds of hazards (Relf, G., Kendra, J. M., Schwartz, R. M., Leathers, D. J., & Levia, D. F. (2015). Slushflows: Science and planning considerations for an expanding hazard. *Natural Hazards, 78*(1), 333–354). People moving from place to place in search of better jobs or housing may move into a hazard milieu that is new to them. Political transformations with an authoritarian bent will probably increase vulnerability amongst populations already at greater risk for experiencing a disaster and for recovering more slowly, such as those in poor housing, those with chronic illnesses, and those with Functional and Access Needs. Robust research is needed, but some critics have emerged to challenge the practice and propriety of disaster research, especially quick-response research. This chapter argues for an affirmative right to conduct research.

Citation

Kim, W. O. (2012). Institutional review board (IRB) and ethical issues in clinical research. *Korean Journal of Anesthesiology*, *62*(1), 3-12. https://doi.org/10.4097/kjae.2012.62.1.3

Abstract

Clinical research has expanded tremendously in the past few decades and consequently there has been growing interest in the ethical guidelines that are being followed for the protection of human subjects. This review summarizes historical scandals and social responses chronologically from World War II to the Death of Ellen Roche (2001) to emphasize the lessons we must learn from history. International ethical guidelines for studies with human subjects are also briefly described in order to understand the circumstances of clinical research. The tasks and responsibilities of the institutions and investigators in human subject research to preserve the safety and welfare of research subjects are summarized. Next, several debated ethical issues and insights are arranged as controversial topics. This brief review and summary seeks to highlight important arguments and make suggestions to institutional review boards (IRBs) to contribute to the future evolution of ethics in clinical research as we advance forward.

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Citation

Kleinsman, J., & Buckley, S. (2015). Facebook study: A little bit unethical but worth it? *Journal of Bioethical Inquiry*, *12*(2), 179-182. https://doi.org/10.1007/s11673-015-9621-0

Abstract

Human research involving the use social media raises many of the same issues as medical research. The publication of a paper in June 2014 investigating "emotional contagion" received extensive publicity recently because of the methods used. The approach involved manipulating the "News Feeds" of Facebook users, but the participants were not informed of their involvement in the research and had no opportunity to consent or opt out. Some commentators have argued that although it would have been preferable to obtain informed consent, it was not strictly required because the research was unlikely to cause significant harm and was important. This paper argues that the research was unethical because (i) it should have been overseen by an independent ethics committee or review board and (ii) informed consent could and should have been obtained. Regardless of the importance of any research and irrespective of its likelihood to cause harm, the ethical principles that have evolved since the 1940s should be followed in all instances when experimental research is being carried out on human participants.

Citation

Kotsis, S. V., & Chung, K. C. (2014). Institutional review boards: What's old? What's new? What needs to change? *Plastic and Reconstructive Surgery, 133*(2), 439-445. https://doi.org/10.1097/01.prs.0000436846.00247.73

Abstract

Institutional review boards have come under fire for being burdened with work, causing delays in the progress of human subject research without improvements in the protection of human subjects. Over the years, there have been increases in the numbers of clinical trials, the use of multisite studies, and the amount of bureaucracy, but there have been no changes to the system to accommodate these advancements. Proposed changes include the use of a centralized institutional review board for multisite studies and harmonization of reporting requirements among agencies. The purposes of this article are to review the history, structure, and purpose of the institutional review board, to assess the criticisms of the current system, and to discuss solutions for improvement.

Citation

Lederman, R. (2006). The perils of working at home: IRB "mission creep" as context and content for an ethnography of disciplinary knowledge. *American Ethnologist, 33*(4), 482–491. https://doi.org/10.1525/ae.2006.33.4.482

Abstract

Among kinds of fieldwork "at home," ethnographies of higher education inevitably draw on informal gleanings of everyday insider experience. Such informality is implicitly outlawed by federal human-subjects research

regulations, which presume a clinical biomedical model that formally demarcates research from other activities. Intricately implicated in these circumstances, this article describes a comparative investigation into the methodologically embedded ethical conventions of anthropology and related disciplines for which institutional review board (IRB) participation itself became inadvertently informative, work that also reveals a conflict between the ethics of human-subjects protections (confidentiality) and of collegial exchange (citation).

