

## **SPA Procedure for Allowable B&I Clinical Trial Start-Up Costs**

This internal procedure is intended to resolve issues relating to Business and Industry (B&I)-sponsored clinical trials that have start-up costs incurred prior to the effective date of the agreement. This procedure will be followed when the project accountant or research coordinator notifies SPA that they are unable to process project expenses because the CUFS account date does not include the date of service for the expense.

### **If start-up costs are included in the approved budget**

If the sponsor-approved clinical trial agreement budget reflects planned start-up costs that will be incurred prior to the effective date of the agreement, Sponsored Projects Administration (SPA) will generate a revised NOGA. The NOGA will retain the project start and end dates as detailed in the agreement, but SPA will add a clarification comment to the NOGA (e.g., "This revised NOGA recognizes allowable budgeted start-up costs incurred between \_\_\_\_\_ [date of first pre-award expense] and the Effective Date of the clinical trial agreement."). SPA will then change the CUFS dates to reflect the date of first pre-award expense, and a note of "start-up date" will be added to the CUFS comments field.

### **If start-up costs are not included in the approved budget**

If start-up expenses are incurred but were not included in the sponsor-approved final budget, the principal investigator (PI) will be required to send a letter or e-mail to certify that the costs were reasonable, allocable, and directly related to start-up activities for the clinical trial. The PI is then required to get the approval of their department head, or their dean if the PI is the department head. A revised NOGA will then be generated by SPA. The NOGA will have the project start and end dates as detailed in the agreement, but SPA will add a clarification comment to the NOGA (e.g., "This revised NOGA recognizes allowable but non-budgeted start-up costs incurred between \_\_\_\_\_ [date of first pre-award expense] and the Effective Date of the clinical trial agreement. The PI has certified these costs as reasonable, allocable, and directly related to start-up activities for the project."). SPA will then change the CUFS dates to reflect the date of first pre-award expense, and a note of "start-up date" will be added to the CUFS comments field.

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