Community, Autonomy and Informed Consent

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Revisiting the Philosophical Foundation for Informed Consent in International Research

By

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Cambridge Scholars
Publishing

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This book first published 2015

Cambridge Scholars Publishing

Lady Stephenson Library, Newcastle upon Tyne, NE6 2PA, UK

British Library Cataloguing in Publication Data
A catalogue record for this book is available from the British Library

ISBN (10): 1-4438-7115-X
ISBN (13): 978-1-4438-7115-0

To my children, Brooke-Lynn and Darrell
I am because we are.

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ACKNOWLEDGMENTS

As with any sizable endeavor, this book would not have been created without the help of others. My work on this book began while I was at the University of Colorado. The problems that I insist occur with current international informed consent guidelines for research on human subjects became apparent to me after sitting in on two classes – a research ethics class taught by Eric Chwang and a seminar on political thought taught by Ajume Wingo. In both classes, I kept raising the same objection regarding the lack of recognizing the role of community in autonomous decision-making and the subsequent constraints to autonomy that went unrecognized. Upon meeting Ajume Wingo, I went to him to discuss a concept of the person that is communally-based (a concept I had previously termed “relational beings” and had written about when addressing universal human rights).[1] Having previously discussed this concept at conferences only to find that my Western liberal audience was unable to fully comprehend what I was saying, I was delighted when Ajume Wingo understood. His knowledge of the *Akan* concept of the person reflected my ideas of what I had been referring to as a communally-based person.[2] It is with sincere gratitude that I thank him for mentoring me in African Philosophy and the *Akan* concept of the person. It is also with sincere gratitude that I thank Alison Jaggar for her profound work on differing concepts of human nature and the ways that these inform different political theories.[3] Her work provided the philosophical framework for me to better understand how concepts of the person inform different models of informed consent. In addition, I thank Eric Chwang, David Boonin, Alison Jaggar, Ajume Wingo and Ben Hale for their comments on the beginning stages of this work, which in its infancy took the form of my PhD dissertation. Also, my sincere gratitude to Hilde Lindemann for recommendations on readings and suggestions on structuring my manuscript. I also thank the many scholars whose work in Bioethics, Feminist Philosophy, Political Philosophy, and African Philosophy provided insights into the various components of international

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[1] Lomelino 2008.

[2] Wingo 2007.

[3] Jaggar 1983.

research on human subjects. And, last but certainly not least, my thanks to Carlo Tarantino, whose editing and indexing skills proved invaluable in getting the manuscript ready for publication.

FOREWORD

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 go 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 we have identified them. Rather than perform an in-depth analysis of the various components at play in this medical context (i.e., autonomy, relational autonomy, constraints to autonomy, informed consent), I have intentionally aimed to present the reader with enough information about each by which to understand how these relate to each other and how this is reflected in public policy. This book is intended to provide a "bigger picture" perspective of community involvement, philosophical foundations, and constraints to autonomy in international research on human subjects.

Although I culminate this broader analysis by proposing amendments to current international informed consent guidelines for research on human subjects, I do so with the hope that advisory committees and policy makers will explore these problems and the ways we can improve current guidelines. In mapping my philosophical analysis onto policy, I use the example of the 2002 Council for International Organizations of Medical Science (CIOMS) Ethical Guidelines for Biomedical Research Involving Human Subjects. Notably, the CIOMS guidelines are currently under review, with an estimated completion date of 2015. According to the Working Group for Revisions of the 2002 CIOMS Guidelines, developments in research ethics (which includes community involvement in research) provide one of the reasons for revising the current guidelines.[1] It will be interesting to see which particular revisions the committee recommends. I am both curious and hopeful that they will attend to the constraints to autonomy I insist get magnified when community becomes involved and provide more concrete direction for involving community in the informed consent process.

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[1] CIOMS Working Group 2014.

My recommendation to amend current guidelines reflects my belief that, whenever possible, we should aim to remedy problems within current frameworks rather than abandoning them. Rather than insisting on the philosophical foundation of autonomy or on abandoning informed consent entirely, I propose making revisions within this framework. My reason for choosing to do so is simple. It is easier to work within a current framework whenever possible rather than attempting to drastically change it. As I argue, implementing additional requirements and safeguards can remedy the current problems with informed consent in international research on human subjects, thereby providing a more immediate solution. This conclusion by no means is meant to imply that these amendments will alleviate all constraints to autonomy in international medical research. As I state in the first chapter, we must also attend to remedying larger social injustices that result in the particular constraints to autonomy in medical research, such as the need to remedy sexism and racism.

