FOREWORD

“The struggle for human rights is like an overflowing river that floods down across the valley making the fields ever more fertile”.\(^{(1)}\) This metaphor has been used to describe the expanding force of the human rights movement, which tends to cover all new areas in which human dignity and human rights are being challenged. The most recent field to be “fertilized” by the principles of human rights law is biomedicine, \(i.e.\) the application of biological and medical technologies to human beings. Because rapid advances in this area present new and complex ethical and policy issues for individuals, society, and humankind as a whole, it has become increasingly clear that specific legal responses are necessary to ensure that biomedical technologies are used in a way which is respectful of human dignity and human rights.

But the new challenges are so formidable and far-reaching that individual countries alone cannot satisfactorily address them. As science becomes increasingly globalized, a coherent and effective response to the new dilemmas raised by science should also be global. This is why coordinated intergovernmental action is required to harmonize legal standards and to establish appropriate mechanisms to ensure that such standards are effectively implemented.

This volume aims to present the recent global efforts to develop common biolcgal norms, as well as some of the specific human rights issues that are at stake in this field. It brings together and updates a number of papers and contributions to edited volumes that I have written over the past decade in relation to this emerging discipline that can be called international biomedical law, or simply international biolaw.

Section I of this book sets forth the pivotal issues in this field, including the overarching principle of respect for human dignity

and a number of other principles that the international community has agreed should guide biomedical research and clinical activities.

Chapter 1 briefly sketches fourteen common principles that can be drawn from the international instruments relating to biomedicine. Among those principles are the requirement of informed consent, confidentiality of health data, non-discrimination on health grounds, beneficence and non-maleficence, special protection for vulnerable persons, and equitable access to health care. Certainly, most of these principles are not completely new, but are derived from previous international human rights instruments. Indeed, the greatest merit of biolegal instruments is not that they have “invented” new principles, but rather that they have adapted existing human rights standards to the specific field of biomedicine, and have drawn them together into coherent legal frameworks.

Chapter 2 examines the first and overarching principle of international biolaw – respect for human dignity – and its concretization by means of human rights. After some preliminary remarks about the relationship between bioethics and law, and about the status of soft law, this chapter explores the meaning and value of the notion of human dignity. Basically, it argues that the combined recourse to human dignity and human rights is the best, if not the only available ground for developing international legal standards in the field of biomedicine.

Chapter 3 is focused on the precautionary principle, which provides guidance to policy makers in deciding the action to be taken if there is good reason to believe that certain products or technologies may be seriously harmful to public health or the environment but when, at the same time, the risk is not currently fully understood. Strangely, while this principle has been formally enshrined in virtually every international treaty dealing with environmental protection, it is lacking in the international instruments relating to biomedicine. This is strange, not only because promoting public health is no less important than protecting the environment, but also because this principle already plays a central role in the domestic and regional (notably, European) policies in the public health area. This chapter aims to highlight the scope of the precautionary principle and to identify the conditions for its reasonable use.

Section II of this volume analyzes the work of two major intergovernmental bodies – UNESCO and the Council of Europe – in
the development of biolegal principles. Chapter 4 examines the
Universal Declaration on the Human Genome and Human Rights of
1997, which embodies the first concerted effort of the international
community in setting up global standards on genetic issues. The
Declaration aims to ensure the protection of the human genome
against improper manipulation and all uses of genetic information
that are incompatible with respect for human dignity and human
rights. Taking this general purpose into account, this chapter
explores, among other features of the document, the status of the
human genome as the “heritage of humanity”.

Chapter 5 argues that the Universal Declaration on Bioethics
and Human Rights, adopted by UNESCO in 2005, represents an
important step in the search for a comprehensive framework of
principles in the field of biomedicine. Drawing on my experience
as a member of the International Bioethics Committee between
1998 and 2005, and on my involvement in the drafting of the
Declaration, I sketch the principal features of this document
before responding to two general charges that have been leveled
against both UNESCO’s engagement in the field of bioethics and
the Declaration itself.

The European Convention on Human Rights and Biomedicine
(Oviedo Convention) is analyzed in Chapter 6. This instrument is
unique in that it is the only comprehensive binding intergovern-
mental instrument addressing issues at the intersection of health
law and human rights. In addition, despite the fact that it is a
regional rather than a global instrument, it has an undeniable global
significance, as its wide ranging approach has inspired the drafting
of the Universal Declaration on Bioethics and Human Rights.

Section III elaborates upon certain human rights issues that
are the subject of contemporary international standard-setting
efforts in the field of biomedicine, including biomedical research,
population biobanks, the right not to know one’s genetic information,
and advance directives. Chapter 7 examines the ethical and policy
dilemmas raised by the establishment of large-scale biobanks from
the perspective of the rights of participants. To this end, it focuses
on the experiences of Iceland and Estonia during the 2000s, and
analyzes the special laws passed by both countries to regulate this
matter. The comparative study of the experiences of both countries,
very different in many respects, provides a basis upon which to
suggest possible solutions to specific issues raised by biobanks, in
particular those regarding the modalities of the informed consent; the importance of confidentiality safeguards; the feedback to participants; and issues of property and benefit-sharing.

Dealing also with the field of genetics, Chapter 8 focuses on the right not to know one’s genetic status. Despite having being formally recognized by several international instruments relating to bioethics, the basis and conditions for the exercise of this right still remain unclear. This chapter provides arguments in favor of such a right and tries to specify the conditions for its exercise. It argues, firstly, that individuals may have a legitimate interest in not knowing their genetic makeup to avoid serious psychological consequences; secondly, that this interest, far from being contrary to autonomy of patients and research subjects, may constitute an enhancement of their autonomy; thirdly, that the right not to know cannot be presumed, but must be “activated” by the individual’s explicit choice; and fourthly, that this right is not absolute, in the sense that it may be restricted when disclosure is necessary in order to avoid a risk of serious harm to third parties, especially, family members.

Chapter 9 aims to highlight the human rights approach to biomedical research adopted by the Council of Europe’s Biomedicine Convention, and to contrast it with the more market-oriented provisions of the EU’s Clinical Trials Directive. While admitting that this difference of approach is understandable in the light of the dissimilar objectives of both European bodies, it stresses that this discrepancy has resulted in a number of unfortunate inconsistencies which might lead to less protection of research participants, in particular those who are most vulnerable.

The final chapter of this volume is devoted to an end of life issue which has generated much controversy in recent years, especially in Europe: the legal efficacy of advance health care directives. This chapter first outlines the strengths and shortcomings of Article 9 of the Biomedicine Convention, which specifically deals with this matter. Then, it analyzes the Council of Europe’s Recommendation (2009)11 on continuing powers of attorney and advance directives for incapacity, which attempts to fill some of the gaps of the Convention in this regard.