

Ready or not? A role play on taking stem cells to the clinic

Guidelines for the Research Ethics Committee

Your task is to review Stem Cell Therapeutics' application

In reaching a decision the REC should take into account scientific data, and other evidence, concerns and recommendations presented by Stem Cell Therapeutics and other stakeholders.

In deliberating, it is important to consider the following aspects:

- the safety of the proposed treatment for participants
- the quality of the scientific data on which the trial is based
- the expected effectiveness of the treatment
- future implications of a successful clinical trial (the decision on this clinical trial may open a precedent for future, similar trials, by other companies)
- how this treatment compares with existing treatments

The Committee will have to arrive at a decision through consensus, since it is made up of an even number of members (four). You will not be able to vote on the final decision.

The decision does not have to be a simple "Approved" or "Rejected". It may be something along the lines of "Approved, as long as...", or "Rejected, unless/until the following conditions are in place..." The Committee may ask for further experiments in the laboratory, or restrict the source of stem cells used in the trial, for example.

The Committee should indicate at the time of approval any progress reports it requires from time to time from the applicant.

Regardless of the outcome, the Committee should be able to demonstrate that it has acted reasonably in reaching a particular decision. Whether the proposal is accepted or rejected, the reasons for that decision should be made available to the company and to the audience at the Open Public Hearing.

Therefore, when presenting decision, you may want to follow the outline below:

- the name of the company
- a simple summary of the proposal
- the issues discussed by the committee
- the committee's conclusions.

One of you will have been chosen to act as the Committee Chair. He/she should:

- act as a moderator during consensus building;
- act as a facilitator for other members and the audience;
- focus the discussion on the relevant issues;
- manage the meeting time;
- ensure the questions of the committee are all answered

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Acknowledgements



This role play draws on research funded by the MRC and the ESRC, and further developed by REMEDI.



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