

Stem Cells, Human Embryos and Ethics

Lars Østnor
Editor

Stem Cells, Human Embryos and Ethics

Interdisciplinary Perspectives

 Springer

Editor
Lars Østnor
MF Norwegian School of Theology
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Foreword

The successful isolation of human embryonic stem cells by Dr. Jamie Thomson in 1998 has led to subsequent derivation of over a hundred additional lines. There has been a significant improvement in the efficiency of derivation and a number of variations on the basic methodology have been described. These include isolation of parthenogenetic lines, isolation from the morula stage embryo and isolation from later stages of embryonic development. Equally importantly there have been reports of successful reprogramming of adult cells into embryonic stem cells and derivation of epiblast like cells. Thus there are possibilities of obtaining cells that may not make teratomas or contribute to the germline or be classified as living embryos and may even bypass the ethical issues raised by oocyte donation while still retaining many of the characteristics of a pluripotent stem cell.

These successes and the ethical and social issues that manipulating ones own genome raise have led to a fierce debate that has not simply been confined to scientists or ethicists but has spilled into the mainstream and in some cases been politicized. Each group has taken its own extreme position and in the case of the United States individual states have taken positions that differ from the official federal policy. National-level review is required in only a few countries (e.g., the Human Fertilization and Embryology Authority in the UK) and in the US, the idea of national review is still under consideration.

Despite the ongoing ethical debate research under current guidelines has proceeded relatively rapidly and attempts to translate basic stem cell research into treatments for neurological diseases and injury are well underway. Although there are perhaps more policy and ethical discussion papers and reviews on ESC then there are research reports one can perhaps make a case that stem cell science is proceeding faster than the social debate concerning the ethical integrity of the research and the protection of potential human subjects in the research.

Indeed, in the United States (US), the Food and Drug Administration (FDA) has approved an Investigational New Drug application (IND) for using human central nervous system stem cells, isolated from fetal brain tissue, in clinical trials testing a treatment for Batten disease, a fatal inherited disorder of the nervous system and unconfirmed reports indicate that the FDA is reviewing an application from Geron to use hESC derived oligodendrocytes to treat spinal cord injury and press reports from India, China and other countries of ESC derive cell transplants.

The European Union perhaps represents a region where opinions differ markedly from country to country. There are complete bans in some countries, relatively liberal regulations in others and some intermediate (although different) compromises in most other countries. It is in this context that a book such as this one is welcomed. It is a comprehensive collection of chapters covering all major aspects of the ethical debate presented in an unbiased way. It is a fitting culmination of the numerous research projects on bioethics that Dr. Lars Østnor has either lead or participated in. Dr. Lars Østnor is to be commended for the effort he has taken in recruiting a stellar group of contributors that represent the continuum of opinion on ESC in Europe. It deals with the topic of the moral status of human embryos with special regard to stem cell research and therapy. The book contains contributions from top professionals within biology, medicine, philosophy and theology. The different chapters are the result of a major international research project in the years 2005 and 2006 with participants from USA, United Kingdom, The Netherlands, Germany and the Nordic countries. Among the contributors to the project and among the authors of the book are Professor William B. Hurlbut from Stanford University, Professor LeRoy Walters from Kennedy Institute of Ethics, Georgetown University and Professor Dagfinn Føllesdal from University of Oslo and Stanford University.

There are not many truly comprehensive books on these contentious issues where one can examine the opinions of both religious and scientific scholars side by side. To see this in one book where the topics are covered in a forthright and non contentious fashion is even rarer. Dr. Østnor has done an exceptional job and I hope the readers will find this book as useful as I do.

Mahendra Rao

Introduction

This book is a multidisciplinary study investigating the field of embryonic stem cells from different professional perspectives. The book has both a biological/medical perspective, dealing with new technological possibilities in medical research and putative clinical therapy, as well as an ethical perspective, including philosophical and theological approaches focusing on the question of the moral status of human embryos.

The researchers involved in the study represent different scientific, philosophical and theological positions, and different views concerning the ethical problems at issue. The idea is that cooperation in such a group creates a critical and self-critical dialogue where differing opinions and evaluations can be reexamined.

There are several reasons for writing this book: (a) The stem cell field is a very 'hot' and promising field of research in many countries around the world. (b) At the same time it is a controversial field, especially with regard to some of the ethical implications. Ethical aspects of stem cell research are highly debated among people from biology, medicine, law, philosophy, theology etc. (c) There are different regulations concerning stem cell research within the legislation of various countries. (d) The public discussions among citizens and among politicians are to a large extent dividing the populations of many countries in the West and the East. (e) On this background I decided to bring together professionals from different disciplines involved in the topic in order to start an international and interdisciplinary work concerning some of the burning ethical questions raised by stem cell research and eventual therapy. This work was carried out as a two year research project financially supported by the Norwegian Research Council, with the title "The moral status of human embryos with special regard to stem cell research and therapy". The reason for this approach was that the international debate has been especially concentrated on the use of embryonic stem cells. (f) Selected presentations from this project have later been rewritten with a view to publishing these final texts in a common book. On the one hand the contributions give comprehensive and updated information on the current situation within stem cell research, and on the other hand they give a presentation and an evaluation of the ethical argumentation related to the field. (g) Finally, I am of the strong opinion that the debate going on in many countries concerning stem cell research, and especially the use of human, embryonic stem cells, will profit substantially from a sufficient overview of the different aspects relevant for an ethical evaluation.

