**ICTS Pilot Project’s Implementation Plan**

**1. Where does this project fall on the translational science continuum? (*check all that apply*)**



|  |  |
| --- | --- |
| Basic Science Study (T0) |  |
| Translation of Basic Science to Humans (T1) |  |
| Translation from Human Studies to Patients (T2) |  |
| Translation from Clinical Trials to Practice (T3) |  |
| Dissemination of findings to the Community (T4) |  |

**2. What are the purposes of this Pilot Study? (*check all that apply)***

|  |  |
| --- | --- |
| a. To determine feasibility of participant recruitment |  |
| b. To determine estimation of effect size |  |
| c. To determine estimation of the safety of a new procedure |  |
| d. To determine feasibility of assessment procedures |  |
| e. To determine feasibility of implementing a novel intervention |  |
| f. To determine feasibility of new methods |  |
| g. To determine feasibility of participant retention |  |
| h. To determine feasibility of preliminary hypothesis testing |  |
| i. To determine feasibility of randomization |  |
| j. To establish feasibility of a hypothesis or concept utilizing cell/molecular  approaches |  |
| k. To establish physiological relevance of an important in vitro finding in an appropriate in vivo model |  |
| l. To validate findings with cell lines in native (primary) tissue |  |
| m. To extend findings with animal models to the human situation |  |
| n. |  |

***NCATS describes a research collaboration as 2 or more individuals combining knowledge, expertise, and resources to work together in achieving a common and mutually beneficial translational research goal.***

***A NEW collaboration means you have never previously jointly worked on a publication, grant or presentation.***

**3. Is this research a collaboration? \_\_\_\_\_\_**

**a. Is this collaboration new? \_\_\_\_\_\_**

**4. Is your pilot research relevant to the following groups? (*check all that apply*)**

|  |  |
| --- | --- |
| a. Children |  |
| b. Under-represented populations |  |
| c. Geriatric populations |  |
| d. Rare Disease populations |  |
| e. HIV/AIDs patients |  |

**5. Will you be recruiting study participants from the following groups? (*check all that apply*)**

|  |  |
| --- | --- |
| a. Children |  |
| b. Under-represented populations |  |
| c. Geriatric populations |  |
| d. Rare Disease populations |  |
| e. HIV/AIDs patients |  |

**6. If you will be conducting human subjects’ research, what is the status of your IRB application?**

 a. Pending \_\_\_\_

 b. Approved \_\_\_\_\_

 IRB number, if approved \_\_\_\_\_\_\_\_\_

 IRB date, if approved \_\_\_\_\_\_\_\_\_\_\_\_\_

c. N/A \_\_\_\_

**7. If you will be conducting animal subjects’ research, what is the status of your IACUC**

**application?**

 a. Pending \_\_\_\_

 b. Approved \_\_\_\_\_

 IACUC number, if approved \_\_\_\_\_\_\_\_\_

 IACUC date, if approved \_\_\_\_\_\_\_\_\_\_\_\_\_

c. N/A \_\_\_\_

**Milestones** (*Milestones are intermediate objectives that are necessary steps toward project completion). Please specify the time period expected for the completion of each milestone:*

**Milestones** are not the same thing as **Specific Aims**. An example of a **Specific Aim** is the following:

*This study aims to test the efficacy a school-based evaluation to promote physical activity among sedentary adolescents.*

Associated **Milestones** might be the following:

|  |  |
| --- | --- |
| **SAMPLE MILESTONES** | **Month of Completion****(relative to start of funding and/or actual date)** |
| Milestone 1 | Obtain IRB approval for study | Month 1 (July, 2016) |
| Milestone 2 | Obtain School District approval for study | Month 2 (August, 2017) |
| Milestone 3 | Recruit 40 sedentary adolescents  | Month 4 (Sept., 2016) |
| Milestone 4 | Complete baseline assessments | Months 4-6 (Sept-Nov, 2016) |
| Milestone 5 | Implement the intervention | Months 8-10 (Jan-Mar 2016) |
| Milestone 6 | Complete follow-up assessments | Months 11-12 (March/April, 2016) |

**8. *Please list your project-specific milestones in the table below. Feel free to add more milestones if needed.***

|  |  |
| --- | --- |
| **Project-Specific Milestones** | **Month of Completion** |
| **Milestone 1:**  |  |
| **Milestone 2:** |  |
| **Milestone 3:** |  |
| **Milestone 4:** |  |
| **Milestone 5:** |  |
| **Milestone 6:** |  |

**Anticipated date of Publication Mo/Year of Completion**

If this project is expected to result in at least one publication,

Estimate the month/year that a manuscript will be submitted \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Anticipated date of Grant Application**

If this project is expected to result in a grant application,

Estimate the month/year that a grant will be submitted \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Intended Funding Source** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Anticipated ICTS Project Start Date Mo/Day/Year**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**