



Community, Autonomy and Informed Consent: Revisiting the Philosophical Foundation for Informed Consent in International Research

Pamela J. Lomelino

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In using the example of informed consent guidelines for international research on human subjects, this book demonstrates one of the many useful ways that philosophy can be used to move from theory to praxis by providing a general picture of how a philosophical analysis of underlying concepts can affect the way that public policy is framed; the ways that such policies are exclusionary; and a general methodology for remedying injustices in public policy and practice once they have been identified. With diseases, such as AIDS, reaching epidemic proportions in less developed countries, medical research on human subjects in these areas is on the rise. Current international guidelines for research on human subjects stress the importance of informed consent, which is meant to ensure that people freely choose whether to participate in research trials. In an effort to be more globally applicable, many current international ethical guidelines for informed consent in research on human subjects attempt to incorporate community in the informed consent process. This book explains how these attempts encounter two primary problems: (1) they fail to adequately acknowledge the importance community has for many people in less developed countries; and (2) they fail to attend to the constraints to autonomy that oftentimes become magnified once community is involved in the informed consent process. The reason for these shortcomings can be traced to the current account of autonomy reflected in international informed consent guidelines, which is here referred to as the traditional account of autonomy. Although traditional autonomy can account for what this book defines as external constraints to autonomy, it is unequipped to recognize the internal constraints which arise in the medical context. In order to adequately recognize the importance of community in autonomy and to attend to internal constraints to autonomy, it is essential to adopt an account of relational autonomy. Using such a relational autonomy account, the book provides a set of minimally sufficient ethical conditions that can assist policy makers in revising international informed consent guidelines in research on human subjects, so that these guidelines better attend to community involvement in the informed consent process. To demonstrate how these conditions might be used, the book also presents examples of possible revisions to the CIOMS Ethical Guidelines, one of the leading international ethical guidelines for research on human subjects.

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