



Clinical Trial Checklist

This form should be included with all clinical trial agreement and amendment submissions

Date: _____

PI Name: _____ Department: _____

Sponsor: _____ Protocol Number: _____

New or Existing agreement? If existing, index number: _____

Has a CDA been processed through WSU for this Study? Yes No

The following has been included with this submission (check all that apply):

Agreement

Amendment /Modification # _____

Affirmation Memo completed by the PI

Final sponsor budget

Protocol / Protocol amendment

An email has been sent to lianehowey@wayne.edu with agreement or amendment processing instructions as received from the sponsor or this information has been uploaded as a proposal attachment

Only applicable for agreements:

When negotiating the budget, the department will ensure that the budget adequately covers all costs associated with conducting a clinical trial. The following fixed and upfront costs will be/have been included in the final sponsor budget (check all that apply):

IRB Fees (initial, renewals and amendments, as applicable)

DMC Fees

OnCore/CRSC Fees

Indirect Cost Rate of 32%

If these fees are not/will not be included in the final sponsor budget, please explain why:

IRB approval and the approved Informed Consent Form(s), if applicable, will be provided to SPA as soon as they have been received. Please note: SPA is not responsible for delays in account establishment for failure to provide these forms in a timely manner.