

## **Proposed Language for NIH Applications which include Fixed Price Subawards**

### **Draft Guidance to include with proposals that do not include a Clinical Trial (as defined by NIH):**

The subaward to [name of subrecipient] documented in this proposal meets the criteria described in 2 CFR 200.201(b.) The University of Rochester is therefore requesting prior agency approval to issue this subaward as a Fixed Price Subaward. The University of Rochester will consider this subaward approved if an award is made and no contrary guidance from the agency is included in the award notice."

### **Draft Guidance to include with proposals for Clinical Trials (as defined by NIH):**

Pursuant to 2 CFR 200.332 and 45 CFR 75.201, we intend to enter into clinical trial subawards in a fixed price manner. Subaward payments will be made when the subrecipient meets the enrollment milestone as outlined in the subaward and as required by the regulations. As we have not selected all subrecipients who will be enrolling in the trial, we are seeking universal approval for any clinical trial subaward we enter into during the duration of the project in order to expedite clinical site activation, provided that such subawards based on fixed amounts (as defined in 45 CFR Part 75.2) satisfy the conditions for such subawards cited in the NIH GPS Section 8.1.2.11 (1) through (5) [omit if not NIH]. University of Rochester will consider this universal request approved if an award is made and no contrary guidance from the agency is included in the award notice.

May also include pricing information as applicable- Example: The pricing structure is as follows: \$X [enter cost] for Y # of "patients" [enter quantity].