

# THE JOURNAL OF LAW, MEDICINE & ETHICS C O N T E N T S

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## Symposium Articles

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### SYMPOSIUM

## Return of Research Results: How Should Research Results Be Handled?

Guest Edited by

Bartha Maria  
Knoppers and  
Emmanuelle  
Lévesque

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*Letter from  
the Editor*

Cover image ©Corbis

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### Introduction

*Bartha Maria Knoppers and  
Emmanuelle Lévesque*

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### Return of Results: Towards a Lexicon?

*Bartha Maria Knoppers and Amy Dam*

Currently, the return of results in the domain of biobanking constitutes an ethical and legal quagmire, whether it involves population or specific clinical research studies. In light of the fact that population biobanks are often not seen as distinct from those biobanks created for disease research, as well as the uncertainty as to what "return of results" means concretely, this lexicon attempts to demystify the terminology. The terms — results, return, clinical significance, and utility — are discussed. Through an analysis of international and national normative guidance on this issue, the authors propose a concordance of meaning and a simplified lexicon.

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### Return of Research Results: General Principles and International Perspectives

*Emmanuelle Lévesque, Yann Joly, and Jacques Simard*

Five years ago, an article co-written by two of us (Joly and Simard) presented an emerging trend to disclose certain individual genetic results to research participants. Since then, both technologies and research practices have evolved significantly. Given this rapid evolution, our goal is to provide updated and thorough guidance on this issue. Our paper begins by identifying the ethical principles that support the return of results: justice, beneficence, and respect for persons. Then, it presents the results of an analysis of international norms on the return of results, covering both general and individual research results. It reveals existing divergence and consensus on these topics within the international community. With the goal of promoting greater harmonization, we conclude by proposing a flexible framework for the return of individual research results.

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### Pediatric Research and the Return of Individual Research Results

*Denise Avard, Karine Sénécal,  
Parvaz Madadi, and Daniel Sinnett*

The return of individual research results to participants raises many socio-ethical issues and is even more challenging when the participant is a child. The objective of this article is to present an overview of the few ethical guidelines and relevant literature addressing the return of individual results in pediatric research. By reviewing policies and the literature, we present some overarching considerations and delineate contextual issues in order to propose a framework.

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### Familial Communication of Research Results: A Need to Know?

*Lee Black and Kelly A. McClellan*

Research now provides participants greater indications of genetic risk for disease, even for conditions incidental to the research study. Given this development, should such information also be disclosed to the family of research participants? There has been some indication at the national level that genetic risk information can be disclosed to participants' families; however, limited attention has been given to returning research results to family. Thus, we have also incorporated the discussion surrounding the disclosure of genetic risk discovered in the clinic (e.g., genetic testing). A number of important questions are examined: Should genetic research results be provided to family? Are there differences between clinical and research findings that would prevent research results from being disclosed to family? Who should make the disclosure, if in fact it is done at all? We conclude by noting that the return of results is increasingly accepted as technology permits the discovery of more and more medically useful data. However, debates of whether results should be returned to participants must first be settled before moving to familial disclosure.

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**Biobanks and the Return of Research Results: Out with the Old and In with the New?**

*Ma'n H. Zawati and Amélie Rioux*

This article examines the complex and contemporary issue of the return of research results in biobanks. After suggesting the exclusion of some adjacent issues usually flanking the debate, this article reviews the current practices of biobanks on the disclosure of research results to participants. It then focuses more specifically on the debate in the literature before turning to a review of the typology of recent reforms being put forward.

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**The Return of Results of Deceased Research Participants**

*Anne Marie Tassé*

The death of a research participant raises numerous ethical and legal issues regarding the return of research results to related family members. This question is particularly acute in the context of genetic research since the research results from an individual may be relevant to each of the biological relatives. This paper first investigates the ethical and legal frameworks governing the return of a deceased participant's individual research results to his or her related family members. Then, it weighs the rights and interests of both the deceased individual and related family members in an attempt to identify key ethical considerations underlying the return of such results. This analysis of international guidelines and national laws and regulations reveals that though the legal framework regarding privacy and confidentiality of clinical and research information is well established (albeit not homogenous), guidelines are generally absent in the post-mortem context. Nevertheless, a brief analysis of this issue through two ethical perspectives (principlism and consequentialism) allows us to identify six key elements to be taken into consideration when returning a deceased participant's research results.

