APPENDIX B: COLLABORATIVE FUNDING PARTNER OVERVIEW AND CONTACT INFORMATION: MEDICAL RESEARCH COUNCIL (MRC), UNITED KINGDOM

THE FOLLOWING MATERIAL IN APPENDIX B WAS PREPARED BY THE MEDICAL RESEARCH COUNCIL, UK:

Funding available

- MRC has made up to £5m available to support UK participation in the CIRM Disease Team III RFA 13-01.
- It is anticipated that this will fund the participation of UK groups in one or two of the top-ranked fundable proposals involving a UK team.

Who can apply

- Proposals must involve UK activity that is critical to the progression of the collaboration
- UK-based applicants must have strong collaborative links with Californian PIs.
- MRC support will be provided to fund the UK component of competitive proposals where the UK team leader has the status of Co-PI and is fully involved in the project's leadership plan.
- UK based applicants will need to meet standard MRC eligibility rules apply; please see the MRC applicants' handbook and the Research Council UK website.
- Commercial links can be accommodated under UK state-aid rules. Funding requests will need to meet MRC Industry Collaboration Application eligibility criteria. In general, MRC will not meet industrial collaborator costs.
- All UK applicants must have first discussed their proposal with MRC Head Office.

How to apply

- Teams with UK participants must submit to CIRM a single joint Letter of Intent (LOI), to the LOI due date (March 13, 2013). LOIs will be assessed by CIRM for fit to RFA 13-01 eligibility.
- The likely overall funding request associated with the UK component should be indicated although details of the resource request need not be specified at the LOI stage.
- The proposed clinical trial must include at least one clinical trial site in California and may include site(s) in the UK. The UK site can be the lead site.
- Evidence of relevant regulatory engagement must be provided:

i) **Applicants with projects commencing with definitive late-stage preclinical development** must, by the Letter of Intent (LOI) due date (March 13, 2013), provide a record of discussion with the FDA and, as necessary, the Medical and Healthcare Products Regulatory Agency (MHRA), indicating

- either the completion of a pre-IND meeting with the FDA or evidence of a FDA-confirmed date for a pre-IND meeting that will take place prior to the application due date (May 15, 2013); and
- if proposing UK clinical trial site(s), either completion of a scientific advice meeting with the MHRA (covering the same topics as a pre-IND meeting with the FDA), or evidence of a MHRA-confirmed date for such a meeting that will take place prior to the application due date (May 15, 2013).

ii) **Applicants with projects beginning with a clinical trial** must

- have filed a complete IND application package with the FDA, by the Letter of Intent (LOI) due date (March 13, 2013); and
- if proposing UK clinical trial site(s), have filed a complete Clinical Trial Authorisation (CTA) application package with the MHRA and provided evidence of this filing to the MRC by September 13, 2013, this being shortly prior to the MRC review meeting.

- Applicants meeting the eligibility criteria will be invited to submit a full application. In such cases, full submissions, using where possible common forms, will need to be made to both CIRM and MRC (details of the MRC submission process will be provided to relevant successful LOI applicants). The funding to be requested from MRC will need to be indicated and justified in sufficient detail on the CIRM application form as well as within the MRC submission
- At the Full Application stage, UK participants will need to submit the same information as required of Californian applicants.
- Following submission, parallel and independent reviews will be undertaken by each organization with a positive recommendation of support from each being required in order for a joint award to be made.

How funding will be provided to the UK partner

- UK participation will be funded as an MRC award to the eligible UK organization under standard arrangements. Funding will be provided at 80% FEC.

Terms and Conditions of the MRC award

- Standard MRC terms and conditions will apply to the UK component of a collaborative disease team III award. These are specified in the applicants' handbook, and encompass:
    - the core Research Councils UK terms and conditions
    - the additional MRC-specific terms and conditions relating to medical research
    - the MRC supplementary terms and conditions for research grants involving human stem cells, where relevant

Specific terms of the CIRM-MRC collaborative award

- The consortium partners (CIRM-funded or otherwise) agree to abide by the Code of Practice for the UK Stem Cell Bank and for the Use of Stem Cell Lines. This includes the requirement to deposit any hESC line derived using MRC funds in the UK Stem Cell Bank, and to seek approval from the Steering Committee for the UK Stem Cell Bank for the import, export or use of any hESC lines in the UK.
- The consortium partners (CIRM-funded or otherwise) agree to provide free access to the UK research community to all publication related biomedical materials generated during the course of the project, to provide consistency with the CIRM requirements for California.

Intellectual property

- Intellectual property generated in the course of the collaborative project through MRC funding will be owned by the host UK institution, who will have the right to manage and exploit the project intellectual property.
- Participating UK groups will be bound by the specified CIRM IP provisions in relation to activities within the State of California. UK partners would only be required to comply with the CIRM IP provisions relating to joint inventions when these were directly linked to CIRM funded research.
- MRC wishes to assure itself that the funded UK institutions are able to manage and exploit effectively the intellectual property generated from the MRC-funded research. In agreement with the CIRM position, MRC will reserve march-in rights to ensure that IP generated during the course of the project using MRC funding can be fully exploited for the national benefit and that of the research organization involved.

Consortium agreement

- The terms of the collaboration funded under the Disease Team Therapy Development Awards III RFA must be determined early in a proposal's development and relevant agreements put in place by the start of the project. Collaboration arrangements should ensure transparency in the project design and in the analysis and publication of results (including if these are negative). Consideration should also be given to issues such as: relative responsibilities, governance arrangements, indemnity, intellectual property rights, reporting and access to data and samples.
- MRC funding will not be released until an appropriate consortium agreement has been agreed and signed by all collaborative partners, and approved by MRC and CIRM (and any other collaborative funding partner).

Monitoring Performance of Collaborative Projects

- For collaborative disease team awards involving UK groups, MRC and CIRM will be involved with the project PIs in the active management of the projects. In addition to annual Progress Reports, the PIs will be expected to provide 1) quarterly updates; 2) routine communication by the PI or Project Manager; and 3) participation in Evaluation Meetings. MRC and CIRM will have access to all grantee-generated progress and financial reports across the full scope of the project's work.
- MRC and CIRM will meet periodically to review the progress of the collaboratively funded projects, and funding may be withdrawn should there be a failure in making satisfactory progress. These Evaluation Meetings will typically occur at the key decision points in development projects, at which time go / no go decisions will be made.

Further information

- Available from Dr Jonathan Pearce, MRC Programme Manager with responsibility for regenerative medicine (jonathan.pearce@headoffice.mrc.ac.uk)