Office of Research Administration Overview

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WHEN TO ENGAGE ORA IN THE RESEARCH PROCESS?

- Department conducts a feasibility assessment
- Obtain departmental approval
- Fully submit study to HSRO
- Then, engage ORA by sending Contract (word format), sponsor contact information, budget, protocol, draft informed consent, Proposal/Contract Routing Form (PCRF-L) to cris@med.miami.edu.
- ORA will assign your project to a team member. You will receive an email informing you of who your work has been assigned to. Our team member will keep you informed as progress is made.
- Inform ORA when: protocol will be amended, study has a deadline, study is closed to its enrollment cap, and/or PI chooses not to pursue study.
Clinical Budget Development Hot Topics

- Institution determination – Budgets are developed at Medicare X 2
- 29% Facilities & Administrative Cost for Industry-funded Clinical Trials
- Patient Stipends
  - Harmonize between sponsor’s budget and Informed Consent
  - Keep them reasonable
- Shared Service Facilities – identify their involvement prior to budget development
- Special items (storage of documents, equipment, travel for subjects or study team, etc.) must be identified in the PCRF-L
- PCRF-L - reflect accurate estimates of personnel time per subject
- JMH involvement – ORA CAN review study calendar prior to providing to JMH
Budget Information, Including Faculty & Study Personnel Time And Study-Specific Items

Please estimate the average administrative time, per visit, that study personnel will spend per patient. Examples of administrative time include recruiting, administration of ICF and questionnaires, and any other assessments generally not billable (no CPT code). It does not include time for performing billable clinical procedures such as Physical Exam, ECG, Vital Signs, CT, etc. Please do not account for time more than once by including it in multiple categories.

<table>
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<tr>
<th>PI:</th>
<th>Study Coordinator:</th>
<th>Nurse:</th>
<th>Biostatistician:</th>
<th>Other Position Title:</th>
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Estimate of Total Start-Up Costs For Department (Exclusive of F&A, CRIS, Pharmacy, IRB/Compliance and JHS Fees): | Other Position Est. Time: |

Does ICF or Other Document Require Translation? Yes | No | Into How Many Languages? | Provide Per Word Translation Quote, If Available: |

What Is The Expected Ratio of Screen Failures to Enrolled Patients? | In Addition to Start-Up, What Amount of Advanced Payment is Required, If Any? |

Average Time Anticipated Performing The Following Tasks, Hours (Blended PI/Coordinator Time, If Applicable)

| SAE Reports (Each): | Re-Consenting (Each): | Monitor/FDA Visits (Each): | IRB Submissions (e.g., Amendments, Renewals): |

Average Dollar Amount Anticipated For This Project For The Following Items, If Applicable

| Travel: | Trainings: | Recruiting/Advertising: | Equipment/Supplies: |

Other Costs (List): Estimated Other Costs: |
Medicare Coverage Analysis

- DRAFT MCA provided to PI and study coordinator
- PI Review MCA
  - Confirm all procedures are listed correctly
  - Verify determinations – Medicare versus Sponsor
  - If any ? Exist, ORA requires PI input (location, procedure, method, etc.)
- Provide answers to questions, inform ORA of anything missing, etc.
- Approve MCA