Citation

Lerner, B. H. (2004). Sins of omission—Cancer research without informed consent. *The New England Journal of Medicine*, *351*(7), 628-630. https://doi.org/10.1056/NEJMp048108

Abstract

At Brooklyn's Jewish Chronic Disease Hospital (JCDH) in 1963, 22 patients received injections of cancer cells without their knowledge. What is so striking about this story is not primarily that enthusiastic researchers convinced themselves that is was acceptable to inject cancer cells into unknowing patients but, rather, that a few young physicians refused to participate and even resigned in order to protest the ethical impropriety of using people as a means to an end.

Citation

Librett, M. & Perrone, D. (2010). Apples and oranges: Ethnography and the IRB. *Qualitative Research, 10*(6), 729–747. https://doi.org/10.1177/1468794110380548

Abstract

This article outlines the trials and tribulations encountered in negotiating institutional review board approval of ethnographic research among undercover police officers and recreational drug users in dance club settings. While Institutional Review Boards (IRBs) and ethnographic research seek to protect the participants of research, they operate on two diametrically opposed paths. Ethnographers enter the research field with the goal of observing natural behavior, and taking steps to ensure they do not influence activity; anonymity is impossible, while confidentiality essential. IRBs, on the contrary, mandate an informed consent and oversight process that can compromise confidentiality. This has greatly affected contemporary ethnographic research and has had serious consequences for both the research participants and the production of knowledge.

Citation

Liesegang, T. J. (2009). Revealing the faults in medical journals. *Archivum Immunologiae et Therapiae Experimentalis, 57*(2), 75-83. https://doi.org/10.1007/s00005-009-0012-2

Abstract

Medical journals hold an exalted position in medicine, but have many shortcomings. This perspective reviews some of the shortcomings of medical journals which are primarily related to inexperience, bias, and commercialism. The issues discussed include the uncertain mission of the traditional medical journal in the modern digital age, the inherent inexperience of voluntary editorial boards, the weaknesses and capricious

nature of decisions made by the peer-review process, the uneven value of most journal articles, the bias in what gets submitted and published in journals, the misunderstanding about the criteria for authorship, the misunderstanding of the need for ethical review board approval of studies, the misunderstanding of the need for informed consent for research from patients and ethical review boards, the various sources of assistance to editors and authors in dealing with the many ethical issues arising in the publication process, the commercialization and manipulation of medical journals by industry, the prevalent and complex financial entanglements of authors with industry, and the imperfect impact factor, which has the potential to be abused. The perspective concludes with theorization of the role of medical journals in the future. Readers need to scrutinize data in the literature carefully and interpret the discussions and conclusions critically, as there are biases in what is published in medical journals.

Citation

Macpherson, C. C. (1999). Research ethics committees: A regional approach. *Theoretical Medicine and Bioethics, 20*(2), 161–179. https://doi.org/10.1023/A:1009989104496

Abstract

Guidelines for Institutional Review Boards (IRBs) or research ethics committees exist at national and international levels. These guidelines are based on ethical principles and establish an internationally acceptable standard for the review and conduct of medical research. Having attained a multinational consensus about what these fundamental guidelines should be, IRBs are left to interpret the guidelines and devise their own means of implementing them. Individual and community values bear on the interpretation of the guidelines so different IRBs attain different levels of effectiveness. In the Caribbean and Pan American regions there are few IRBs. Obstacles to the establishment and function of IRBs are exacerbated in developing regions like these by differences in language, literacy, and local value systems; education, administrative expertise, facilities, and access to information are also limited. A regional IRB network might facilitate more uniform ethical review in developing countries, and simplify IRB procedures.