The reader should also note that, although I focus on constraints to autonomy in international research on human subjects as it applies to the informed consent process, much of what I argue can be applied to other contexts. For example, the negative impact of social structures is at play in most cases in which people make autonomous choices. Thus, my arguments regarding the ways that social structures impede autonomy have implications beyond the research context and extend to other contexts in which people make autonomous personal choices.

In closing, allow me to provide the reader with an idea where this work fits within the current literature. In addressing constraints to autonomy, I discuss what I call internal and external constraints. In doing so, I bridge aspects of political philosophy and philosophical psychology. Traditionally, political philosophy has focused on how social structures result in external constraints that impede a person’s ability to exercise his or her choices. For example, political philosophers may be concerned that a woman is unable to exercise choices that reflect her beliefs and values due to unjustly limited options that result from sexist practices within society. In comparison, philosophical psychology is concerned with how a person internally formulates his or her choices. A philosophical psychologist might be concerned that a person has adopted beliefs that stand in the way of his being able to formulate choices that are self-governed. For example, someone who was abused as a child might mistakenly believe that abuse is acceptable and, consequently, chooses to have abusive relationships. In bridging these two areas of philosophy, the reader can supplement this work with work by scholars in political philosophy and philosophical psychology to better understand how social injustices and psychology impact autonomous decision-making.

CHAPTER ONE

INTRODUCTION

Nearly seventy percent of all those infected with HIV reside in Sub-Saharan Africa.[1] With this disease reaching epidemic proportions in less developed countries, research on human subjects in these areas is on the rise.[2] Current international guidelines and regulations for research on human subjects stress the importance of informed consent, which is meant to ensure that people freely choose whether to participate in a research trial. As many of the current international guidelines for informed consent in research on human subjects spell out, informed consent rests on the principle of respect for autonomy,[3] that is, the ability to make self-governed choices regarding research participation that reflect one's beliefs and values.

Although some have written about research on human subjects from less developed countries, these writers have tended to focus on such issues as fair benefit sharing[4] and what constitutes adequate and comprehensible information for the purposes of obtaining informed consent.[5] What is missing is an analysis of whether the current philosophical foundation for informed consent guidelines adequately respects important cultural differences. In providing the philosophical foundation for informed consent in international research on human subjects, the principle of autonomy both justifies the reason for requiring informed consent and guides the way that informed consent should be structured within the research context. Because the philosophical foundation informs the guidelines by which researchers determine whether they have ethically

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[1] UNAID 2012.

[2] Although I refer to the HIV/AIDS epidemic in less developed countries, it should be noted that this epidemic takes different forms in different countries.

[3] Belmont Report 1979, Part B:1; CIOMS Ethical Guidelines 2002, Introduction; UNESCO Declaration on Bioethics and Human Rights 2005, Article 5.

[4] For example, refer to Conference on Ethical Aspects of Research in Developing Countries 2002 and Arras 2004.

[5] For example, refer to Ingelfinger 2003 and Mystakidou K, Panagiotou I, Katsaragakis S, Tsilika E, Parpa E. and Sahara, J. 2009.

obtained subjects' informed consent to participate in research, it is important to examine the possible shortcomings of this foundation in light of relevant cultural differences.

In the chapters that follow, I argue that the current account of autonomy reflected in international informed consent guidelines and regulations, which I refer to as the traditional account of autonomy, does not adequately address important cultural differences – namely, the importance that some cultures place on community to the extent that they would want to include community in their decision-making process. Because community involvement is of the utmost value to many in less developed countries, and because the principle of autonomy demands respecting this, it is necessary for informed consent guidelines that are intended to be globally applicable to address community involvement and the ways in which this might enhance or impede a subject's autonomy.

Although my focus is on subjects from less developed countries, my arguments also apply to certain subcultures within more developed societies that tend to place great importance on community. While one should keep in mind the overall applicability of my arguments, I have chosen to focus on less developed countries due to the urgent need for research in these countries in response to various epidemics.

In order to understand how the current foundation fails to adequately attend to community involvement, I examine what I call the traditional account of autonomy, which underlies the current foundation. Autonomy is the ability to make self-governed choices that reflects one's identity, beliefs, and values, and which one believes is in one's best interest. While all theories of autonomy share minimal conditions for autonomy, they differ in how they define the necessary and sufficient conditions for autonomous choice.

