1. For help with your budget, contact the Office Clinical Research....567-0651 (Che Kelly or Leo Nosser)
   a. Refer to Excel Cost-Estimator and Grid Template on OCR website
   b. Final budget must be consistent with 3 things:
      i. Billing grid for separating sponsor funding from standard of care
      ii. Clinical Trial Agreement (CTA)
      iii. Certificate of Proposal to OSP
   c. Attach supporting documentation – affiliate(s) fee schedules/contracts or verbal/email agreements

2. After evaluating applicable costs, consider this guidance in budgeting for a non-refundable start up amount, which can easily range between $6,000 and $20,000

<table>
<thead>
<tr>
<th>Non-negotiable</th>
<th>Negotiable</th>
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</thead>
<tbody>
<tr>
<td>• IRB fee – Institutional amount</td>
<td>• Plus Administrative Fee to prepare IRB and OSP packets</td>
</tr>
<tr>
<td>• F&amp;A rate – Institutional, based on sponsorship source</td>
<td>• Plus Dept Overhead as applicable to eligible direct costs</td>
</tr>
<tr>
<td>• Pharmacy fee</td>
<td>• Coordinator time to contract for lab/ancillary affiliate fees</td>
</tr>
<tr>
<td></td>
<td>• Pharmacy, as applicable, variable by facility and fund source</td>
</tr>
<tr>
<td></td>
<td>• Translation of Consent Forms English to Spanish Per consent, invoice to sponsor at cost plus 5%</td>
</tr>
</tbody>
</table>

3. Hidden Costs to watch for (NB. these do not have to be itemized to the sponsor, they may be rolled into Hourly Fees or other sponsor category that is acceptable)
   a. Personnel Costing for Study Execution and Activities
      i. Attending initiation visit
      ii. Investigator and/or coordinator travel to investigator meetings (this is for time not travel expense reimbursement)
      iii. Managing adverse events – clinical and regulatory time
      iv. Attending monitoring visits
      v. Close out costs (additional time for data queries, added time for end-study visit and patient education or referral; reconciliation of budgets and invoices)
   b. Non-personnel
      i. Patient care costs – lab, pharmacy, radiology, surgery, facility fees for clinic room
      ii. Reimbursements to study subjects – stipends for time and travel, meals, parking
      iii. Office supplies
      iv. Clinical supplies
      v. Secondary lab tests if a certain test is not enough
      vi. Close out costs (room fee for monitor meetings; copying subject documents for sponsor)
   c. Equipment
      i. Cost for equipment being used – fee for service use; confirm what sponsor will provide?
      ii. Additional storage cabinets – for securing study drug and sponsor-provided equipment or devices
   d. Other
      i. Postage and Shipping – who pays for what
      ii. Travel contingencies – sponsor will limit what they reimburse for travel expenses; make sure you include a little for unreimbursed costs
      iii. Records retention and storage