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**The Needle in the Haystack: International Consortia and the Return of Individual Research Results**

*Susan E. Wallace*

Returning individual results to participants in research studies is gaining acceptance and policy guidance is now available for investigators to develop a plan for returning results at the local level. However, returning results discovered through the work of an international scientific research consortium presents additional ethical and procedural difficulties. No general guidance is available for international consortia that wish to consider this issue, but there are examples of internal policies that are being used by consortia such as the International Cancer Genome Consortium (ICGC) and the Type 1 Diabetes Genetics Consortium (T1DGC). This paper presents the policy stance these studies have adopted regarding returning individual research results and their reasons behind it, and gives specific examples from their policy documents and project consent materials. Finally, it suggests an oversight mechanism these and other international consortia can use to ensure that this important issue is addressed appropriately.

Independent Articles

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**Conflicts over Control and Use of Medical Records at the New York Hospital before the Standardization Movement**

*Eugenia L. Siegler and Andrew B. Cohen*

Historians of medicine generally credit the hospital standardization movement of the early 20th century with establishing the record as a sign of hospital and staff quality. The medical record's role had already been the subject of intense interest at the New York Hospital several decades before, however. In the 1880s malpractice and insurance concerns caused the administration to attempt to supervise record creation, quality, and access, over the objections of physicians. Contemporary concerns about the uses of the medical record were in play well before 1910.

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**An Ethics Expertise for Clinical Ethics Consultation**

*Lisa M. Rasmussen*

The legitimacy of clinical ethics consultation is often implied to rest on the legitimacy of moral expertise. In turn, moral expertise seems subject to many serious critiques, the success of which implies that clinical ethics consultation is illegitimate. I explore a number of these critiques, and forward "ethics expertise," as distinct from "moral expertise," as a way of avoiding these critiques. I argue that "ethics expertise" succeeds in avoiding most of the critiques, captures what clinical ethics consultants might justifiably do, and expresses a subject matter which can be taught and assessed.

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**Reforming Pharmaceutical Industry-Physician Financial Relationships: Lessons from the United States, France, and Japan**

*Marc A. Rodwin*

This article compares the means that the United States, France, and Japan use to oversee pharmaceutical industry-physician financial relationships. These countries rely on professional and/or industry ethical codes, anti-kickback laws, and fair trade practice laws. They restrict kickbacks the most strictly, allow wide latitude on gifts, and generally permit drug firms to fund professional activities and associations. Consequently, to avoid legal liability, drug firms often replace kickbacks with gifts and grants. The paper concludes by proposing reforms that address problems that persist when firms replace kickbacks with gifts and grants based on the experience of the three countries.

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**Symposium articles** are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine, and ethics. Each article is peer reviewed.

**Independent articles** are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

**Columns** are written or edited by leaders in their fields and appear in each issue of JLME.

**Next Issue:**

**The Graying of America: Challenges and Controversies**

A Symposium  
Guest Edited  
by Robert M.  
Sade

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**Me and My Body: The Relevance of the Distinction for the Difference between Withdrawing Life Support and Euthanasia**

*Andrew McGee*

In this paper, I discuss David Shaw's claim that the body of a terminally ill person can be conceived as a kind of life support, akin to an artificial ventilator. I claim that this position rests upon an untenable dualism between the mind and the body. Given that dualism continues to be attractive to some thinkers, I attempt to diagnose the reasons why it continues to be attractive, as well as to demonstrate its incoherence, drawing on some recent work in the philosophy of psychology. I conclude that, if my criticisms are sound, Shaw's attempt to deny the distinction between withdrawal and euthanasia fails.

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**Communitarianism and the Ethics of Communicable Disease: Some Preliminary Thoughts**

*Cara M. Cheyette*

Communicable diseases, especially those that are highly contagious, are on the rise and each of us, no matter who we are or where we live, is equally at risk of transmitting contagious diseases to others as we are of contracting such diseases from others. Because contagious diseases are as readily passed state-to-state as person-to-person, we all have a stake in every country's ability to enact effective infectious disease control policies, while policies grounded in shared values are more likely to gain widespread acceptance and thereby prove most effective. This paper suggests that principlism proved invaluable as an ethical framework for resolving hard medical cases and setting health care policy because it nicely "fits" dilemmas that arise in the context of the special relationship between doctors and patients or within family units. It then argues that communitarianism provides the better foundation for crafting infectious diseases control policies because contagious diseases, which often pass between perfect strangers, raise questions about the moral obligations we owe to (or are entitled to demand of) people with whom we share no "special" relationship. Accordingly, a socially embedded framework such as communitarianism may be a better fit for the more socially embedded ethical dilemmas of communicable diseases.

Columns

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**Currents in Contemporary Bioethics**

*Mark A. Rothstein*

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**Teaching Health Law**

*Roberta M. Berry*

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**Reviews**

*James G. Hodge, Jr.*