One way of understanding these differences is to look at the particular account of the person that informs the general account of autonomy. Something like this has been done before in political philosophy with regards to the account of human nature that is implicit in accounts of political autonomy, or the ability to make self-governed choices in the political realm.[6] Although my focus is personal autonomy, or the ability to make self-governed personal choices, I build on the idea of turning to accounts of the person to better understand theories of autonomy.

In doing so, I examine the three accounts of the person that have become popular in the philosophical literature – the abstract individual, the embedded self, and the relational self. I believe that these inform three general accounts of personal autonomy respectively -- accounts that I refer

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[6] Jaggar 1983; Sandel 1998.

to as the *traditional, embedded*, and *relational accounts*. I first show that the traditional account of autonomy currently underlies most informed consent guidelines and regulations on international research on human subjects. I then explain how this account fails to adequately attend to the ways that social structures can impede autonomy.

The term, social structures, is commonly used in the social sciences to refer to patterned social arrangements in society, such as people being grouped into economic classes or categorized by race, and the ways that these arrangements influence the actions of the people who are socialized into this structure.[7] In referring to the ways that social structures impede autonomy, I am concerned with the ways in which being a member of an oppressed race, class, gender, sexuality, or disability, affects both the beliefs and autonomy skills they may have, and the constraints that they may encounter in society when trying to put their autonomous choices into action. Although there are numerous types of oppressed groups within society, I oftentimes shorten the list to include race, class and gender. This by no means implies that these are the only oppressed groups within society with which one should be concerned.

In addressing social structures, I categorize the ways that social structures impede autonomy into two general categories, internal and external constraints. Internal constraints deal with the ways in which oppressive socialization can impede autonomy, such as when a person has been raised to adopt common societal beliefs about members of her race and makes choices in light of these beliefs that further perpetuate her oppression. External constraints are those an individual encounters while trying to realize her choices within society. These constraints exist out in the world, so to speak. Being unable to exercise one’s autonomous choices due to racist practices in society is an example of an external constraint that arises from social structures.

With regards to social structures, my concern is the ways that involving community in the informed consent process in medical research on human subjects oftentimes magnifies the extent to which social structures impede subjects’ autonomy.

In examining the three general accounts of autonomy, the traditional, embedded and relational accounts, I conclude that only relational accounts of autonomy adequately attend to the internal and external constraints to autonomy. Because the current philosophical foundation for informed consent is the traditional account of autonomy, I conclude that policymakers must revise the current philosophical foundation to rely on a relational account of autonomy. Once the philosophical foundation has

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[7] Abercrombie 2000, 326–327.

been revised, I explain how current informed consent guidelines for research on human subjects also must be revised in order to aptly reflect the change in foundation.

1.1 Internalized Oppression and Adaptive Preferences

In speaking of "internalized oppression," some might be reminded of "adaptive preferences." "Adaptive preferences," which are also sometimes called "deformed desires," refer to preferences that people from oppressed groups formulate as a result of their oppressive socialization. The idea is that, if an individual were removed from the social context in which she is oppressed, she would see how her preferences further oppress her. As a result, she would no longer have these preferences. The concern therefore is that adaptive preferences are not autonomously chosen and so impede a person's ability to flourish in society. For example, some have insisted that women's preference to not pursue intellectual careers stems from the deformed desire that results from their being indoctrinated to believing that women are best suited for domestic work.[8] Internalized oppression and adaptive preferences both highlight concerns over the ways in which oppressive socialization can result in internal constraints on one's ability to make self-governed choices.

In the chapters that follow, I have chosen to use the term, "internalized oppression," since I believe this term more fully captures the harmful effects that arise when one relies on oppressive beliefs in formulating one's choices. However, one can read this as also referring to adaptive preferences that impede one's ability to make self-governed personal choices.

1.2 Internalized Oppression and Privileged Groups

Prior to proceeding, allow me to make a clarification with regards to internalized oppression. Although people from privileged groups in society might also formulate choices based on mistaken beliefs that arise from their socialization, this does not amount to internalized oppression. Internalized oppression refers to the idea that mistakenly adopted beliefs result in desires and choices that reinforce a position of lesser power that people from oppressed groups have within society.

To illustrate how persons from privileged groups in society who adopt mistaken societal beliefs do not suffer internalized oppression, consider

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[8] Bartky 1990; Nussbaum 1999.

the following two examples. First, consider the parable from the Bible in which a Pharisee thanks God for not having been born "like other men, robbers, the unjust, adulterers, or even this tax collector."[9] Although the Pharisee operates under the mistaken belief that he is a far better person than others, his belief does not result in his making choices that cause him to suffer.

