For many years, the discussion of the ethical aspects of human embryonic stem cell research focused on only one question: the moral status of the embryo. It soon became clear that there were three or four different basic positions, the arguments became well-known and were discussed over and over again, and the likelihood that any interesting new arguments would appear decreased over time.

In this book, we want to show that research on human embryonic stem cells, as well as research on stem cells of other kinds, also raise other issues that deserve to be discussed, over and above the issue on the moral status of the embryo, where little progress has been made during the last decade. The various parts of this book identify such issues and discuss ways of dealing with them.

The focus of this book, as indicated by its title, is on translational stem cell research, that is, not in the first place on stem cell research aiming at new, basic knowledge of stem cell biology. Instead, the focus is on ethical, legal, and social aspects of research, which aims at paving the way for clinical applications and translating the results of stem cell research into diagnostic and therapeutic applications.

It has become increasingly clear that different diseases raise different problems and offer challenges which are not identical. The book therefore opens with a part describing the state of the art in stem cell research focusing on a number of specific diseases such as diabetes; neurodegenerative, cardiovascular, and muscular disorders; oncologic and genetic diseases; as well as treating burn victims. How far have we arrived today, and what remains still to be achieved? Important aspects include the severity of the disease, whether alternative treatments exist, and how common the disease is.

The traditional way from bench to bedside involves a number of steps: first research in vitro, then research on small animals, then on large animals, then trials of unproved treatments in emergency situations, and finally small-scale trials – and later (we are not there yet) randomized clinical trials. What do we have to have demonstrated on each of these steps in order to proceed to the next one? Some of these steps raise ethical issues that are discussed in the latter half of the first part of this book. Children, of course, raise special problems since their capacity of giving a free and informed consent is limited. These issues are discussed in Part II of this book.
In the next part, some scientific, regulatory, and ethical challenges to basic research are discussed. Human eggs are required to produce human embryonic stem cell lines, and women can be exploited or put under pressure to deliver eggs. If eggs are collected in the course of IVF treatments, problems of gratitude and psychological pressure cannot be dismissed; so the forms of obtaining informed consent become an important ethical issue. To avoid some of these problems, and diminish the demand for human ova, some scientists have made experiments by using ova from cows or rabbits to create human–animal entities for translational research. This research raises other issues that are discussed in Part III.

Stem cell banks are becoming an increasingly important resource for research. Therapeutic cloning is emerging as a costly and unlikely way to achieve clinical progress on a large scale. Against that background, stem cell banks, repositories of stem cell lines, and registries are likely to become important in the future if and when stem-cell-based therapies exist. These banks raise issues about the procurement of the tissues (information, consent, etc.); about the processing and testing necessary for safety, as well as standardization; and finally about access: who is going to have access to the samples and the information collected, on what conditions, and who is going to decide about this? Such issues are discussed in Part IV of this book.

The long and winding road from bench to bedside, via the first idea, the first experiments, via proof of concept, and proof of principle, contains many steps, requires considerable economic resources, and many things can go wrong. No university institution by itself has the resources required to develop research results into commercially viable products. Collaboration with industry is necessary. Such collaboration is not always unproblematic, as a number of disputes between scientists and industrial sponsors have indicated, and it raises also ethical and strategic issues, which are discussed in Part V of this book.

To scale up and succeed on a competitive market, first rate science and economic resources are required. But in addition to that, also intellectual property rights. Industry is not likely to be interested in investing large amounts of money in a project if there is no protection of intellectual property, and their competitors can use the results of their investments for free. The possibility to patent methods and products based on stem cell research then becomes an important issue. Controversies have surrounded a number of patent applications, particularly involving human embryonic stem cells. Praxis in different parts of the world is not the same, the US Patent and Trademark Office being more liberal than its European counterpart, the European Patent Office.

In Part VI, the legal problems raised by patents on human stem-cell-based inventions are discussed, followed by a discussion of the extent to which there can be technological solutions to a moral dilemma. Finally, in this part, ethical issues raised by stem cell patent applications including and beyond the so-called morality clause in the European Patent Convention are discussed.

Many stakeholders are involved in the future of stem cell research, not just politicians and regulators, doctors, researchers, present and future patients, and their organizations. The stakeholders also include health-care providers, research-funding
organizations, pharmaceutical industry, and taxpayers. A broad and constructive
debate on the development of this rapidly developing research area is essential,
particularly since recent research results (Cell Stem Cell, May 2010) have indicated
important differences between human embryonic stem cells and induced pluripotent
stem cells, suggesting that one type of cell may not in all contexts be able to replace
the other.

Accordingly, communicating results and concerns has become a crucial issue,
especially in research involving human embryonic stem cells. Transparency and
openness have proved to be successful, and “hype” creates problems. Imaginative
ways of communicating research to the general public and creating conditions for
a constructive dialogue have been tried successfully and are described in Part VII.

There are a number of psychosocial and cultural factors affecting judgment and
decisions about translational stem cell research. Age, gender, and culture are such
factors, and it has become increasingly clear that they play a role in decision mak-
ing. To neglect them would be to give a distorted picture of the complex back-
ground and would make it difficult to understand why people’s views can differ so
sharply. This is discussed in Part VIII of this book.

One stumbling block on the road from bench to bedside can be the evaluation of
stem cell research projects in research ethics committees. Since this research is
rather new and rapidly developing, it also presents challenges to the members of the
research ethics committees. The systems of research ethics committee examination
is not exactly the same, but international guidelines are used as a basis, like the
Declaration of Helsinki and the Oviedo Convention and its protocols. The problems
and procedures raised by this examination are discussed in Part IX.

In the final part, we take a look at the future of the translational stem cell
research and stem-cell-based therapeutic applications. Which ethical issues are then
likely to emerge? Risks, long-term effects, priority setting and social justice are
such issues discussed in this concluding part.

During many years, both editors were involved in several EU-funded research
projects: EuroStemCell, ESTOOLS, NeuroStemCell, Eurostemcell CA, and others.
Over the years, we also learned something about the scientific aspects of the stem
cell research, and we got to know many of the leading experts in the field. Finally,
it is a pleasure to express our thanks to them and to all others who have contributed
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Kristina Hug
Göran Hermerén
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Hug, K.; Hermerén, G. (Eds.)
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