Citation

McCormack, D., Carr, T., McCloskey, R., Keeping-Burke, L., Furlong, K. E., & Doucet, S. (2012). Getting through ethics: The fit between research ethics board assessments and qualitative research. *Journal of Empirical Research on Human Research Ethics, 7*(5), 30-36. https://doi.org/10.1525/jer.2012.7.5.30

Abstract

In this paper, we draw on the authors' collective experiences as qualitative researchers undergoing research ethics reviews. We highlight specific areas within our standard national guidelines that support qualitative research. Using case examples, we illustrate how diverse interpretations of these guidelines can be inconsistent and problematic for qualitative researchers. We outline recommendations for transparency, reciprocity, and streamlining of the review process. It is our hope that adoption of these recommendations will lead to a more collegial evaluative process, thereby contributing to the advancement of knowledge.

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Citation

Murphy, C. M., & Verden, C. (2011). *A student's guide to navigating the IRB: How to successfully navigate a potentially overwhelming process* (EJ1136504). ERIC. https://files.eric.ed.gov/fulltext/EJ1136504.pdf

Abstract

Graduate students must complete a research project to receive their degree. In addition to this basic requirement, the student may be required to submit a research proposal and application to the governing Institutional Review Board (IRB) for approval prior to beginning the research project. This article describes the IRB process and offers tips for successful navigation of the procedure.

Citation

National Institute of Environmental Health Sciences. (2021, May 27). *Disaster research response (DR2): Human studies & research ethics*. U.S. Department of Health and Human Services, National Institutes of Health. https://dr2.nlm.nih.gov/protocols.

Abstract

N/A

Citation

National Institute of Mental Health. (n.d.). *Conducting research with participants at elevated risk for suicide: Considerations for researchers.* U.S. Department of Health and Human Services, National Institutes of Health. https://www.nimh.nih.gov/funding/clinical-research/conducting-research-with-participants-at-elevated-risk-for-suicide-considerations-for-researchers.shtml#consent.

Abstract

N/A

Citation

Neuman, L. W. (1997.) *Social research methods: Qualitative and quantitative approaches* (3rd ed.). Allyn and Bacon.

Abstract

N/A

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Citation

O'Connor, M. K., Netting, F. E., & Thomas, M. L. (2008). Grounded theory managing the challenge for those facing institutional review board oversight. *Qualitative Inquiry*, *14*(1), 28-45. https://doi.org/10.1177/1077800407308907

Abstract

The authors examine one of the earliest systematic forms of qualitative inquiry to identify some of the boundaries needed in grounded theory designs to provide a small corner of clarity in the discourse about what is acceptable science from the Institutional Review Board (IRB) perspective. Beginning with an overview of grounded theory research as it was originally conceived and extended, the challenges for establishment of a uniform standard are put forth. Within this background and context, the authors report the results of a content analysis of a sampling of dissertation abstracts claiming to use grounded theory. Results reveal the need to clarify standards for different types of grounded theory research to help those facing IRB oversight. The authors assert that there are two useful sets of standards that should be applied to the assessment of the quality of a grounded theory design and researchers should not confuse the two.

Citation

Office for Human Research Protections. (1979, April 18). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research.* U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.

Abstract

N/A

Citation

Office for Human Research Protections. (1998, November 9). *OHRP expedited review categories (1998)*. U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html.

Abstract

N/A

Citation

Office for Human Research Protections. (2007, January 15). *Unanticipated problems involving risks & adverse events guidance (2007)*. U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#Q2.

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Abstract

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Citation

Office for Human Research Protections. (2010, November 10a). *Approval of research with conditions: OHRP guidance (2010).* U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-irb-approval-of-research-with-conditions-2010/index.html.

Abstract

N/A

Citation

Office for Human Research Protections. (2010, November 10b). *Continuing review guidance (2010)*. U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-k.

Abstract

N/A

Citation

Office for Human Research Protections. (2018, June 19). *Subpart A-Basic HHS policy for protection of human subjects.* U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html.

Abstract

N/A

Citation

Office for the Protection of Research Subjects. *Levels of IRB review*. University of Southern California. https://oprs.usc.edu/irb-review/types-of-irb-review/.

Abstract

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Citation

Office of Human Subject Research. (n.d.). *The informed consent process with children.* Rochester Institute of Technology. https://www.rit.edu/research/hsro/informed_consent_process_children#parent.

