

ICTR

The Johns Hopkins Institute for Clinical and Translational Research

ATIP Application: Development of Milestones and Project Schedules

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1. Introduction

More efficient translation of promising discoveries is the impetus behind the ICTR Accelerated Translational Incubator Pilot (ATIP) program. The limited time frame in which a project must be completed sets ATIP apart from other traditional funding programs more familiar to academia. One way to introduce investigators to this rapid approach to academic research is the introduction of Project Management principles to the process.

Project Management is the discipline of planning, organizing, and managing resources to bring about the successful and efficient completion of specific project goals and objectives. There are a number of **Project Management** terms used below (**in bold**) that may not be familiar. For that reason, a Glossary of Terms and Acronyms is included at the end of this document. **All Project Management principles discussed in this overview can be found in “A Guide to the Project Management Body of Knowledge (PMBOK® Guide), Third Edition.”**

Although there are many components of **Project Management**, the focus of this tool is to offer guidance with regard to the development of **milestones** and **project schedules** needed for the timely completion of an ATIP project. **ATIP projects must be completed within 12 months.** Awarded Principal Investigators (PIs) will receive notification of their award within two months of the ATIP submission deadline. **This essentially means that the date of the ATIP award letter is Day 1 of the 12-month funding award timeline.** To this end, it is vital that investigators 1) take into consideration the time of year, upcoming holidays, vacations, and/or other upcoming critical deadlines or events that will impact their project timeline (**project schedule**), and 2) scrutinize the feasibility of their overall project. If it is unlikely that all identified **project milestones** can be attained within the 12-month funding time period, the investigator must examine and revise what is planned to be accomplished (**project scope**.) If, as has happened with several research teams to date, an awarded ATIP project is not reaching self-set milestones, leadership may withdraw project funding and redirect that support to other investigators. For this reason, it is in the best interest of the applicant to pay special attention to the **scope** of their project, to develop realistic schedules, and to describe attainable milestones as measures of progress.

2. Milestones

The identification of project milestones is the first process in the creation of a realistic **project schedule**.

a. Identifying Milestones

ATIP project **milestones** should encompass all significant **events, activities, and/or deliverables** that are crucial to the successful completion of the overall project.

The milestones can be portions of the Specific Aims of the project, critical events such as regulatory approvals, acquisition of necessary supplies/equipment, and completion of critical experiments and portions of a study. The milestones identified should be ones that can be broken down or decomposed into individual steps or components.

For example, if an investigator is looking to develop a diagnostic test for indeterminate types of tumor tissue using microarray analysis techniques, breaking the study's Specific Aims down into individual activities might yield the following milestones:

- Perform microarray analysis of 3 different tumor tissue types
- Validate differentiating patterns in a new set of tumor tissue samples with RT-PCR.
- Generate a final molecular diagnostic panel tested and applicable to tumor tissue samples.
- Test the diagnostic panel on samples from a tumor tissue bank
- Prospectively test tumor tissue samples collected from patients undergoing open biopsy.

b. Milestone Decomposition

Once identified, the project milestones must then be further broken down or, in Project Management terms, “decomposed” into smaller, quantifiable components or steps required to complete each one that will eventually become the **project schedule**.

When decomposing milestones, the number of components/steps will depend of the complexity of the particular milestone activity. These smaller and more manageable components of the larger milestone should be described in sufficient detail to provide the investigator with a means to accurately estimate the amount of time required for completion. The last step/component will be documentation of the completion of the milestone. This process is crucial to the creation of a realistic and comprehensive **project schedule** that will help the investigator monitor progress.

If, for example, a project milestone is the “Approval of an eIRB Application”, this could be **decomposed** into the following steps:

- (1) Writing a protocol
- (2) Writing the consent form
- (3) Completing the eIRB application
- (4) Study Team Agrees to Participate
- (5) PI submits application
- (6) IRB approval

Once the milestones are decomposed, the next process is to estimate the amount of time that is required to complete each step and each milestone.

c. Time Estimation

After decomposing the milestones, estimating the amount of time needed to complete each of the individual components is the next process in the development of the project schedule.

Time estimates should be based on previous experience, experience of colleagues or other experts, and the resources you have or will have to complete each step. The estimates should be as realistic and accurate as possible.

Using the eIRB application milestone example in #2 above, the time to complete each step could be estimated as per the following table.

Milestone # 1 Components	Timeline	Estimated Time of Completion
(1) Writing protocol	Weeks 1 & 2	2 weeks
(2) Writing Consent form	Week 3	1 week
(3) Completing eIRB application	Week 4	1 week
(4) Study Team Agrees to Participate	Week 5	1 week
(5) PI Submits application		
(6) IRB approval	Weeks 6 thru 10	5 weeks
Milestone Completion time	Week 10	10 weeks

**This is provided as an example only and may not accurately reflect the actual times needed for completion of each activity.*

Commitments and resources of the PI should be taken into consideration when making these estimates. If the PI is due to be on-service for a month, will be preparing a grant application or manuscript, or traveling for conferences and/or has no study coordinator or research fellow to assist with the work, the above example estimates will likely not be realistic which will adversely affect the **project schedule**.

In an effort to help PIs to create accurate and realistic project schedules, a completed “**Project Readiness Checklist**” is now required with all ATIP applications.

