**2.7 Clinical Trial Study Timeline**

*Attach as a PDF file. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates. Activities in the timeline should be consistent with the budget.*

**SAMPLE 1: CLINICAL TRIAL**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Year of Funding** | | | |
| **Milestones** | **Y1** | **Y2** | **Y3** | **Y4** |
| Completion of regulatory approvals | X |  |  |  |
| Enrollment of the first subject | X |  |  |  |
| Enrollment of 25% of projected recruitment for all study subjects (15 of 60 projected) | X |  |  |  |
| Enrollment of 50% of projected recruitment for all study subjects (30 of 60 projected) | X |  |  |  |
| Enrollment of 75% of projected recruitment for all study subjects (45 of 60 projected) |  | X |  |  |
| Enrollment of 100% of projected recruitment for all study subjects (60 of 60 projected) |  |  | X |  |
| Completion of data collection time period |  |  |  | X |
| Completion of primary endpoint and secondary endpoint data analysis time period |  |  |  | X |
| Completion of final study report |  |  |  | X |
| Perform genetic analysis to assign patients to risk groups | X | X | X |  |
| Perform mechanistic analyses (see Research Strategy) |  |  | X | X |

**SAMPLE 2: MECHANISTIC STUDY USING EXISTING BIOBANKED SAMPLES**

**AND NEW, ONE-TIME SAMPLES FROM EXISTING COHORTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Year of Award** | | | | |
| **Task** | **Y1** | **Y2** | **Y3** | **Y4** | **Y5** |
| Patient recruitment and new sample procurement per Recruitment and Retention Plan | X |  |  |  |  |
| Molecular profiling (Aim 1) | X | X | X |  |  |
| Sequencing (Aim 2) | X | X | X |  |  |
| Plasma biomarker assays on samples from Aim 1 and in vitro stimulated samples (Aim 3) |  |  |  | X | X |
| Data analysis | X | X | X | X | X |

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Contact: Rebecka Bourn, PhD, OSCTR Science Writing Unit

OSCTR Website: <http://osctr.ouhsc.edu>

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