ANNEX D

ETHICAL, LEGAL AND SOCIAL ISSUES FOR CONSIDERATION

A. Science

1. Definition of stem cell

2. The sources of stem cells for research

- What are the sources of stem cells? eg. from embryos, adult tissues etc.
- What are the properties and potential of stem cells from the different sources?
- Is there a need to prefer one source to the other?

3. The sources for embryos

- What are the sources for embryos? eg. in-vitro fertilisation ('spare' embryos from infertility treatment or specially created for research), therapeutic cloning methods (cell nuclear replacement) etc.
- What are the properties and potentials of embryonic stem cells from the different sources?
- Is there a need to prefer one source to the other?

4. Development of an embryo

- What is the developmental history of an embryo after conception?
- Is there a period post conception which is optimal or appropriate for obtaining stem cells?

5. The reasons for stem cell research

- Why must stem cells be used for research?
- What are the potential benefits?
- How real or speculative are the potential benefits?
- Are there any other alternative forms of research?

6. What is the current state of the science and its technologies?

- What are the current areas of research using stem cells?
- What are the achievements to date?
- When would the potential benefits be reaped?

B. Ethical Issues

1. Do the potential benefits justify stem cell research generally?

2. What source of stem cells should be used, and to what extent?

- In particular, should embryonic stem cells be used?
- Are there no viable or adequate alternative sources? Eg. stem cells from umbilical cord, adult stem cells, embryonic germ cells?
- Status of the embryo as 'life'-
- Definition of life under current legislation eg. in relation to the Penal Code, abortion etc?
- What status should be accorded to an embryo?
- Should the embryo be accorded full human status from conception?
- Should the embryo be accorded full human status at a particular stage of development, and if so, when? eg. day 0, day 14 or day 40 etc.
- Would the potential benefits of research outweigh the concerns of 'violation' of the embryo in order to obtain stem cells, and under what circumstances?

3. Should stem cell research be restricted to certain areas of research with certain levels of benefits, eg. for cancer research as opposed to areas of research which are not life threatening, especially in view of the use of embryonic stem cells?

4. What are the rights of those who donate materials for stem cell research? eg. issues of amount and degree of information to be provided to potential donors, informed and genuine consent, privacy and confidentiality, whether donors are to share in the fruits of successful research either by (a) getting treatment; or (b) payments etc.

5. What are the rights, duties and responsibilities of those who handle stem cells for research? Eg. issues of proper use or code of conduct etc.

6. Sources of embryonic stem cells

- Should stem cells from aborted foetuses be used, and under what circumstances?
- Should 'spare' embryos from infertility treatment be used, and under what circumstances?
- Should embryos be created for research in-vitro, and under what circumstances?
- Should there be therapeutic cloning to produce embryos?
- Is there a need to use therapeutic cloning to produce more embryos?
- Are there objections of producing embryos 'genetically identical' to another human being?

- What are the restrictions on the use of therapeutic cloning? In particular, what is the status of reproductive cloning?
- Should the sale and commercial supply of embryos be permitted, and under what circumstances?

7. What happens once a stem cell line has been established?

- What restrictions, if any, should be placed on the use of such stem cell lines? eg. related issues would include xenografting and xenotransplantation.
- Issues with regard to donors of stem cells as per paragraph 4 above.
- Should the sale and commercial supply of stem cells be permitted, and under what circumstances?

8. Should cross-species experiments be allowed? [Embryonic Stem Cells Sub-Committee to clarify whether it should fall under Human Genetics Sub-Committee's purview]

- eg. issues of trans-species fertilisation, inserting animal DNA into human embryos and vice versa.

9. Controls for trials

- To what extent should trials be conducted on animals and humans?
- Issues of informed consent, privacy and confidentiality.
- Should participants be entitled to some benefits or a share in the fruits of success?
- Questions of compensation to persons injured or placed at increased risk as a result of such trials?

C. Legal and Regulatory Issues, and Public Education

1. Should formal legislation be enacted to govern stem cell research, and its subsequent commercial exploitation, according to a position reached on the ethical considerations, and to what extent eg criminal sanctions and penalties?

2. Should there be a regulatory body formed to license, supervise and monitor the research activities taking place within Singapore, whether government funded, private or otherwise?

3. Established stem cell lines can have considerable commercial value. Issues which would arise would include public and private funding, patenting and commercial issues, claims of donors and users of tissue, and how to manage the demand for forms of stem cell therapy.

4. The amount of public education, awareness and understanding that should be raised and the methods of so doing.