

Consortia to Accelerate Therapeutic Applications of Stem Cells FAU # 0911051012

QUESTIONS AND ANSWERS AND MODIFICATIONS – SECOND SET Accepted October 26, 2011 through January 10, 2012

1. We expect to have made some significant additional findings between the application deadline and the start of the contract. Will there be an opportunity to submit that information for consideration of peer review?
 - A. We are unable to accept additional information after the deadline. Also see Q&A # 7 below.

2. At the time of application, are we expected to have fully-established all agreements for sharing of intellectual property, data and resources among the participating organizations?
 - A. While having such agreements established in advance is likely to strengthen the score for the related evaluation criteria, this is not a specific requirement of the RFA. See the instructions for completion of application Form 13 – Workplan, Section f, and the Review Criteria in Section VI.D. of the RFA.

3. Our consortium members have several NIH R01 awards that can be leveraged to strengthen the consortium research. There will not be overlap in aims, but findings from R01s will be incorporated to advance the work of the consortium. Is that allowable?
 - A. Yes.

4. We anticipate that there will be opportunities to license and patent various technologies along the way to developing the final product that is the focus of our consortium. Is that allowable?
 - A. Yes, provided that the terms of the contract regarding intellectual property (see Appendix C of the Sample Grant Contract, Attachment 4 to the RFA) are met.

5. Will the Oversight Panel also function partially as an advisory panel? We would like to have our own Internal Advisory Committee that we select, as well as an internal Data Safety Management Board (DSMB). We would need to compensate the members for travel and time. Would this be acceptable?
 - A. The Oversight Panel will advise NYSTEM and the consortium about a variety of topics (see Section III.A., General Expectations, of the RFA). If you choose to set

up your own internal (or external) advisory board and/or DSMB, you will need to justify their roles and related expenses in the application.

6. Where will meetings of the Oversight Panel take place?
 - A. Meetings of the consortium with the Oversight Panel are expected to be “held within the facilities of the consortium member institution most appropriate to the milestone(s) under review...” (see Section C of the RFP “Scientific Oversight of Stem Cell Consortia” posted at <http://www.health.ny.gov/funding/rfp/10003250404>).

7. We expect to have made some significant additional findings between the application deadline and the start of the contract. Will there be an opportunity to submit that information?
 - A. We are unable to accept information after the deadline for the purposes of peer review. However, after letters of award are issued and the contracting process has begun, NYSTEM **may** request scientific updates to share with the Consortia Oversight Contractor. These updates will be used to ensure that membership of the Oversight Panel is consistent with research advancements made after the application deadline.

8. We have been ironing out the details of our experimental design and find that we need a large portion of our budget to go to another institution that is applying for a different project. We see this as an essential part of the success of the research project. Will the reviewers see this as trying to get around the requirement of one application per institution?
 - A. When evaluating the applications, the reviewers will follow Sections VI.B and D and the board will follow Section VI.E. of the RFA. It is advisable for the application to clearly demonstrate that the best team and resources have been assembled to accomplish the research goals.

9. The RFA states “It is expected that applicants will have previously established proof-of-principle data to support the feasibility and timeliness/readiness of the proposed project. Because GLP and GMP will be necessary for development of clinical therapies and devices, it is expected that the experimental design and implementation will be carried out in accordance with those GLP and GMP standards.”

During a pre-pre-IND meeting with the FDA, we were advised that our pre-clinical studies, as we described them, can be conducted under GLP standards. Will NYSTEM require more rigorous standards than that required by the FDA in the conduct of NYSTEM-funded studies? Would we need to provide documentation of the FDA’s guidance on this issue in our application?

- A. No. As stated in Q&A #26 in the first round of Questions and Answers posted for this RFA, NYSTEM expects that the experimental design and implementation will

meet the FDA's standards. It is advisable to justify experimental design decisions and to provide supporting documentation where possible.

MODIFICATIONS TO FAU # 0911051012

There are no additional modifications to this RFA. **Also see** Questions, Answers and Modifications to the RFA posted previously at:
<http://www.health.ny.gov/funding/rfa/0911051012/>