

ETHICAL REVIEW REPORT

Proposal Reference 516943

Acronym : NANOBIOCOM

Programme: FP6-NMP

Scientific Officer: E. Calvet / G.3

Proposal Number: 516943

Title: Intelligent Nanocomposite for Bone Tissue Repair and Regeneration

Proposal Type: STREP

Co-ordinator Name: Dr Alava

FUNDACIÓN INASMET

Ethical Issues Raised

- **animal experimentation (rabbit, rat, mouse?)**
- **human primary osteoblast cultures from bone marrow**
- **data protection**

If the proposal involves the use of human embryonic stem cells in culture, does the scientific evaluation ESR confirm that the use of hESCs is **necessary** for the research objectives to be achieved?

Not applicable

Comments and Conclusions on Ethical Issues

- The project describes plans for rabbit and rat experiments in WP5.1. and provides technical information for the rat experiments. The additional information provided contains information on the technological procedures for rabbit (in great detail). For both species there is no information on the number of animals to be used, nor on the application of the 3R principles. On page 70 of the proposal it is stated, that only rabbits and mice will be used in the experiments – this may be a mistake, but needs clarification.
- On page 55 WP3.3. in vivo experiments are mentioned, however, no description of the experiments, including species and procedures, is given.
- Despite potential serious suffering caused by the experiments (fracturing the tibia and long healing period), there is no clear definition of humane endpoints for the animal experiments. The panel noted, however, that information on the reduction of suffering was given on page 69, but it is unclear whether this refers to the fracturing only, rather than the healing period.
- There is no description of the procedures to obtain bone marrow samples from animals, and neither the species, nor the number of animals are defined.
- Animal experimentation approvals for the facilities are provided for the Netherlands and Spain, but no local ethics committee approvals are provided to cover specific aspects of the present experimental protocol.
- Human primary osteoblast cultures are established from bone marrow samples

obtained from surgical procedures from otherwise discarded material. Ethical approvals of human experiments are provided for UK and Italy, and consent forms exist according to these documents (at least in the UK). There is no information on the data protection measures for such samples.

Requirements:

- Provide number of animals necessary for the experiments, describing the species, estimated total numbers for each type of experiments, potential adverse effects and the humane endpoints in case of suffering.
- Describe procedures for animal bone marrow extraction.
- Describe how the 3R principles are respected and implemented during the project (for example with regard to refinement, how pain will be recognised and alleviated during the healing period).
- Provide information on the anonymisation procedure for human bone marrow samples and data, with special emphasis on genetic data (WP 3.1.).

Recommendations:

- Copies of local ethics committee approvals regarding animal experimentation protocols should be provided to the Commission.

Reporting Obligations

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Follow-up (e.g. is there a later phase to the project that may require ethical review – such as for an IP or NoE?)

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