The book differs from others in the field in two ways: (a) It gives interdisciplinary perspectives from several relevant professional fields, and (b) it has a specific focus by concentrating on one main problem. This problem is further elaborated by the raising of various biological, medical and ethical sub-problems.

The main problem at the center of this book is: What is the moral status of human embryos with regard to the use of embryonic stem cells in scientific research and clinical therapy, and what are the weaknesses and strengths of various opinions and positions when they are critically evaluated?

This involves some biological/medical sub-problems: What is the state of biological and medical research regarding embryonic stem cells? What are the prospects for the future regarding the therapeutic use of embryonic stem cells? And what about the possibilities of other sources of stem cells?

Further, the main problem also involves several ethical sub-problems: What is moral status and what characterizes the moral status of human embryos? What is the moral status of human embryos according to different philosophical and theological traditions and what are the weaknesses and strengths of the various traditions? Are there ethically relevant differences between the various ways in which embryonic stem cells are made available, including therapeutic cloning? What are the main ethical problems and dilemmas generated by research with and therapeutic use of embryonic stem cells? How do we balance respect for embryos over against the need to advance life-saving and suffering-reducing medical progress?

Chapter 1 of the book contains a common statement from the Norwegian project group. It is a summary of the discussions during the project period and in the group. It gives priority to some aspects of the problem that are interesting from an ethical point of view. Chapters 2–6 bring several contributions from top professionals within science. Chapters 7–9 contain contributions from philosophy and theology with regard to the different social and political aspects of the stem cell field, the public discussions, and the state legislations regarding stem cell research. Chapters 10–14 give philosophical contributions concerning some burning ethical problems arising from stem cell research. In chapters 15–17 three theologians present and evaluate the theological argumentation in the human stem cell debate and in part also give their own reflections regarding certain central ethical aspects in the stem cell field.

The various chapters all together give a comprehensive, multifaceted and balanced treatment of the subject of the book. A few of the chapters touch in part upon some common aspects of the problem discussed, but they do this from different professional angles and because of that they complement each other rather than repeat the same perspectives.

This book is a multi-author or edited book. It is not a conference proceeding. The authors have been selected because of their professional competence, many of them being respected scholars at a top international level. They have also been chosen in order to give an updated contribution from their own disciplines and enlighten different, defined aspects of the common theme.

This book is written for several audiences: (a) a range of scholars or professionals working with stem cell research and the ethical questions arising from this field:

people from biology, medicine, law, philosophy, theology etc.; (b) advanced and graduate students within the same professional disciplines; and (c) politicians and the general public interested in the burning ethical problems which at present are debated and need social and legal regulations.

Being the editor of the book I would like to express my gratitude to the authors for using their insights and time in giving substantial contributions! Thanks to the Norwegian Research Council for financial support, to their Senior Advisor Helge Rynning for practical assistance and to MF Norwegian School of Theology and President Vidar L. Haanes for including this work among the research projects of this institution! Thanks also to Professor Mahendra Rao for his willingness to write a preface for the book and to Torhild Øien for her careful preparation of the manuscripts for publication! Finally, but not least, a thank you to Associate Editor Max Haring at Springer Publishers for his positive engagement and excellent cooperation during the publication process!

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Lars Østnor

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Contributors

The editor **Lars Østnor** is Professor of systematic theology with special regard to ethics at MF Norwegian School of Theology, Oslo. He was the founder of and coordinator for The Nordic Theological Network for Bioethics 1992. He is a member of Societas Ethica (a European organization for ethicists) 1998 – and a member of the board of The Nordic Society of Theological Ethics 2001. He has published five books and edited many books, among them: *Bioetikk og samfunn (Bioethics and Society)*. Oslo 1995; *Bioetikk og teologi (Bioethics and Theology)*. Oslo 1996; *Bioetikk, evtanasi og omsorg (Bioethics, Euthanasia and Care)*. Oslo 1997; *Bioethics and Cloning*. Oslo 1998; and *Etisk pluralisme i Norden (Ethical Pluralism in the Nordic Countries)*. Kristiansand 2001.

Mahendra Rao is the Vice President of Research in Stem Cells and Regenerative Medicine for Invitrogen Corporation, Carlsbad, California. He holds an M.D. from Bombay University and a Ph.D. in developmental neurobiology from California Institute of Technology. He has been teaching at Johns Hopkins University School of Medicine, the National Centre for Biological Sciences in Bangalore and the University of Utah School of Medicine. He has published more than 100 papers on stem cell research and several books, among them *Stem Cells and CNS Development* and *Neural Development and Stem Cells*.

Steinar Funderud has been heading the stem cell research at the Comprehensive Cancer Center, The Norwegian Radium Hospital and is at present chairman of the board for tumor stem cell center. He has been Professor in tumor immunology at the Faculty of Medicine, University of Oslo. His doctoral thesis is *Mechanisms of DNA Replication in Physarum Polycephalum*. University of Tromsø, Norway, 1978. His speciality is hematopoietic stem cells.

