**Instructions to complete the Paper Clinical Trial Submission Form**

The Clinical Trial submission form has to accompany ALL cancer related protocols and the paper form is accepted for:
- Non-interventional trials: e.g. Retrospective chart reviews, tissue collection trials.

The submission form is in the PDF format and can be completed on-line. The signature page (page 6) will need the signatures of the Principal Investigator (PI) and the Disease Leader. Please note that the submission form is periodically updated. When completing the form, please be sure to obtain the latest version on-line.

**Page 1**

1. **Title:**
   a. Copy and paste the Title from the protocol in the space provided.
2. **Protocol Number:**
   a. Leave the space blank for all trials, except cooperative group trials (CALGB; SWOG; COG; GOG; RTOG).
3. **PI Name:**
   a. Add name, phone # and e-mail address.
4. **Co-PI:**
   a. Add name, phone # and e-mail address. For more than 2 Co-PIs', please add information on a separate sheet.
5. **Emergency Contact:**
   a. Can be the trial manager/clinical research coordinator/regulatory officer (CANNOT BE THE PI)
6. **Phase of Study:**
   a. This is usually-stated in the title of the protocol. However for investigator initiated trials (IITs) please add "Pilot study" if phase not indicated.
7. **Did the PI author the protocol?**
   a. Marking "Yes", indicates that it is an Investigator Initiated study (IIT).
8. **Sponsor:**
   a. Mark the sponsor type. "Investigator Initiated" indicates that the funding is internal/local e.g. OSU.
   b. Other: This could include NCCN
9. **Scope:**
   a. Mark Local (OSU only) or National (more than one site)
10. **Type of Study:**
    a. Under "Non-Therapeutic" please indicate which type.
11. **Does this protocol involve the transfer of recombinant DNA or RNA, or DNA or RNA derived from recombinant DNA into patients?**
    a. Please indicate or add N/A
12. **Does this protocol involve live, recombinant, and/or attenuated microorganisms for the purposes of vaccination of patients?**
    a. Please indicate or add N/A
1. Total Protocol Target Accrual (multi-site trials/OSU only):
   a. This is the national overall accrual goal for the multicenter trials and the local overall accrual goal for the OSU/Children’s trial.
2. Total Accrual Goal:
   a. Upper limits:
      i. For local trials, it will be same as Total Protocol Target Accrual.
      ii. For multicenter trials the sponsor will indicate the upper limit for each site.
   b. Lower limits:
      i. Minimum overall accrual goal.
3. Accrual Duration (months):
   a. This is the scheduled duration that the trial will be open to accrual at the institution.
4. Estimated Screen Failure Rate (percentage)%:
   This is the % of patients you expect to be ineligible for the trial after consent and screening has been completed. We need this % to calculate the total number of consents we need to request from the IRB.

**Cancer Research Programs and Disease Groups**

1. Disease Specific Research Group:
   a. Mark the disease groups the protocol falls under. In case of multiple sites mark all that apply.
2. CCC Program Area:
   a. Mark the program the protocol belongs to.

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**Tumor Types**

1. Select ALL that apply

**Institution/Study Site Information:**

Mark all the sites that apply.

1. Subsites:
   a. Indicate if the protocol have any subsites:
      i. Please specify whether OSU is the Main site or a subsite of another institution.

**Data and Safety Monitoring**

1. Please indicate
   • Please make sure the Data and Safety Monitoring verbiage is added to all investigators Initiated trials (IITs).

**IND**

1. Please specify
Resource Utilization

- Trials not requiring regulatory/budgetary help from the CTO may skip this section
  1. Protocol Management:
     a. Please mark all that apply.
  2. Clinical Trials Processing Laboratory:
     a. Mark all that apply
  3. If this is an investigator-initiated trial, has it been reviewed by CTPL
     a. Please indicate, and if yes include reviewers name
  4. Will OSU be the Reference Laboratory
     a. Please indicate
  5. Are other research-related laboratories needed
     a. Please indicate, if yes please include lab names
  6. Project Management help needed
     a. Please mark all that apply
  7. How will this trial be funded
     a. Please indicate
        i. Sponsor: please include name and protocol number
        ii. PI Lab/Start-up Fund: Please specify
        iii. Other Fund: Please specify

Trial Overlap

This applies to ONLY therapeutic trials; this information is not necessary.

Signatures

1. Please print the PI name and have them sign the form
2. Disease Leader Name:
   a. A Disease Specific Research Group Leader signature is required for all protocols submitted to the CSRC. Please see the table below for the list of Leaders.

<table>
<thead>
<tr>
<th>Disease Specific Research Group Leader(s)</th>
<th>Disease Specific Research Group Leader(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CNS</td>
<td>Arnab Chakravarti, M.D. or Vinay Puduvalli, M.D.</td>
</tr>
<tr>
<td>Thoracic</td>
<td>Gregory Otterson, M.D.</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Kristen Ciombor, M.D.</td>
</tr>
<tr>
<td>Breast</td>
<td>Julia White, M.D.</td>
</tr>
<tr>
<td>Thyroid/Neuro-endocrine</td>
<td>Manisha Shah, M.D.</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>Steve Clinton, M.D., Ph.D.</td>
</tr>
<tr>
<td>Gynecologic</td>
<td>David O’ Malley, M.D.</td>
</tr>
<tr>
<td>Head &amp; Neck</td>
<td>James Rocco, M.D., Ph.D.</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Kari Kendra, M.D., Ph.D.</td>
</tr>
<tr>
<td>Sarcoma</td>
<td>Joel Mayerson, M.D.</td>
</tr>
<tr>
<td>CLL</td>
<td>Jeffrey Jones, M.D.</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Kristie Blum, M.D.</td>
</tr>
<tr>
<td>Acute Leukemia</td>
<td>William Blum, M.D.</td>
</tr>
<tr>
<td>Myeloma</td>
<td>Craig Hofmeister, M.D.</td>
</tr>
<tr>
<td>BMT</td>
<td>Steven Devine, M.D.</td>
</tr>
</tbody>
</table>