Abstract

N/A

Citation

Office Research Ethics & Compliance. (2020, August 19). *Waivers of informed consent guidelines*. University of Michigan. https://research-compliance.umich.edu/waivers-informed-consent-guidelines.

Abstract

N/A

Citation

Office Research Ethics & Compliance. (2020, September 29) *Informed consent guidelines & templates.* University of Michigan. https://research-compliance.umich.edu/informed-consent-guidelines.

Abstract

N/A

Citation

O'Rourke, P. P., Carrithers, J., Patrick-Lake, B., Rice, T. W., Corsmo, J., Hart, R., Drezner, M. K., & Lantos, J. D. (2015). Harmonization and streamlining of research oversight for pragmatic clinical trials. *Clinical Trials, 12*(5), 449–456. https://doi.org/10.1177/1740774515597685

Abstract

The oversight of research involving human participants is a complex process that requires institutional review board review as well as multiple non-institutional review board institutional reviews. This multifaceted process is particularly challenging for multisite research when each site independently completes all required local reviews. The lack of inter-institutional standardization can result in different review outcomes for the same protocol, which can delay study operations from start-up to study completion. Hence, there have been strong calls to harmonize and thus streamline the research oversight process. Although the institutional review board is only one of the required reviews, it is often identified as the target for harmonization and streamlining. Data regarding variability in decision-making and interpretation of the regulations across institutional review boards have led to a perception that variability among institutional review boards is a primary contributor to the problems with review of multisite research. In response, many researchers and policymakers have proposed the use of a single institutional review board of record, also called a central institutional review board, as an

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important remedy. While this proposal has merit, the use of a central institutional review board for multisite research does not address the larger problem of completing non-institutional review board institutional review in addition to institutional review board review—and coordinating the interdependence of these reviews. In this article, we describe the overall research oversight process, distinguish between institutional review board and institutional responsibilities, and identify challenges and opportunities for harmonization and streamlining. We focus on procedural and organizational issues and presume that the protection of human subjects remains the paramount concern. Suggested modifications of institutional review board processes that focus on time, efficiency, and consistency of review must also address what effect such changes have on the quality of review. We acknowledge that assessment of quality is difficult in that quality metrics for institutional review board review remain elusive. At best, we may be able to assess the time it takes to review protocols and the consistency across institutions.

Citation

Packenham, J. P., Rosselli, R., Fothergill, A., Slutsman, J., Ramsey, S., Hall, J. E., & Miller, A. (2021). Institutional Review Board preparedness for disaster research: A practical approach. *Current Environmental Health Reports*, 1-11. https://doi.org/10.1007/s40572-021-00311-x

Abstract

Purpose of Review: Disasters are becoming more common and challenge national and global resiliency and response efforts. As a result, government agencies have increased interest in disaster research to understand their environmental impact and health related consequences. With the research field greatly expanding, Institutional Review Boards (IRBs) are being asked to review research protocols aimed at assessing health risks, exposures, and outcomes from disaster survivors. Few IRBs have experience reviewing disaster research protocols. This article describes approaches for IRB preparedness in reviewing disaster research.
Recent Findings: From a human research protections perspective, primary attention has focused on vulnerability of individuals and/or populations affected by a disaster who may serve as research participants [3, 4]. From our review of the current literature, there is a lack of best practices and/or guidance for IRBs in the review of disaster research protocols.
Summary: The growth of the disaster research field has brought more attention to potential ethical concerns of disaster research studies. Disaster survivors, responders, and those that assist in cleanup and remedial efforts may be left with significant unmet needs and long-term physical and emotional challenges as a result of their experiences. It is important for IRBs and investigators to collaboratively address how best to protect the welfare of individuals and communities affected by a disaster. A new approach is needed to systematically consider the various factors relevant to an assessment of human research protection issues following disasters.