Ole Johan Borge is Senior Advisor at The Norwegian Biotechnology Advisory Board. He has a Ph.D. in stem cell research from Lund University. His doctoral thesis is *Maintenance and Commitment of Hematopoietic Progenitors: Role of flt3, c-kit and c-mpl*. Lund University, Sweden, 1999. Borge is the co-editor of many publications within the field of biotechnology.

Iver Langmoen M.D., Ph.D., is Professor at the Department of Neurosurgery, Ullevål University Hospital in Oslo, and teaches at the Faculty of Medicine,

University of Oslo. He is also head of the Vilhelm Magnus Laboratory for Neurosurgical Research, which is an integrated research unit for the two neurosurgical departments at the University of Oslo. From 1997 to 2005 he was Professor of Neurosurgery at Karolinska Institutet, Stockholm, Sweden. His doctoral thesis is *Synaptic Mechanisms in Hippocampal Pyramidal Cells*. University of Oslo, Norway, 1981.

Håvard Ølstørn, M.D., and **Mercy Varghese**, M.D., work at the Department of Neurosurgery at Ullevål University Hospital, and are Ph.D. students in Professor Langmoen's research group. **Morten C. Moe**, M.D., Ph.D., is a postdoctoral fellow in Langmoen's group, and is working at the Department of Ophthalmology at Ullevål University Hospital.

Joel C. Glover Ph.D. is Professor at the Department of Physiology, Institute of Basic Medical Sciences, University of Oslo and is also affiliated with the Norwegian Center for Stem Cell Research and the Cancer Stem Cell Innovation Center. He received his doctorate from the University of California, Berkeley in 1984. His research focuses on spinal cord development and regeneration, the potential of human somatic stem cells for neural differentiation, and the evolution of the vertebrate brain.

William B. Hurlbut M.D. is Consulting Professor at The Neuroscience Institute at Stanford, Stanford University Medical Center, USA. He is a member of The President's Council on Bioethics, Washington, DC. He is especially known worldwide for his scientific publications concerning Altered Nuclear Transfer (ANT) – a specific technique for deriving human embryonic stem cells without creating and destroying an embryo.

Professor **LeRoy Walters** is a theologian and philosopher at the Kennedy Institute of Ethics and in the Department of Philosophy at Georgetown University, Washington, DC. He is coauthor of *The Ethics of Human Gene Therapy*, Oxford University Press, New York 1997 and coeditor of *Contemporary Issues in Bioethics*, 7th ed., Wadworth, Belmont, CA, 2008, *Source Book in Bioethics*, Georgetown University Press, Washington, DC, 1998, and the annual *Bibliography of Bioethics*, Kennedy Institute of Ethics, Washington, DC, 1975–2007.

Egbert Schroten received his Ph.D. from Utrecht University in 1970 (thesis on the meaning of corporeal existence). He was lecturer in philosophy of religion from 1969 to 1987 at the Faculty of Theology of Utrecht University. From 1987 to 2004 he was Professor for Christian ethics at the same faculty and director of the University Centre for Bioethics and Health Law. From 1994 to 2001 he was a member of the European Group on Ethics in Science and New Technologies to the European Commission. He has also been the Moderator of the Working Group on Bioethics of the Church and Society Commission of the Conference of European Churches (CEC).

Theo A. Boer is Associate Professor of ethics at the Protestant Theological University in Utrecht and Associate at the Ethics Institute of Utrecht University.

He studied theology and ethics in Utrecht and Uppsala. He publishes both about fundamental theological ethics and about various applied ethical issues.

Dagfinn Føllesdal studied science and mathematics in Oslo and Göttingen before going to Harvard to study with Quine. After his Ph.D. in 1961 he taught at Harvard and then in Oslo (1967–99) and also at Stanford since 1968, where since 1976 he has been C.I. Lewis Professor of Philosophy. Publications in philosophy of language and on phenomenology. Editor, *The Journal of Symbolic Logic*, 1970–82. Member of American, English, German and Scandinavian Academies of Science. Former President of the Norwegian Academy of Science. Headed the Norwegian Research Council's ethics program 1992–2002.

Øyvind Baune is Professor in philosophy at the Department of Philosophy, Classics, History of Art and Ideas, University of Oslo. He has worked within philosophy of mathematics, natural science and language, and in later years mainly in ethics. He has been member of The National Committee for Medical Research Ethics in Norway and been part of an EU-project in the development of assessments tools for agriculture and food production. He has published articles within these areas and written books within the fields of scientific methodology, logic and theory of argumentation.

Sir Anthony Kenny is Professor emeritus from the Faculty of Philosophy, University of Oxford, Great Britain. He has been Master of Balliol College, Oxford, President of the British Academy and Chairman of the Board of the British Library. Since the 1960s he has written a great number of influential books on the history of philosophy. Among them is *A Brief History of Western Philosophy*. Blackwell Publishers. Malden, MA, 1998. Other books are studies in Aristotle, Aquinas, Descartes, Wittgenstein etc.