However, people from privileged groups can adopt mistaken beliefs that result from how they have been socialized as a member of a specific race, class, or gender that do lead to suffering. Yet, this suffering does not amount to decreasing the power they have in society. Consider the second example of a privileged individual who adopts mistaken societal beliefs. A father might adopt the mistaken belief that he should devote his time to working to make money rather than spend time with his children. Although he suffers by having missed out on spending time with his children, his suffering does not decrease his position of power *within society*.

1.3 Oppressed Groups and Vulnerable Populations

Although members of oppressed groups have lesser power in society, they do not constitute a vulnerable population. The term, *vulnerable populations*, is used in international guidelines for research on human subjects to refer to "those who are relatively (or absolutely) incapable of protecting their own interests" to the extent that they are unable to provide valid informed consent.[10] According to the CIOMS, this includes children and persons who suffer from mental or behavioral disorders that make them incapable of consenting to research participation.[11] I encourage dispensing of the term, vulnerable populations, since it mistakenly implies that all members of a particular group, such as persons with mental or behavioral disorders, are incapable of making autonomous decisions. Yet, even if one grants the use of the term as indicating populations in which a *majority* of the members lack the requisite autonomy skills, this is not the case for all members of oppressed groups in society. Instead, many of these persons face additional constraints to autonomy which can be remedied, thereby freeing these individuals to be able to provide valid informed consent.

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[9] Cf., Luke 18:9-14. My thanks to Alison Jaggar for suggesting this example.

[10] CIOMS 2002, Guideline 13.

[11] *Ibid.*

1.4 Internal Constraints and Ethical Guidelines

Having insisted on attending to the internal as well as the external constraints on autonomy, I must clarify a concern that I have with regards to my arguments and the current informed consent guidelines and regulations. I insist that one should be concerned with internal constraints on autonomy that can arise if one is a member of an oppressed group within society. Because internalized constraints are difficult to identify, some might wish to err on the side of caution, so to speak, and assume that members of oppressed groups are unable to provide valid consent due to these constraints. This is problematic. Denying those who are already oppressed the right to make choices that pertain to their well-being adds to their oppression.[12] Instead, one must strike a delicate balance between (1) acknowledging the problem of internal constraints, and (2) not denying those who are at risk of suffering from these constraints the ability to exercise their choices.

In response to this problem, one can glean a lesson from what I believe are the most progressive informed consent guidelines for research on human subjects as laid out in the Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*.[13] The CIOMS Guidelines are the only guidelines that take internal constraints seriously -- although they do not explicitly use the term, “internal constraints”. According to Guideline 16, researchers should take special care to promote women’s autonomy in the informed consent process due to concerns over their being socialized to not be assertive, to submit to authority, and to tolerate pain and suffering.[14] At the same time, however, they do not assume that women lack the requisite skills for providing valid consent. I build on this approach, in Chapter 10, where I argue for providing subjects from oppressed groups the option to participate in support groups that can assist them in identifying and remedying the internal constraints that can arise from social structures, while at the same time not presuming that members of oppressed groups cannot provide valid consent.

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[12] For arguments regarding how oppression results in decreased autonomy, refer to McLeod and Sherwin 2000. For arguments regarding how oppressed people continue to make autonomous choices, even in the face of oppression, see Narayan 2001.

[13] CIOMS 2002. To understand why I believe the CIOMS Guidelines are the most progressive, refer to Chapter 9: Current Guidelines.

[14] CIOMS 2002, Guideline 16.

1.5 Community

Since I refer to community throughout this book, allow me to indicate what I mean by community. Because providing the necessary and sufficient conditions for what constitutes a community would comprise a book in itself, I have opted to provide an idea of what I mean by community by laying out certain parameters. First, community does not equate with community leaders. Similarly, community decision-making is not reducible to community leaders' decision-making. Instead, community must include appropriate representation of its various members. For example, in Chapter 6, I discuss community involvement in the decision-making process as it relates to research. In doing so, I argue for including those who are more directly affected by the research. So as to ensure that oppressed groups within society have a role in the decision-making process, I also argue for including members from oppressed groups based on ethnicity, race, class, gender, sexuality, and disability.

