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| **Precision Oncology Actively Managed Portfolio (PO AMP)**  **Letter of Intent (LOI) Template for Precision Oncology AMP Accelerated Review Clinical Trials** |
| **Principal Investigator (PI) Name:** |
| **Project Title:** |
| **Desired Accelerated Review Type: (check box)**  **Accelerated Review**  Research proposals eligible for **accelerated review** must:   * Have the potential for immediate and/or direct impact on clinical care or clinical decision making * Be pilot studies that are responsive to critical clinical problems that require initial findings to establish evidence for a robust priority project and endorsed by an AMP workgroup or clinical/VHA leadership (I.E. when the achievement of longer, collaborative goals require a specific finding to progress). * Address topics that urgently respond to an issue of importance to the Veteran population   **Critical Accelerated Review**  Research proposals eligible for **critical accelerated review** must meet accelerated review requirements and:   * Have high Congressional, Presidential, ORD, or clinical operations relevance or priority   Address cancer that requires immediate action to reduce high hospitalization, mortality, and morbidity rates |
| The sections below must be completed and attached to VHA Research & Development Letter of Intent Cover Page (VA Form 10-1313-13) (<http://www.research.va.gov/funding/process/forms.cfm>). In section 3, check “other” and enter “PO AMP” in the box under “other”.  Please complete each of the fillable boxes below. Your text may not exceed the max characters indicated. Please submit references cited as separate PDF. |
| 1. Provide (1) a brief overall summary of the objectives of the entire project and the hypotheses to be tested; (2) a description of how the project aligns with the priorities of the Precision Oncology AMP; and (3) how the proposed study is precision oncology or takes a precision-based approach *(max 500 characters)* |
| 1. Provide a brief description of why the project warrants accelerated or critical accelerated review *(max 1500 characters)* |
| 1. Brief description of the primary aims of the clinical trial *(max 1500 characters)* |
| 1. Description of intervention and control/s *(max 500 characters)* |
| 1. Description of the primary endpoint. Include measurable clinical outcome(s) for precision oncology or explain why it is not the primary outcome *(max 1500 characters)* |
| 1. Describe the scientific rationale, significance to the Veteran population, and any background or preliminary studies/evidence that support the concept for this individual study. *(max 1500 characters)* |
| 1. If a proposed medication trial, do you already have an agreement with a company to receive the medication? Do you have a matched placebo? Describe how the medication will be obtained. Note: The quality of the agent/product should be consistent with FDA manufacturing standards *(max 1500 characters)* |
| 1. Sample Details. Describe the assumptions for sample size. *(max 500 characters)* |
| 1. Description of how the results will impact clinical practice (or plans for further studies) and/or healthcare decision making. Specifically, what will this trial lead to? *(max 1500 characters)* |
| 1. Description of any anticipated problems or challenges regarding timely start up and execution (including whether the study will be FDA regulated and/or will require agreements with industry or other non-VA entity, patents/licensing, etc.). *(max 500 characters)* |
| 1. Please address the following:   Duration = years  Number of subjects =  Number of sites =  List sites and name site PIs: |
| 1. Description of the study category using FDA Phase Definitions (e.g., Phase 0, 1, 2, 3, or 4; <http://clinicaltrials.gov/ct2/help/glossary/phase>) *(max 500 characters)* |
| 1. Brief description of subject screening/recruitment methods and projected recruitment rate. As evidence of feasibility, data describing the size of the subject population available at the recruiting site(s) and verification of access to the appropriate Veteran population must be provided. What is your projection of how many subjects will be able to participate? *(max 500 characters)* |
| 1. A list of any local or national competing trials on this topic that would draw subjects from the same Veteran population must be included. If competing trials exist, the distinction from the proposed trial must be accurately described. If no competing trials are underway, indicate NONE. See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) as one source for this information. *(max 1500 characters)* |
| 1. Attach optional waivers (*see Adobe Acrobat instructions for attaching files*)   Enrollment of non-Veterans  Supplemental funds for planning activities  Over the budget cap (e.g., for multi-site trials) |
| 1. Please submit LOI to [CLIN-Review@va.gov](mailto:CLIN-Review@va.gov). Notification of the outcome from the LOI review will be sent to the station. |