Citation

Packenham, J. P., Rosselli, R. T., Ramsey, S. K., Taylor, H. A., Fothergill, A., Slutsman, J., Miller, A. (2017). Conducting science in disasters: Recommendations from the NIEHS working group for special IRB considerations in the review of disaster related research. *Environmental Health Perspectives*, *125*(9). https://doi.org/10.1289/EHP2378

Abstract

Research involving human subjects after public health emergencies and disasters may pose ethical challenges. These challenges may include concerns about the vulnerability of prospective disaster research participants, increased research burden among disaster survivors approached by multiple research teams, and potentially reduced standards in the ethical review of research by institutional review boards (IRBs) due to the rush to enter the disaster field. The NIEHS Best Practices Working Group for Special IRB Considerations in the Review of Disaster Related Research was formed to identify and address ethical and regulatory challenges associated with the review of disaster research. The working group consists of a diverse collection of disaster research stakeholders across a broad spectrum of disciplines. The working group convened in July 2016 to identify recommendations that are instrumental in preparing IRBs to review protocols related to public health emergencies and disasters. The meeting included formative didactic presentations and facilitated breakout discussions using disaster-related case studies. Major thematic elements from these discussions were collected and documented into 15 working group recommendations, summarized in this article, that address topics such as IRB disaster preparedness activities, informed consent, vulnerable populations, confidentiality, participant burden, disaster research response integration and training, IRB roles/responsibilities, community engagement, and dissemination of disaster research results.

Citation

Peek, L., Tobin, J., van de Lindt, J. W., & Andrews, A. (2021). Getting interdisciplinary teams into the field: Institutional Review Board preapproval and multi-institution authorization agreements for rapid response disaster research. *Risk Analysis*. https://doi.org/10.1111/risa.13740

Abstract

This article describes an interdisciplinary community resilience research project and presents a case study that supports bringing researchers together before a disaster to develop plans, procedures, and preapproved Institutional Review Board (IRB) protocols. In addition, this article explains how researchers from various academic institutions and their federal agency partners can effectively collaborate by creating an IRB Authorization Agreement (IAA). Such preparations can support interdisciplinary rapid response disaster fieldwork that is timely, ethically informed, and scientifically rigorous. This fieldwork preplanning process can also advance interdisciplinary team formation and data collection efforts over the long term.

Citation

Phillips, B. D. (2014). *Qualitative disaster research*. Oxford University Press.

Abstract

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Citation

Resnik, D. B., Miller, A. K., Kwok, R. K., Engel, L. S., & Sandler, D. P. (2015). Ethical issues in environmental health research related to public health emergencies: Reflections on the GuLF STUDY. *Environmental Health Perspectives, 123*(9), 277-231. https://doi.org/10.1289/ehp.124-A29

Abstract

Health research in the context of an environmental disaster with implications for public health raises challenging ethical issues. This article explores ethical issues that arose in the Gulf Long-term Follow-up Study (GuLF STUDY) and provides guidance for future research. Ethical issues encountered by GuLF STUDY investigators included *a*) minimizing risks and promoting benefits to participants, *b*) obtaining valid informed consent, *c*) providing financial compensation to participants, *d*) working with vulnerable participants, *e*) protecting participant confidentiality, *f*) addressing conflicts of interest, *g*) dealing with legal implications of research, and *h*) obtaining expeditious review from the institutional review board (IRB), community groups, and other committees. To ensure that ethical issues are handled properly, it is important for investigators to work closely with IRBs during the development and implementation of research and to consult with groups representing the community. Researchers should consider developing protocols, consent forms, survey instruments, and other documents prior to the advent of a public health emergency to allow for adequate and timely review by constituents. When an emergency arises, these materials can be quickly modified to take into account unique circumstances and implementation details.

Citation

Rice, T. W. (2008). How to do human-subjects research if you do not have an institutional review board. *Respiratory Care*, *53*(10), 1362-1367.

Abstract

Biomedical research with human subjects has expanded outside of traditional medical centers and hospitals into other health care entities, such as rehabilitation facilities, free-standing out-patient treatment centers, and even home-health agencies. Regardless of the location, federal regulations mandate that all human-subjects research must be overseen by an institutional review board (IRB) or ethics committee to ensure the research abides by the Code of Federal Regulations. Consequently, all human-subjects research must be reviewed and approved by an IRB prior to initiation of any research procedures. Unfortunately, many of these nontraditional research facilities do not have easy access to an IRB. This does not render such research exempt from federal oversight. Clinicians at these facilities have viable options for obtaining IRB approval and legally conducting such research. This paper outlines the available options and their pros and cons.

