UNIVERSITY OF MIAMI

RESEARCH ADMINISTRATION

Clinical Budget Checklist (03.27.23)

Please use this checklist when you are developing a study budget.

Federally-Funded Clinical Trials/Research		
1.	**Have you determine whether the study is Clinical Trial or Clinical Research?** Please Note: Medicare/insurance coverage of patient care costs is more limited in clinical research, than in clinical trials. More costs need to be covered by the grant in the case of clinical research.	☐
2.	**Have you checked the National Institutes of Health's definition of Patient Care Costs?** Patient care costs include costs of routine and ancillary services which **do not** include personal expense reimbursement, costs of ancillary tests done outside the hospital, recruitment/retention fees, data management or statistical analysis.	☐
3.	**Does the PI have a measurable effort on the budget?** If not, the department is required to cost-share effort. PI's effort includes professional fees for clinical care.	☐
4.	**Did you use the most current and appropriate Facilities & Administrative and Fringe Benefit Rates?** These rates are available on the ORA website: www.miami.edu/ora.	☐
5.	**Are your clinical procedures priced at the research rate for Federally-funded research?** Contact ORA for pricing.	☐
6.	**Are you aware that general administrative expenses should NOT be included as direct costs?** Some exceptions may apply.	☐
7.	**Are you aware of the direct costs which are not subject to our F&A Rate?** Patient Care Costs, Equipment valued at $5,000 or more, the portion of each Subcontract in excess of $25,000, Student Tuition Remission, Scholarships and Fellowships, participants' support costs (not research subjects!).	☐
8.	**Are you aware that IRB fees, Feasibility Fee and CRIS fees cannot be included as a direct cost in Federally-Funded clinical trials/research budgets?**	
Non-Federally Funded Clinical Trials/Research		
9.	**Did you carefully review study Protocol and other materials? Did you conduct general and financial feasibility review as it applies to resources, personnel time and costs of study-specific items?** Ensure your justification and documentation are available to support such costs.	☐
10.	**Did you contact CTRS, outside laboratory, other research facilities you plan on using to obtain costs?** This is only applicable if you use or plan to use these facilities.	☐
11.	**If non-standard services are required from the Research Pharmacy, did you contact them directly to obtain costs?** Standard Research Pharmacy costs are available from RA.	☐
12.	**If use of JHS facilities is anticipated, did you 1) complete and provide signed Jackson Health System Clinical Trials Office (CTO) Application and Draft Study Calendar to ORA 2) submit study to IRB to enable JHS CTO review?** ORA will review JHS CTO application and Study Calendar to avoid discrepancies with the Medicare Coverage Analysis and submit to JHS CTO to facilitate obtaining of JHS budget.	☐
13.	**Did you consider all personnel who will be involved in the study (PI, co-I, coordinator(s), nurse, statistician, data analyst, etc.) and the functions they will perform?**	☐
14.	**Did you estimate 1) personnel time based upon per subject/per visit format, 2) total number of hours based upon per study format for personnel such as data analyst or statistician, 3) number of hours based upon per task format for study-specific tasks?**	☐

15.	**Did you check for the following possible hidden costs related to personnel time beyond what is attributed to a "standard" study visit?** ➢ Expected intensive study monitoring, and CRF queries by sponsor or CRO; audits, including FDA audits ➢ Expected extensive number of SAE reports ➢ High volume and complexity of CRFs, lengthy questionnaires, required extensive training of site personnel	☐
16.	**When calculating time for the PI, did you calculate administrative time only?** Unlike in Federally-funded trials, clinical time is compensated via payment for clinical procedures.	☐
17.	**Did you identify costs of all study-specific items, such as Informed Consent Form (ICF) and other documents translation, advertising, equipment/supplies, subjects' travel/meals/lodging, etc.?**	☐
18.	**Did you check for hidden costs related to Pre-enrollment activities?** Examples: extensive medical records review for subjects' identification and recruitment, expected screen fails ratio, etc.	☐
19.	**Did you check for the following additional hidden costs?** ➢ Expected frequent submission of amendments to IRB; subjects' re-consenting due to amendments ➢ Lengthy collections of PharmacoKinetics (PK) samples and prolonged study visits ➢ ICF/other documents being translated into more than one language ➢ Archiving expenses for high volume of study documents and/or prolonged period of required storage	☐
20.	**Did you 1) calculate subjects-related personnel expenses based on standard hours, salaries and applicable fringe benefits, other standard personnel-related and institutional expenses, such as IRB, CRIS, Compliance Research Pharmacy, CTRS fees, departmental and study-specific expenses, and 2) submit all materials to RA for a proposed budget validation?** This applies if you are conducting a financial feasibility review of a potential contract with a non-Federal sponsor.	☐
21.	**Did you build the complete budget including personnel costs, costs of clinical procedures (obtain research rates from RA), materials and supplies, equipment, travel, subjects' compensation, services by outsiders and any applicable institutional costs, such as Research Pharmacy fees and internal monitoring fees?** This applies if you are building the budget for a proposal to a non-Federal sponsor or for an internal grant.	☐
22.	**Did you apply appropriate institutional F&A rate?** Currently, 36% for industry-supported clinical trials and UM's F&A Rate (by campus) for other non-Industry supported clinical trials and research, unless external sponsor has an official F&A-limiting policy. Check RA website for rates.	☐
23.	**Are you aware that IRB fees, Feasibility fee and CRIS fees are currently not a subject to F&A?**	☐
24.	**Did you make sure that the budget submitted to ORA via IBISResearch is based on the sponsor's offer or the budget the PI deems sufficient, whichever is greater?** Sponsor's budget must be submitted in any case.	☐