Ludger Honnefelder is Professor emeritus of philosophy at the University of Bonn, Germany and Director of the Institute for Science and Ethics at the University in Bonn, Germany. Since 2005 he is Professor of philosophy of religion and Roman Catholic world view (Weltanschauung) at the Department of Theology, Humboldt University, Berlin, Germany. His doctoral thesis at Friedrich-Wilhelms-Universität, Bonn is *Ens in quantum ens: der Begriff des Seienden als solchen als Gegenstand der Metaphysik nach der Lehre des Johannes Duns Scotus*. Aschendorff. Münster 1979. He has published several books on metaphysics, ethics (including applied ethics) and the history of medieval philosophy and its reception in early modern philosophy.

Otfried Höffe is Professor of philosophy at the University of Tübingen, Germany (Philosophisches Seminar), Founder and Director of the Research Center of Political Philosophy and permanent guest Professor at the University of St. Gallen. His professional interests cover Aristotle, Kant, moral and political philosophy, applied ethics and epistemology. His nearly two dozen books have been translated into 20 languages. Among his latest books are *Democracy in an Age of Globalisation*. Springer NL, Dordrecht 2007, *Kants Kritik der reinen Vernunft. Die*

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Gunnar Heiene is Professor of theological ethics at MF Norwegian School of Theology, Oslo. His doctoral thesis is from this institution and has the title *Den menneskelige stat. Antropologi og politikk hos Eivind Berggrav (The Human State: Anthropology and Politics in Eivind Berggrav)* (Norwegian bishop in Oslo during the second world war). Oslo 1991. Later he has published books and articles from different areas of theological ethics, especially within fundamental ethics, family and political ethics. Together with colleagues he has also published several text books for theological studies.

Monika Bobbert, Dr. theol. and dipl. psych., is working at the Department of Medical Ethics at the Institute for the History of Medicine, the Medical Faculty of the University of Heidelberg, Germany. Her doctoral thesis is *Patient Autonomy and Nursing. Foundation and Application of a Moral Right*. Her speciality is bioethics and other fields of applied ethics.

Chapter 1

The Moral Status of Human Embryos with Special Regard to Stem Cell Research and Therapy

Øyvind Baune, Ole Johan Borge, Steinar Funderud, Dagfinn Føllesdal, Gunnar Heiene, and Lars Østnor*

Abstract This chapter contains a common statement from the Norwegian project group. The statement gives an introduction into embryo development and the stem cell field, including the question of different sources for human embryonic stem cells. It delivers a survey of some of the argumentative concepts within philosophical and theological debates regarding the moral status of human embryos and evaluates the relevance, strengths and weaknesses of the arguments. The statement also deals with ethical-normative elements connected to human biological life and ethical norms with relevance for research and clinical therapy. Finally, it includes a reflection about the ethical dilemma between medical progress on one hand and respect for embryos on the other. The conclusion outlines the profile of the two different positions represented in the group.

Keywords The stem cell field, ethical traditions, normativity, dilemmas, alternative sources

1.1 Introduction

The following statement sums up results of a two year research project with the title ‘The moral status of human embryos with special regard to stem cell research and therapy’. The project was financially sponsored by the Norwegian Research Council. This interdisciplinary project had a steering group consisting of Professor Øyvind Baune, University of Oslo (philosophy), Senior Advisor Ole Johan Borge, Ph.D., The Norwegian Biotechnology Advisory Board (biology), Professor Steinar Funderud, Rikshospitalet-Radiumhospitalet HF (biology), Professor Dagfinn Føllesdal, University of Oslo and Stanford University, USA (philosophy), Professor Gunnar Heiene, MF Norwegian School of Theology (theology) and Professor Lars Østnor,

* MF Norwegian School of Theology, Box 5144 Majorstua, 0302 Oslo, Norway.
e-mail: Lars.Ostnor@mf.no

MF Norwegian School of Theology (theology, head of the group). Among active participants in the project were also Professor Daniel Callahan, The Hastings Center, New York, Professor LeRoy Walters, Kennedy Institute of Ethics, Washington, Professor Egbert Schrotten and Dr. Theo A. Boer, both from Ethics Institute, Utrecht University. The participants represent different milieus and various positions.

During the years 2005 and 2006 four workshops and conferences were arranged within the framework of the project. Each time 20–30 persons from many professional fields were invited to give lectures, responses or contributions to the debates. An open, final conference had attendees from research, politics, media, the general public etc. A doctoral student working on her Ph.D. thesis is also included in the project. In addition there have been several meetings in the project group. This statement is a summary of professional discussions during the workshops and in the group. Its aim is to survey those aspects of the problem that are of particular ethical relevance. It does not consider legal questions.

1.2 The Topic

The expression ‘moral status’ has almost become a technical term within several disciplines for the following: that something (human, animal, plant, etc.) has some form of moral status implies that we as moral agents have ethical obligations towards it. Those who have moral status must, from the viewpoint of agents, be protected by certain ethical norms.

When we raise the problem of the moral status of human embryos, we are concerned on the one hand with what *rights* they have to the protection of life, body, health etc., and on the other hand what *obligations* moral agents have towards them in the form of preserving these goods.