Because much of my discussion regarding community focuses on the ways in which involving community can impede subjects' ability to make self-governed choices regarding research participation, some might focus on the negative aspects of community involvement. It is important to note that community can both enhance and impede autonomy. In my discussion of relational accounts of autonomy, I emphasize the ways in which people's essential characteristics, their identities, beliefs, and values, are constituted to some degree by their relationships to others. This illustrates how community provides an important aspect of people's identity. Community is also the framework in which people develop and get a chance to exercise and refine many of their autonomy skills. Admittedly, much of my focus is on how community impedes autonomy; this is due to the larger context of focusing on revising current informed consent guidelines for international research that are meant to protect human subjects.

1.6 Autonomy and Informed Consent

Prior to presenting the chapter summaries, it is necessary for me to make a clarification with regards to my overall project. In arguing for the need to revise the account of autonomy that serves as the philosophical foundation for current international guidelines and regulations for informed consent in research on human subjects, I examine autonomy and its relation to informed consent. Although I draw on the relationship between autonomy and informed consent, it is important to note that informed consent and autonomy are not necessarily related. Informed consent refers to making a voluntary and informed decision to authorize medical interventions or to participate in research.[15] Autonomy refers to making a choice that is self-governed, meaning that it reflects a person's identity, beliefs, and values as these relate to what is in his best interest. Obligations to obtain subjects' informed consent need not be motivated by respect for autonomy. For example, they could be motivated by legal concerns. However, informed consent is motivated by respect for autonomy in the current guidelines and regulations for informed consent in research on human subjects. In this context, the proclaimed reason for requiring that subjects provide voluntary and informed consent to participate in research is to ensure that their decision is autonomous.[16] Consequently, within the context of these guidelines, autonomy has come to normatively frame informed consent requirements. It is this normative relationship that I draw on in arguing that, if one is serious about respecting autonomy, one must make changes to informed consent guidelines.

1.7 Chapter Summaries

Although I draw on the relationship between autonomy and informed consent, it is helpful to think of this book as consisting of two parts. Chapters 2 through 6 deal primarily with autonomy, while Chapters 7 through 10 focus more on informed consent.

In Chapter 2, I provide background information for understanding my arguments regarding autonomy. Chapter 2 consists of three parts. I begin the chapter by providing a general definition of autonomy. This provides the necessary conditions for all theories of autonomy, thereby providing a list for better understanding the various general accounts of autonomy that I address in Chapters 2 through 4. I also explain the purpose behind an autonomy theory. This provides a measure by which to gauge how well each general account of autonomy fares.

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[15] There are two general senses of informed consent – informed consent as autonomous authorization and informed consent as conforming to social rules of consent. International informed consent guidelines and regulations use the former sense of consent in which informed consent "occurs if and only if a patient or subject, with substantial understanding and in absence of substantial control by others, intentionally authorizes a professional to do something quite specific" (Beauchamp and Childress 2013, 122).

[16] The Belmont Report 1979, Part B:1; CIOMS Ethical Guidelines 2002, Introduction; UNESCO Declaration on Bioethics and Human Rights 2005, Article 5.

After addressing autonomy in general, I explain my categorization of theories of autonomy into what I call general accounts of personal autonomy. These accounts differ based on the account of the person that informs each. Addressing autonomy theories in this general form helps highlight how accounts of the person inform and sometimes limit autonomy theories.

To illustrate how an account of the person informs a general account of autonomy, I end the chapter by introducing the most common general account of autonomy, the traditional account. Because I believe that there have been many misinterpretations of this account, I focus on the primary tenant underlying the traditional account. It is not until I have introduced the remaining two accounts and have arrived at a set of strong objections to the traditional account (Chapter 3) that I provide a more detailed analysis of the traditional account (Chapter 4). I believe this provides a more concise interpretation of the traditional account.

Having introduced the notion of the traditional account of autonomy in Chapter 2, I present the remaining two general accounts in Chapter 3: Embedded and Relational Accounts of Autonomy. Those who advocate an embedded account insist that respect for autonomy is justified by its coherence with community beliefs, values, and practices. I argue there are two reasons for this account. First, when a person belongs to multiple communities whose values conflict, it is unclear which community values determine whether and how to respect individual autonomy. Second, even in cases in which one can identify the community values that deal with respect for autonomy, one should be concerned that community values might trump respect for individual choice. Since research subjects are the ones most directly impacted by medical research, their individual choice must always trump community values when these conflict.

Turning next to the relational account, I expand on the reasons for requiring an account of autonomy, which considers how dependency and differences in race, class, and gender can impede autonomy. I end the chapter with the conclusion that the relational account is better than the embedded one, since the relational account both acknowledges dependency and attends to differences in race, class, and gender, or what I call social structures.