Citation

Rosenstein, D. L. (2004). Decision-making capacity and disaster research. *Journal of Traumatic Stress*, *17*(5), 373-381. https://doi.org/10.1023/B:JOTS.0000048950.36359.a2

Abstract

The extent to which victims of a disaster are able to make capacitated and voluntary decisions to enroll in research is an important and virtually unexplored question. Although there are no compelling data to suggest that experiencing a severe trauma, in and of itself, renders all or even most individuals incapable of making autonomous decisions, the assessment of decision-making capacity (DMC) for research participation warrants serious consideration. This paper provides a framework for and procedural approach to the assessment of DMC in research with individuals exposed to disaster. Particular attention is paid to the implementation of additional safeguards to protect subjects who are vulnerable by virtue of impaired DMC. Recommendations are offered to clinical investigators, ethical review boards, and policymakers with regard to the design, review, and conduct of research in the aftermath of disaster.

Citation

Stair, T. O., Reed, C. R., Radeos, M. S., Koski, G., & Camargo, C. A. (2001). Variation in institutional review board responses to a standard protocol for a multicenter clinical trial. *Academic Emergency Medicine, 8*(6), 636–641. https://doi.org/10.1111/j.1553-2712.2001.tb00177.x

Abstract

Multicenter clinical trials require approval by multiple local institutional review boards (IRBs). The Multicenter Airway Research Collaboration mailed a clinical trial protocol to its U.S. investigators and 44 IRBs ultimately reviewed it. Objective: To describe IRB responses to one standard protocol and thereby gain insight into the advantages and disadvantages of local IRB review. Methods: Two surveys were mailed to participants, with telephone follow-up of nonrespondents. Survey 1 was mailed to 82 investigators across North America. Survey 2 was mailed to investigators from 44 medical centers in 17 U.S. states. Survey 1 asked about each investigator's local IRB (e.g., frequency of meetings, membership), whereas survey 2 asked about IRB queries and concerns related to the submitted clinical trial. Results: Both surveys had 100% response rate. Investigators submitted applications a median of 58 days (interquartile range [IQR], 40-83) after receipt of the protocol, and IRB approval took an additional 38 days (IQR, 26-62). Although eight applications were approved with little or no changes, IRBs requested an average of 3.5 changes per site. Changes involved study logistics and supervision for 45%, the research process for 43%, and the consent form for 91%. Despite these numerous requests, all eventually approved the basic protocol, including inclusion criteria, intervention, and data collection. Conclusions: The IRBs showed extreme variability in their initial responses to a standard protocol, but ultimately all gave approval. Almost all IRBs changed the consent form. A national, multicenter IRB process might streamline ethical review and warrants further consideration.

Citation

Substance Abuse and Mental Health Services Administration (SAMHSA). (2016, January). *Disaster technical assistance center supplemental research bulletin: Challenges and considerations in disaster research.* https://www.hsdl.org/?abstract&did=798614.

Abstract

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Citation

White, R. F. (2007). Institutional Review Board mission creep: The common rule, social science, and the nanny state. *The Independent Review, 11*(4), 547-564.

Abstract

In this article, the author scrutinizes the process by which scientific research on human subjects is regulated by Institutional Review Boards (IRBs). Today, the IRB process consumes an inordinate amount of time, energy, and resources in attempting to prevent a growing list of imagined harms, minor harms, or highly unlikely harms. Consequently, IRBs no longer serve their original mandate well. During the past thirty years, the IRB has devolved to become an ineffective means of regulating the diverse activities that the government ambiguously calls "scientific research on humans." Over the years, the IRB regulatory structure has been subject to numerous revisions, restructurings, and elaborations, but the overall drift of these changes has always been toward the expansion of IRBs' scope and authority (AAUP 2001). Federal regulations define research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Citation

World Medical Association. (2001). World Medical Association declaration of Helsinki. Ethical principles for medical research involving human subjects. *Bulletin of the World Health Organization, 79*(4), 373-374. https://doi.org/10.1590/S0042-96862001000400016

Abstract

N/A

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