Within biology and medicine, one distinguishes at times between the various phases in early human development: fertilized ovum (zygote), morula, blastocyst and fetus. The number of phases and decisions concerning terminology vary dependent on empirical, ethical and legal factors. In this statement we use ‘*embryo*’ inclusively to signify human life from fertilization to the eighth week of life. The addition of ‘*human*’ signifies that we are speaking of the human species.

Stem cells are undifferentiated, self-renewing cells with the potential to produce specialized, differentiated cells. There are various kinds of stem cells, based on where they are found in the human organism. *Human, embryonic stem cells* (hES cells) can be derived from the blastocyst ca. 5–10 days after fertilization. Because they have the ability to produce every cell type in the human body, they are often called pluripotent. The possibility of deriving hES cells from an embryo raises the important and difficult question of defining ethically acceptable actions toward human life at this phase of development.

The interest of *science* in being able to make use of hES cells is especially related to three objectives: (a) better knowledge of human biological development

at an early stage of its life (basic research), (b) testing of both new and existing compounds/drugs, and (c) the cultivation of various types of cells, tissues, and perhaps even organs.

Research on hES cells may open up for new *clinical treatments* of illnesses and injuries. Active research is today being carried out in many countries, but no one has yet attained any recognized therapy of the serious illnesses one hopes to be able to fight.

1.3 Embryo Development and the Stem Cell Field

1.3.1 Embryo and Fetal Development

Sperm penetrating the eggshell (*zona pellucida*) initiates fertilization and the creation of the *zygote* – a cell containing genetic material from both parents. The *zygote* divides and generates two *blastomeres*. As the blastomeres continue to divide approximately every 20 hours, they increase in number but become smaller for each division. After three days a ball of about 16 cells, called a *morula*, appears. About four days after fertilization a cavity forms within the morula and the structure is then called a *blastocyst*. At this point, the cells have started to differentiate and are no longer considered totipotent. A totipotent cell has the intrinsic ability to generate a fetus if implanted in a uterus. As the cells continue to divide, the pressure on the eggshell increases, and after 5–6 days the blastocyst ‘hatches’ (leaves the eggshell) and begins to find its place in the uterus. The implantation of the embryo in the uterus is completed at day 12. At day 13 the first signs of a placenta and an umbilical cord can be seen. The first visual sign of organ formation, named the primitive streak, appears around day 14. Splitting of the embryo, generating monozygotic twins, can happen until the presence of the primitive streak.

In the following days and weeks, organ formation continues and all the main organs and structures of the developing embryo are present after approximately 50 days. This is also the time at which the first signs of brain activity can be measured and at which the embryo makes spontaneous movements. By definition the embryo period ends eight weeks/two months (56–60 days) after fertilization, at which time the embryo is 23–26 mm in size.



Fig. 1.1 Photo: David Epel, Stanford, CA, USA and the Norwegian Biotechnology Advisory Board

1.3.2 *Stem Cells Basics*

Results published in the late 1950s and early 1960s established the concept of stem cell when it was demonstrated that lethally irradiated animals could be rescued by transplantation with bone marrow cells from a donor animal.

There are generally two main types of stem cells characterized according to their potential to differentiate: pluripotent and multipotent.

1.3.2.1 **Pluripotent Stem Cells**

By definition, pluripotent stem cells have the potential to differentiate into all cell types in the adult body. However, pluripotent stem cells cannot form an entire individual if implanted in a uterus, because they are unable to give rise to extraembryonal tissues (like the placenta) essential for fetal development.

There are currently demonstrated three sources of pluripotent stem cells: early embryos, fetuses and teratocarcinomas (a rare form of cancer). Stem cells derived from the human embryo are called embryonic stem cells (hES cells). Typically, hES cells are derived from the inner cell mass of blastocysts (5–8 days after fertilization), but hES cells have also been isolated at the 8/16-cell stage (2–4 days after fertilization). Pluripotent stem cells isolated from fetuses are termed EG cells (embryonic germ cells) and pluripotent stem cells from teratocarcinomas are termed EC cells. Whether pluripotent stem cells also exist naturally in adult individuals is highly debated and no definite proof has been given to date. Recent data may however indicate that both the bone marrow of adults and the amniotic fluid potentially contain pluripotent like stem cells.

1.3.2.2 **Alternative Sources for hES Cells**

hES cells have, as described above, generally been looked upon as *one* cell type with *one* set of characteristics and whose only source is the developing, healthy embryo. However, recently a number of alternative sources have been presented. Some of these are merely of theoretical interest, whereas others might represent attractive alternatives to healthy embryos.

Briefly, these alternatives include:

- Embryos incapable of further development. After in vitro fertilization a high fraction of the embryos stop at various phases of development. In relation to fertility treatment, these embryos are simply discarded. It has recently been demonstrated that there are viable cells within these embryos and that they may be used as sources for developing viable hES cells.
- Single blastomeres withdrawn from the embryo without destruction. Based on experience with Preimplantation Genetic Diagnosis (PGD) we know that single cells can be withdrawn from developing embryos. The withdrawn cells may further be used to establish hES cells.

