**Cancer Center Clinical Research: Protocol Submission Form**

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| **Trial Information** | |
| **Protocol Title & Study Number/Short name:** | |
| **HSR number (if known) and NCT Number:** | |
| **Sponsor Name:** | |
| **UVA PI & Title:** | |
| **Sub-investigators & title (Individuals required on the 1572):** | |
| **Please provide a brief summary of the study (**If study is phase 1, describe if UVA will participate in dose escalation, expansion, or both.**):** | |
| **General** | |
| Disease Team: | Breast  GI  GU  GYN  H&N  Cellular Therapies  CALM  Lymphoma  Multiple Myeloma  T-cell/LGL, Benign (HCHT)  Melanoma  Sarcoma  Neuro-Oncology  Radiation Oncology  Thoracic  Other: \_\_\_\_\_\_\_\_\_\_ |
| Disease Stage: | I  II  III  IV  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Phase of trial | Pilot/feasibility  I  II  III +  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Trial Lines of Therapy | First  Second  Third  Adjuvant  Neoadjuvant  Other:\_\_\_\_\_\_\_\_\_\_\_ |
| Is there a complete start-up package/budget/contract? | Yes  No  Other: \_\_\_\_\_\_\_\_\_\_\_ |
| Type of trial  (Select both Sponsor and Protocol type) | ***Sponsor Type***  Investigator-initiated, UVA is lead site  Confirm protocol has all required sections, including inclusion/exclusion criteria, study objectives and endpoints, safety assessments and reporting, statistical analysis plan, and sample size justification. For studies without formal hypothesis testing, precision analysis with confidence intervals for the primary endpoint should be provided for sample size justification.  Investigator-initiated, other center is lead site: \_\_\_\_\_\_\_  Cooperative Group: \_\_\_\_\_\_\_\_\_  Pharmaceutical: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_  ------------------------------------  ***Protocol Type***  Treatment  Basic science  Device  Other (Diagnostic/Prevention/Screening/Supportive care/Health services research): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| UVA PI Role | National PI, Study Chair, overall PI on multi-site study  PI on single site study  Co-Chair (e.g., for cooperative group studies)  Study champion (e.g., NCTN collaborative role for intergroup studies)  Role in study design for industry trial (e.g., Steering Committee Chair)  Local PI for multi-site study |
| Review committees that will be utilized | PRC  UVA IRB  Central IRB  HIRE  IBC  CTO  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Funding | Industry  Cooperative Group  Foundation  Consortium  Seed/grant money  Philanthropy  Department  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Accrual** | |
| Is this a sub-study of an NCI/NCTN basket, umbrella, or master protocol? | No  Yes |
| Number of competing protocols at UVA | n > 3 active or pending competing trials  1-2 competing active or pending trials  0 active or pending competing trials  N/A (for screening protocols or sub-studies of NCI/NCTN basket, umbrella, or master protocols)  **If competing protocols exist, provide justification for opening this trial:**  **Please list this trial and competing trial IRB #s in order of prioritization:** |
| Is this a study of a rare cancer (<6 per 100,000 people per year), rare population or molecular subset that would qualify as rare cancer? (All pediatric cancers qualify as a rare disease.) | Yes (justification required): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No |
| Is this trial using competitive enrollment (slots awarded on a first-come first serve basis)? | Yes  No |
| Anticipated enrollment end date |  |
| Anticipated total enrollment duration | months/years |
| How many patients meet both the inclusion and exclusion criteria per year? |  |
| Accrual estimate per year (PI-please provide conservative estimate) |  |
| Total trial accrual estimate (full duration of study) |  |
| Total study sample size |  |
| Number of patients enrolled at all sites at the time this form is completed |  |
| Total number of planned sites |  |
| Number of sites currently active (only for **industry** multi-site studies) |  |
| Competing sites w/in our region?  (only for **industry** multi-site studies) | Yes  No  Other: \_\_\_\_\_\_\_\_\_\_\_ |
| Does the study have international sites? (only for **industry** multi-site studies) | Yes  No |

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| **Complex Trial Indicators** | | |
| ***Place a checkmark in the box on left if the corresponding indicator is true for this study.*** | | |
| **Indicator** | | **Corresponding page number in the protocol(if applicable)** |
|  | IIT |  |
|  | Sponsor is external academic center |  |
|  | Trial has inpatient aspects. Indicate admitting team |  |
|  | Physician practices in non EC4 location |  |
|  | Non EC4 drug administration with drug expiration less than 2 hours |  |
|  | Treatment requires 6 or more hours of infusion time |  |
|  | More than 4 treatment arms |  |
|  | More than 2 nurse interactions per hour (i.e., multiple vitals, multiple EKGs) |  |
|  | Ophthalmology exams |  |
|  | Trial has a cell therapy component (e.g., CAR-T, BATs, lymphocyte infusion (TIL), Natural Killer cell therapy etc.) |  |
|  | IBC approval required (e.g.: cell therapy, live viral product) |  |
|  | Treatment involves nuclear medicine |  |
|  | Trial involves equipment/process that has never been used at UVA facilities before |  |
|  | Trial involves commercially supplied drug unavailable on UVA formulary for inpatient administration |  |
| Comments: What is the rationale behind doing this study? Why is it important to you? Why is it important to our patients? Please explain the relationship between this trial and any competing protocols. Please assign risk category below. Does the trial translate UVA science, and is there authorship potential for the research team? | | |

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| **Is this an interventional trial?** Per NIH, an intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.  Yes  No  **Risk Category:**    **High risk:** sponsor-investigator INDs (regardless of phase), Phase 1 studies, gene therapy trials, and any other types of trials designated by NIH as high risk    **Medium risk:** all other therapeutic intervention (such as drugs, biologics or devices) trials not designated by NIH, PRC or IRB as high risk (typically Phase II and Phase III trials)  **Low risk**: non-therapeutic intervention trials (examples include trials assessing a new diagnostic approach (e.g., testing a new screening method), behavioral studies seeking to improve or modify health outcomes (e.g., exercise modification to improve survival or quality of life), or nutritional and imaging trials), and non-interventional studies collecting additional blood or tissue samples outside of standard of care procedures.  **Exempt**: non-intervention trials are exempt from providing a monitoring plan (such as epidemiology research, survey, or functional assessment). Intervention trials may not be classified as exempt. |