Building on the second conclusion from Chapter 3, I devote Chapter 4 (Traditional Autonomy Theorists Respond) to an analysis of how adequately traditional accounts can account for the problems of dependency and social structures. My method in this chapter is to examine three contemporary theories in the autonomy literature: those by Beauchamp and Childress, by Thomas Hill, and by Gerald Dworkin. I do so with two goals in mind. My first goal is to illustrate how to identify a theory as either traditional or relational. In analyzing these contemporary theories, I conclude that Dworkin's is relational, while Hill's and Beauchamp and Childress' are traditional.

Next, I examine the extent to which traditional accounts of autonomy make conceptual room for attending to the problems of dependency and social structures. I consider a general account of autonomy to leave conceptual room for this if doing so is consistent with the aspects of the account of the person that informs the general account. For example, if the account of the person claims that people's identities, values, and beliefs can be isolated from their social context, then it would be inconsistent for this account to claim that people's social context can affect the way that they internally structure their values and identities.

In examining the accounts by Beauchamp and Childress and by Hill, I explain how, although traditional accounts can attend to the first problem, dependency, they fail to adequately deal with the second problem, social structures. Underlying this failure is the reliance on the account of the atomistic individual, which prevents an acknowledgment of the internal constraints arising from social structures.

Having explained how traditional accounts of autonomy are unable to adequately attend to the ways in which social structures impede autonomy, I draw the conclusion that traditional autonomy accounts should be rejected and, positively conclude that relational accounts are the best general accounts of autonomy.

In Chapter 5: Relational Autonomy in the Context of International Research on Human Subjects, I specify how a relational account of autonomy is the best account for international research on human subjects. I present two primary arguments in support of this conclusion. First, I explain how a relational account of autonomy is more globally applicable by illustrating how it best acknowledges and respects an account of the person that is popular in Africa, where much research is done in response to the AIDS epidemic there. Second, I present examples of how social structures impede autonomy in the context of international research on human subjects. Dependency due to illness, differences in class, differences in gender, and the Western framework of mistakenly assuming that informed consent is a contract between two fairly equally positioned people are all examples of how social structures can impede autonomy in the informed consent process in international research on human subjects. Because only a relational account of autonomy adequately attends to these problems, I conclude that it is the best account in this research context.

Having provided arguments in support of a relational account of autonomy, I devote Chapter 6 to arriving at a *minimal set* of ethical conditions for best ensuring respect for relational autonomy in the research setting, since doing so provides the flexibility for adapting these guidelines to differing cultural contexts.

I begin the chapter by explaining how to construct an ethical condition directed towards what I pointed out in Chapter 2 is a universal requirement for autonomy: critical reflection of one's beliefs, values, and choices. I then examine ethical conditions, which others have recommended for dealing with the problems of how social structures can impede autonomy. In cases in which others have proposed an ethical condition in other medical contexts, I examine the extent to which the ethical condition might be applicable to the research context. I conclude that providing support systems, and having subjects and community participate in various stages of the research process are two ethical conditions that others have suggested that can be useful in addressing problems that arise from differences in race, class, gender, and disability.

I then examine whether any of the three ethical conditions (viz., critical reflection, support, and participation) are singularly sufficient for ensuring subjects' autonomy with regards to providing valid informed consent. After concluding that none is adequate by itself, I examine whether combining these conditions adequately ensures respect for autonomy in informed consent in research. In doing so, I argue that *a combination is still inadequate*. It is necessary to add an external monitoring system and a safeguard for prioritizing subjects' choices. Adding these conditions results in a list of five minimally sufficient ethical conditions for best ensuring subjects' autonomous decision-making in research on human subjects: critical reflection, support mechanisms, participation, external monitoring system, and prioritizing subjects' choices. I return to this list in Chapter 10, where I illustrate how these can inform changes to current informed consent guidelines.

Having focused on autonomy in Chapters 2 through 6, I turn to the specific concept of informed consent and its relation to autonomy. In Chapter 7 (Informed Consent & Autonomy), I conclude that there is good reason to maintain the connection between autonomy and informed consent once one realizes that respect for relational autonomy overcomes the problems encountered in previous attempts to justify informed consent, which rely on a traditional, account of autonomy.

I begin Chapter 7 by providing a brief history of informed consent in the medical context, explaining how informed consent has come to rest on the principle of respect for autonomy within the context of research on human subjects. Although I do not intend to provide a thorough defense of this relationship, I strengthen my arguments regarding the benefits of relying on a relational account of autonomy in the context of informed consent guidelines and regulations for research on human subjects by addressing what I believe are two of the strongest objections against relying on the principle of autonomy to justify informed consent.