- Somatic cell nuclear transfer (SCNT). In this technique a somatic cell nucleus is inserted into an enucleated egg cell. If such an egg cell is stimulated, the cell starts to divide and progress into a blastocyst from which hES cells may be developed.
- Altered nuclear transfer (ANT). This technique is a variant of SCNT where the transferred nucleus is altered so that no blastocyst develops. The biological entity formed lacks the capacity of an embryo, but hES cells can in principle be derived.
- Redifferentiation of somatic cells to a state enabling the derivation of hES cells. It can be assumed that there are a limited number of genes responsible for defining any given cell type. Results indicate that it might be possible to manipulate adult, somatic cells to convert to a state resembling the hES cell state.

1.3.2.3 Multipotent Stem Cells

Multipotent, somatic stem cells are during adult life responsible for maintaining homeostasis in every tissue, organ and cell system. Multipotent stem cells are currently considered tissue specific. They can only produce tissue of the same type. The stem cells in bone marrow and brain are to date the ones best characterized. Multipotent stem cells can also be isolated from the umbilical cord immediately after birth.

1.3.3 Usage of Stem Cells

All types of stem cells are highly attractive study objects due to their undifferentiated state, proliferative capability, and ability to differentiate into all cell types within their hierarchy. In addition to their key role in developmental biology and tissue regeneration, they are also increasingly acknowledged as a main factor in the development of cancer and a prime target in cancer therapy.

Unfortunately, in all but a few cases multipotent stem cells tend to lose their stem cellness as soon as they are withdrawn from their natural environment. Therefore, it is hard to study multipotent stem cells in a defined culture system. hES cells, on the contrary, can be propagated and stimulated to differentiate in culture. Furthermore, hES cells have the potential to differentiate into all cell types and are not restricted to cells within one tissue system.

In particular, hES cells might also be useful as a tool for drug discovery and toxicology testing.

Bone marrow and umbilical cord blood transplantation, utilizing stem cells, is standard treatment in some groups of patients with bone marrow disorders and cancer. Furthermore, a number of ongoing clinical trials using adult stem cells are exploring other therapeutic potentials. Although stem cells are currently being used to some extent in human medicine, there is considerable hope that stem cells in the future can be utilized in the treatment of a wide array of human disorders. In particular, this may be true where a complete lack, or a deficient number, of specific

cell types causes the disease. Parkinson's disease, diabetes type I, spinal cord injury and stroke are just a few of a long list of diseases theoretically suited for stem cell based therapy.

Although hES cells have been available for more than eight years, not a single clinical trial has been reported started. However, a number of pre-clinical trials are ongoing, indicating that clinical trials are likely to be started in the near future.

1.3.4 Statement Regarding Future Scientific Development

It is impossible to predict the future of the stem cell field in detail. However, some general trends can be described. hES cells have demonstrated their usefulness as a tool for basic research, and provide a valuable supplement to multipotent stem cells from adult individuals. hES cells have furthermore emerged as a symbol of modern stem cell research, facilitating investment into the stem cell field. In relation to clinical usage hES cells face a number of challenges. These include the risk of immunological rejection, potential serious side effects like cancer, many ethical concerns, potentially very high treatment costs, and challenging technology transfer from laboratory to clinic. In addition, governmental approval may be cumbersome to obtain. These challenges apply only to a limited extent to somatic stem cells from adults. However, typically adult stem cells still have limitations, especially with regard to clinical use due to their rareness and difficulty of propagation in culture.

In summary, we believe that adult stem cells are more likely to become the treatment of choice for most patient groups if the isolation and the cell expansion challenges are satisfactorily resolved.

1.4 Philosophical and Theological Traditions

Within philosophical and theological debates certain main arguments have been used regarding the moral status of human embryos. We shall mention some of the argumentative concepts and evaluate their relevance, strengths and weaknesses.

1.4.1 Personhood

From a philosophical and theological standpoint, one has often referred to the fact of being a person, to 'personhood' or 'personality', as a criterion for deciding whether a human life has a unique value and right to life and protection. In some cases, one has identified 'personhood' with being human. In other cases, one has distinguished between being a person and being a human. The criterion of personhood has thus in

practice not been very clarifying in the debate. In the first place, different spokespersons have used different criteria regarding the physical and/or psychological characteristics that mark a person. In the second place, opinions vary as to when these qualities are thought to be present in the development of human life. In the third place, the discussion of the relevance of the concept of person with a view to the value of unborn life has been imprecise in its use of biological, psychological, ethical, and legal language. In the fourth place, it is unclear whether the concept of person is an either-or concept, or a gradualist concept. The project group finds therefore that the distinction between person and non-person is not suited for the identification of the moral status of human embryos.

1.4.2 Potentiality

The potentiality argument states that that which has the potentiality of becoming a developed human being with moral status, has a right to life.

Two objections are often raised against this argument:

- First, the notion of potentiality is held to be unclear. Thus, for example, the further development of the embryo is dependent not only on the genetic potential, but also on other factors, such as for instance insertion into the uterus, the care of the mother and health professionals etc. However, stem cell research itself is based on the notion of potentiality. What makes stem cells so important is their potentiality to develop into any kind of cell in our body. And this development depends not only on the stem cell, but also on its being given the right kind of protective environment and growth conditions. Such factors do not contradict the embryo having its potentiality from the very beginning.
- Secondly, it has been objected to the potentiality argument that although a child is potentially an adult, an adult has many rights that the child does not have, for example the right to vote. However, the potentiality argument does not claim that the embryo has all the rights of a fully developed human being. Some rights, like the right to vote, or the right to practice medicine, require a certain age, a certain education, etc. The right not to be exposed to pain requires ability to feel pain, etc. But the right to life does not seem to require any such extra conditions, and it is difficult to see what can exclude an embryo from this right, given that it has potentiality of becoming a developed human being.

