Addendum to RFA# 67-175

Spinal Cord Injury Research Grant

Date: February 8, 2024

Addendum Number: 2

This addendum is to provide answers to all questions per the RFA potential applicant letter.

Question 1

(1) This query relates to section C.2.g of RFA #67-175, “Certification for the Protection of Human Subjects and Regarding Use of Human Embryonic Stem Cell Research.” That section of the RFA says, first, “Grants involving human subjects do have to be approved or exempted from review by the applicant’s Institutional Review Board (IRB) prior to the submission of the application.” (underling mine). However, the very next sentence says, “All research involving human subjects must be approved by the applicant’s IRB prior to the initiation of the research involving human subjects and prior to the use of Grant funds to pay for research involving human subjects.” (italic and underlining in RFA). These two statements contradict one another. Which is it? Does the institution need IRB approval prior to submission of the application or prior to initiating research involving human subjects using grant funds? Thanks for clarifying.

Answer 1: This addendum makes the following change to the RFA:
Amend the first full paragraph on pages 11 and 12 of Part One, General Information, Section C.2(g) (page 14 of the PDF file) to read:

“Certification for the Protection of Human Subjects and Regarding the Use of Human Embryonic Stem Cell Research – Complete and sign the form. The authorized institutional official must sign this form. Grants involving human subjects do not have to be approved or exempted from review by the applicant’s Institutional Review Board (IRB) prior to the submission of the application. All research involving human subjects must be approved by the applicant’s IRB prior to the initiation of the research involving human subjects and prior to the use of Grant funds to pay for research involving human subjects. If the research project involves human subjects and approval is pending from the applicant’s IRB, “check the third option on the first page of this form. If the research project involves the

use of human embryonic stem cells, only human embryonic stem cell lines that are approved by the NIH and derived from outside of Pennsylvania can be used."

*Except as clarified and amended by this Addendum, the terms, conditions, specifications, and instructions of the RFA and any previous addenda, remain as originally written.