The first objection I address is by Neil C. Manson and Onora O'Neill, who insist that relying on autonomy to justify informed consent justifies too much in some respects and too little in others.[17] I explain how their objections rest on a mistaken assumption about what it means for the principle of autonomy to justify informed consent. The second objection I examine comes from the work of Joan Tronto.[18] Tronto argues that the reliance on the principle of autonomy as justifying informed consent results in structuring informed consent so that it overlooks the ways that social injustices and disparate power impede a person's ability to make a self-governed decision about medical care or research participation. I respond by showing how a relational account of autonomy remedies these problems.

To further illustrate the benefits of relying on relational autonomy, I devote Chapter 8 (Addressing Alternative Solutions) to analyzing the feasibility of other possible solutions to structuring informed consent so that it is still aimed at ensuring that people make self-governed choices regarding medical treatment and research participation, but does not rely on the traditional principle of autonomy to accomplish this. My purpose of this chapter is not to examine all of the arguments for possible alternative accounts of informed consent that are aimed at ensuring that subjects make autonomous choices. Instead, my aim is to strengthen my conclusion that a relational account of autonomy should underlie the concept of informed consent. To do so, I examine two alternative accounts of how to structure informed consent, recently proposed by Manson and O'Neill (2007) and by Tronto (2009).[19] Due to insurmountable problems that I believe each account encounters, I conclude that relying on a relational autonomy account to guide how to structure the informed consent process provides a better solution.

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[17] Manson and O'Neil 2007.

[18] Tronto 2009.

[19] Because I only address two proposals, I am not implying that my arguments lead to the conclusion that relational autonomy is the only feasible solution for providing a philosophical foundation that aptly justifies, and informs how to structure informed consent.

I devote Chapter 9 (Current Informed Consent Guidelines) to an analysis of the current informed consent guidelines and regulations for international research on human subjects. I examine these to determine on which general account of autonomy each relies. In doing so, I conclude that none of the current international guidelines or regulations for informed consent in research on human subjects adequately attends to the problems arising from social structures. I argue that this illustrates the failure of current guidelines and regulations to adequately respect a relational account of autonomy.

Because I am concerned with how current policy guides researchers' conduct in obtaining informed consent, I address guidelines that carry some force, whether this is as the master document that guides other guidelines (i.e., *Declaration of Helsinki*) or a particular enforceable regulation (i.e., *Federal Code of Regulations*). With this in mind, I address the following guidelines and regulations: *Declaration of Helsinki*; *Belmont Report*; the Council for International Organizations of Medical Sciences (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*; the United States Department of Health and Human Services (HHS) *Code of Federal Regulations*; and the United Nations Educational, Scientific and Cultural Organization (UNESCO) *Universal Declaration on Bioethics and Human Rights*. In examining these, I insist that many of the guidelines and regulations dealing with informed consent rely on a traditional account of autonomy. However, the more progressive ones rely on a relational account. As I explain, even the most progressive document, the CIOMS Ethical Guidelines, requires revisions in order to better ensure subjects' autonomous decision-making in the research context.

In Chapter 10: Revisions to Informed Consent Guidelines, I propose amendments to the current guidelines and regulations for better ensuring respect for relational autonomy as it relates to informed consent in research on human subjects. Drawing on the set of ethical conditions arrived at in Chapter 6, I show how these can be translated into specific guidelines. To illustrate, I map these changes onto the most progressive guidelines, the CIOMS Guidelines, to show how one can improve these guidelines to better attend to cross-cultural differences regarding community value and the problems that can arise from differences in race, class, gender, and disability, especially when community gets included in informed consent.

CHAPTER TWO

AUTONOMY AND THE TRADITIONAL ACCOUNT OF AUTONOMY

In this chapter, I provide background information for understanding the general accounts of autonomy. There are three parts to this chapter. In the first part, I introduce the notion of autonomy. I provide a general definition of autonomy, which includes laying out the necessary conditions for all accounts of autonomy. I then clarify the purpose of a theory of autonomy, which helps elucidate how the general accounts of autonomy fit the more general definition of theories of autonomy.

In the second part, I categorize theories of autonomy into what I call "general accounts," according to the account of the person informing each of them.

In the final part of the chapter, I illustrate how accounts of the person inform general accounts of autonomy by briefly explaining what I call "the traditional account". This then sets the stage for presenting the remaining two general accounts, the embedded and relational account respectively, each of which rests on an account of the person that functions in part as a response to the atomistic account of the person in the traditional account. I address these two accounts more fully, however, in the next chapter.