The group agrees upon the ethical relevance of this argument. But there are different views among us regarding the weight and the consequences of the argument.

Some in the group hold that ascribing human embryos potentiality does not necessarily include an absolute right to life and protection from harm, but an increasing right to life through pregnancy (see section 1.4.4).

Others maintain that such potentiality implies certain rights, such as right to life, right to care and to protection etc. They oppose the view that such rights emerge only later in the development.

1.4.3 Biological Continuity

The main substance of this argument is that there is a continuous development in the life of an embryo, beginning with fertilization, without any possibility of differentiating between clear stages with corresponding, variable right to life.

Against this it has been maintained that biological continuity does not exclude that there are morally relevant stages during the life of an embryo. According to this view, new elements are introduced, for instance when the primitive streak is created after approximately 14 days or when the brain is beginning to form. The development of an embryo includes initiation of new capacities throughout the pregnancy.

However, all members of the group agree that there are no morally relevant reasons for drawing sharp lines between different stages in the development of the embryo. Although we agree on the relevance of this argument, we differ regarding its strength.

Some members of our group evaluate this as a strong argument for full protection of a human embryo from its beginning through all phases. They see fertilization as the starting point of an uninterrupted biological development and a life history without any morally relevant leap with regard to protection of life. The sperm and the egg cells do not have this continuous identity with the fully developed human being. During its development, the embryo and later the fetus acquire new features, such as the ability to feel pain, and these features give it more rights, for example the right to be protected against pain, but there is no stage in the development where the right to life is changed.

Other members agree that there is a continuity in the biological development of the embryo, but do not consider this as a decisive argument for full protection of a human embryo from its beginning. This view is called the gradualist view. The gradual biological development yields a gradual increase in right to protection.

1.4.4 Graduality

Graduality is an alternative for answering the question: At what point does a human being obtain its full moral status: At fertilization? At some point during pregnancy? At birth or at some point after birth? And how does it happen? As a complete either-or change? As a step by step process? Or as a gradual continuous process?

Some of us will argue from the full moral status of a grown up human being with its mental capacity, with a consciousness of itself, with rationality, with an understanding of the future etc. But does it follow that an embryo, which has these capacities only in potentiality, can still be ascribed the same moral standing? According to this position, this is not the case. The line of argumentation is such that we have to base our understanding of this on our moral feelings and intuitions, modified through a process towards a reflective equilibrium. We have to accept what such intuitions tell us: that the moral status of an embryo or a fetus is a growing

process towards a full moral standing some time during pregnancy. This means that potentiality counts, but not by yielding a full right to life from fertilization. These members find that the rights of an embryo in its earliest phase, for example before organ and neuronal formation, in some cases can be weighed against other rights and highly valuable purposes.

Other members of the group argue that the right to protection of the embryo and the fetus does not depend on the degree of biological and psychological development. Our obligations towards human life in this phase do not presuppose that the embryo has acquired certain organs or consciousness. In addition these members maintain that our moral feelings and intuitions are not unambiguous and satisfactory sources for insight regarding ethical rights and duties.

1.4.5 Individuality

The argument from individuality states that a human embryo should be treated as an individual human life from the time when it is clear that ‘twinning’ is no more possible. This is supposed to be about 14 days after fertilization. According to this view it is up to this time not possible to securely identify an embryo as an individual human life.

It has been argued that this biological aspect is ethically relevant. Consequently, one will differentiate between a human embryo before 14 days and an individual human life after this limit, regarding the kind of protection which it deserves: During the first two weeks of its existence an embryo must be shown respect, but only an individual human life has a full right to be protected.

All members of the group hold that individualization has no relevance to the moral status of human life before and after the 14-day limit. The only difference may be numeric. A single embryo with the potentiality of twinning is still entitled to protection, even though it could split into two individuals.

1.4.6 God’s Creation

In the stem cell debate religious arguments have also been used. Here we shall concentrate on a Christian perspective. Churches and theologians have often used what can be called a creation argument in their evaluations of acceptable ethical actions regarding the human embryo: A human being is a unique creation, brought into existence by a divine act and with the right to live and not be harmed. A human, considered in this manner, is presupposed to be a reality already from fertilization. This is sometimes supported with references to biblical texts that speak of human creatures as being created ‘in the image of God’ (Gen. 1:26–28, 5:1 f., and 9:6 f.), an expression of human uniqueness and of humanity’s special role within creation, in contrast to all else that exists.

Within the group there is agreement that humans have uniqueness and a special role within the framework of existing reality. There is disagreement, however, concerning the value that can be ascribed to human life based on references to Christian belief in creation. Some wish to give this understanding universal ethical relevance as an articulation of an exclusive standard of value for exemplars of the human species. They consider this as possible regardless of whether one bases the valuation on Christian faith in God, in a non-Christian, religious position or in a non-religious conception of life. Others point to the existing disagreement within society with regard to the use of human embryos in research. They maintain that religious arguments for an ethical evaluation of humanity in all phases of its life can not be valid except as internal arguments within a fellowship of religious believers.

1.5 Normativity and Terminology

The project group is of the opinion that the most adequate approach to the question of the moral status of the embryo with a view to using embryonic stem cells in research and therapy, is found in an *anthropological and cultural approach*, where one identifies various concepts and categories that are connected to human uniqueness and expression, and decides which normative content these carry. In addition to the normative aspects in section 1.4, we will here focus in part on elements connected to human biological life, and in part on norms with relevance for research and clinical therapy.

1.5.1 Human Life

A concept such as ‘*human life*’ can be given content from different perspectives. Biologically, ‘life’ can be defined based on the criteria (movement, growth, reproduction etc.) that all life allegedly fulfills. In our context, it is important to maintain that we are not talking of the responsibility of moral agents toward life in general, but toward human life. And we are using this concept in a descriptive, biological sense. In this statement human life is not understood as human material in general (eggs, cells etc.), but as the entity existing from the fertilization and onwards. According to this a human embryo is human life.

1.5.2 Human Being

The project group has been aware that probably no one will be able to deliver a complete and precise definition of what a human being is in terms of moral status. For the research project that involves biology/medicine, philosophy, and theology,

the choice of professional perspective will be of great importance. A possible approach that can be agreed upon is to claim that a human being is a creature that descends from a woman and a man. In any case, one can maintain that a human being is an entity who biologically belongs to the species *Homo sapiens*.

In the opinion of the group, it is necessary to underline that an embryo originating from human beings is itself a human life, a *human* embryo. But there are different evaluations of whether such an embryo should be regarded as a *human being* or not. The reason for differing views is the normative implication of stating that a human *life* is a human *being*.

1.5.3 *Dignity*

Several normative concepts have been used in order to express the valuing of human life. From the side of an existing human life: sanctity, dignity, worth, value, inviolability etc. From the side of moral agents: reverence, respect etc. In this context we will concentrate on three of them: dignity, value and respect.

The idea of a unique dignity in an ethical sense for human beings is a central and fundamental part of both the humanistic and the Christian moral tradition. This dignity is held to be universal, understood as a common normative standing for all human beings.

The project group differs, however, regarding the question of the justification of and possible variations within dignity. Some wish to anchor dignity in empirical characteristics that distinguish humans (rationality, sense of identity, perhaps the potential of achieving these). An important distinction here is the difference between early life phases and later stages of fetal development. A consequence of such differentiation is variable human dignity (step by step or gradualistic), lower in an embryo than in a viable fetus or in a born human being. Others in the group wish to anchor human dignity in humanity's belonging to a specific biological species and/or in relation to God as its creator. With such an anchor, independent of varying, qualitative characteristics, it follows that dignity is valid in its own right.

Both positions in the group maintain that dignity is the basis for normative standards, in the sense of duty to protect human life. In the one case, this is seen as a gradualist duty, in the other case as a unitary and stable duty.

1.5.4 *Value of Human Life*

The concept of value is normally used for positive values. With regard to humans one must differentiate between the value of biological existence and the value of a complete life history.

The project group understands the value of human life as a value in itself, an intrinsic value, arising from the existence of a human. Such a value is not merely

instrumental and is not dependent on consciousness and abilities. Nor is it deduced from what a human being has of importance for other humans, not a result of the valuation of others. Only on these premises is it possible to maintain a value of human life which is universal in the sense of common for all.

The high ranking of the biological life of humans is also a consequence of the fact that it is a condition for being able to register and receive all other ethical values or goods.

1.5.5 Respect

Generally it may be said that valuable entities shall be respected in the sense that they shall not be destroyed. In cases of highly valued things or creatures a great respect will usually be required.

In daily life the degree of respect toward human beings may vary according to situation. In the public debate on stem cell research one can notice various claims of respect maintained.

The project group agrees that human embryos shall be shown respect in attitudes, words and actions. This means in a concrete way that cells, tissues and organs from embryos shall not be used for every kind of purpose (for instance as animal food or cosmetics). But there are different understandings within the group with regard to the question of how radical or absolute this respect shall be applied. Some maintain that it is not contrary to this respect to use hES cells from embryos when there is an ethical, superior aim, such as new biological insights or the possibility of therapeutic progress. Others claim that respect for human life is ethically so fundamental and weighty that it can not be exempted from by referral to an eventual, new knowledge in research. They interpret the concept respect in this context as including the duty not to do harm.

1.5.6 Knowledge as Ethical Value

In addition to the anthropological elements already mentioned there are some important ethical norms or values linked to human, cultural activities such as research and clinical treatment.

Knowledge within natural sciences, social sciences and humanities is generally evaluated as being of great importance on both an individual and a communal level. Within the framework of ethical reflection we find it justified in a broad spectrum of different secular and religious ethical systems.

Medical knowledge is a main ethical value both with regard to its potential utility for an advanced health care system, but also for its basic insights before any application of it in relation to human illness and disorder.