2.1 Distinctions

Before presenting a general definition of autonomy, it is important for me to clarify a few distinctions in the autonomy literature. In the first two subsections, I explain two types of distinctions that will come into play in my discussion of autonomy: the distinction between *moral* and *personal* autonomy, and the distinction between *political* and *personal* autonomy. In the third subsection, I briefly attend to a distinction that has become popular in the autonomy literature, but which is not directly related to my focus – namely, the distinction between *procedural* and *substantive* theories of autonomy. I do this to provide a general idea of where my proposed solutions might fall within this now popular distinction.

2.1.1 Personal vs. Moral Autonomy

Philosophers draw a distinction between *moral* and *personal* autonomy.[1] *Moral* autonomy refers to one's ability to formulate and follow the objective moral law. For example, treating others with respect is objectively morally good. Regardless of the time and place, all people deserve a minimal level of respect, and one who has moral autonomy both recognizes and follows this moral law.

Personal or individual autonomy, however, deals with an individual's ability to make self-governed choices regarding how to act in such a way that adds to her overall well-being.[2] As Joseph Raz explains, "the ideal of personal autonomy is the vision of people controlling, to some degree, their own destiny, fashioning it through successive decisions throughout their lives."[3] An example of personal autonomy is the career choice that a person makes.

Of course, some of the choices that an individual makes that concern what she believes is a good life are also moral choices. For example, one might think that treating others with respect is part of a good life. Yet, not all personal choices relate to the objective moral law. An individual's decision to participate in a research trial is a personal choice that deals with personal autonomy, but not moral autonomy. Since I am concerned with research subjects' choices regarding research participation, my focus is therefore on personal and not moral autonomy.

2.1.2 Personal vs. Political Autonomy

Another important distinction for my discussion of autonomy is that between *political* and *personal* autonomy. Because I draw lessons from political philosophy, it is important for me to clarify that my overall concern is with personal and not political autonomy. Political autonomy deals with the extent to which people are able to make self-governed decisions in the political sphere. For example, those who have political autonomy are able to participate in constructing political policies and in providing social criticism.[4] In contrast, recall that personal autonomy deals with choices that a person makes with regards to his personal life.

Notably, limitations to people's political autonomy can bear on their personal autonomy. For example, a couple might wish to have a family but

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[1] Christman 2009, 1-3.

[2] More on this below.

[3] Raz 1986, 369.

[4] *Ibid*, 3.

may be unable to do so due to current laws that bar homosexuals from adopting children. Although political and personal autonomy may be causally interrelated, it is possible to distinguish between the two. As I have mentioned, my focus is on personal autonomy as it relates to a person's choices regarding research participation.[5] Thus, it is important not to confuse my focus on international informed consent guidelines as indicating that I am also concerned with political philosophy. I do not attend to the question of whether and to what extent such guidelines are justified, which is a question for political philosophy. Instead, my arguments are situated within the already existent structure of having these guidelines in place.

2.1.3 Substantive vs. Procedural Theories of Autonomy

Recently, a distinction that has become popular in the autonomy literature is that between procedural and substantive theories.[6] Procedural autonomy theorists focus on the *process* of critical reflection that a person uses in making her choices rather than on the *content* of her choices. Harry Frankfurt, for example, presents a procedural autonomy theory in "Freedom of the Will and the Concept of a Person".[7] He insists that autonomy consists in aligning one's first-order desires – the desires from which one makes a particular choice – with one's second-order desires, namely, those desires that reflect one's true self or the desires with which one identifies. Suppose, for example, that an individual identifies herself as a health-conscious individual. She then has the second-order desire to be healthy. To ensure that her choices are self-governed or stem from what one might refer to as her true self, she would critically reflect on her choices to ensure that they aligned with her second-order desire to be health-conscious. In doing so, she would choose to eat a healthy diet and exercise regularly.

In addition to focusing on the critical reflection process, substantive autonomy theorists argue by contrast that one also must consider the content of a person's choices to determine whether her choices are

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[5] Although I focus on public policy in the form of international informed consent guidelines, my focus does not specifically attend to ethical issues that arise in political philosophy. For example, I do not attend to the question of whether and to what extent such guidelines are justified, which is a question for political philosophy. Instead, my arguments are situated within the already existent structure of having these guidelines and regulations in place.

[6] Chrisman 2009, 5; Mackenzie and Stoljar 2000, 12-21.

[7] Frankfurt 1971.