3. Project Readiness Checklist

To assist in developing and decomposing milestones, estimating timelines, and creating a project schedule, the “**Project Readiness Checklist**” tool must be used to help identify equipment, staff, materials, contracts, and regulatory approvals that are needed for successful completion of the research project. The list is not meant to be all-inclusive and PIs should add to the list as needed. This checklist a required element of the grant submission and is designed to:

- help the investigator realistically examine how much time will be needed for a particular regulatory process or delivery of a piece of equipment
- help identify what activities can be and are feasible to be prepared in advance of project initiation in order to make things move more expeditiously if funded
- help identify which processes’ initiation are dependent upon completion of others
- help identify which processes may be done in parallel

The investigator can then use the checklist to work on completing the **project schedule**. Time estimates, dependent activities and activities that may be done in parallel can be incorporated into the project schedule.

If, for example, milestone #1 cannot be initiated until a piece of equipment is purchased and received, the amount of time required to purchase the equipment through SAP as well as the time required for the manufacturer to deliver the equipment, training needed, etc. must be taken into account. Variables that can affect the time required for completion of a milestone such as this include:

- whether or not the manufacturer is an SAP “approved vendor”
- obtaining a quote for the equipment
- the amount the quote (is it more than \$5,000?)
- installation of equipment
- training required for use of the equipment
- Clinical Engineering approval

Any of these variables could add anywhere from 1 to 6 or more weeks to order the equipment. Then, if it takes another 6 weeks from the time it is purchased for delivery, the time to complete the entire ATIP project has diminished from 12 months to 9 months.

Because delays, such as the example above, may be unavoidable, you will need to see what activities may be done in parallel. Use of the Readiness Checklist will assist applicants in the identification of activities that can be performed in parallel and which should be taken into consideration when creating the project schedule. **A completed Project Readiness Checklist is a required component of the ATIP application.**

If a project cannot, according to the project schedule, be completed in the one-year award timeframe, time estimations should not be manipulated just to “make it fit.” The point of this tool is to help the investigator identify whether or not the project is feasible as designed. If the project schedule indicates that it is not, re-examination of each activity, dependencies, possible means to shorten the schedule should be examined. If this is not possible, the scope of the project should be revisited.

4. Project Schedule

Once all milestones have been decomposed and time to completion has been determined, the **project schedule** should be created using the **Project Schedule Template**. **A completed Project Schedule is a required element of the ATIP application.**

A well-constructed **project schedule** allows the PI and study team to monitor progress and make adjustments in response to obstacles. It can also be used to accurately estimate the amount money and other resources required to complete the project at any point in the project.

Because ATIP projects are to be completed within 12 months, the ability to accurately monitor progress toward completion of the study is vital. Knowing exactly where in the study timeline progress is faltering allows the team to evaluate what is left to be done and aids in the development of a plan to get back on schedule.

PLEASE NOTE: For reasons of continuity, we prefer that all applicants use the Project Schedule template provided. Other schedule formats may be used, but must be approved by the Navigators prior to submission.

5. Summary

- Start by identifying the overall purpose of the project (e.g., submission of IND/IDE application, designing a research tool, designing an assay or other diagnostic tool, etc...). This defines the **project scope**.
- Once the project scope is defined, identify each of the major events, **deliverables**, and objectives that must be achieved or attained in order to successfully complete the project's Specific Aims. These are the **project milestones**.
- Each project milestone is then decomposed or broken down into smaller components, tasks, or steps that need to occur in order to achieve the particular milestone.
- Estimate the time needed to complete each of the decomposed milestones' components/steps, and thus the time required to complete each milestone.
- Use the **Readiness Checklist** to help determine time required for completion of all project related activities and which activities may be done in parallel.
- Create a **Project Schedule**, analyzing each milestone and milestone component/step to see which are dependent activities and which can be done in parallel.
- **Submit a completed Project Schedule and Readiness Checklist with the ATIP application.**

It is in the best interest of the ATIP applicant to pay close attention to the scope of their project, to develop realistic schedules, and to describe attainable milestones as measures of progress. It is for these reasons that the Project Schedule and Readiness Checklist are now required elements of the ATIP application.

6. ATIP Application

When submitting an ATIP application, investigators are required to include the **milestones** within the Research Plan as stated in the RFA. The Project Readiness Checklist and Project Schedule Template documents must be submitted for review along with the other required documents.

7. Consultation

The ICTR Research Navigators are available for consultation regarding development of ATIP project schedules and milestones via the ICTR Connection Request System: <http://ictr.johnshopkins.edu/connection/>

8. Appendix

(A) Glossary of Terms

Glossary of Terms

Activity: A component of work performed during the course of a project.

Decompose

- (decomposition):** A planning technique that subdivides the project scope [overall purpose] and project deliverables into smaller, more manageable components, until the project work associated with accomplishing the project scope and providing the deliverables is defined in sufficient detail to support executing, monitoring, and controlling of work.
- Deliverable:** Any unique and verifiable product, result, or capability to perform a service that must be produced to complete a process, phase, or project.
- Event:** Something that happens, an occurrence, an outcome.
- Milestone:** A significant point or event in the project.
- Objective:** Something toward which work is to be directed, a strategic position to be attained, or a purpose to be achieved, a result to be obtained, a product to be produced, or a service to be performed.
- Project Schedule:** The planned dates for performing a scheduled activity and the planned dates for meeting schedule milestones.
- Project Scope:** The work that must be performed to deliver a product, service, or result with the specified features and functions
- Project Scope Statement:** The narrative description of the project scope, including the major deliverables, project objectives, project assumptions, project constraints, and a statement of work, that provides a documented basis for making future project decisions and for confirming or developing a common understanding of project scope among the stakeholders.
- Schedule Milestone:** A significant event in the project schedule, such as an event restraining future work or marking the completion of a major deliverable
- Scope:** The sum of products, services, and results to be provided as a project.

Reference:

A Guide to the Project Management Body of Knowledge (PMBOK® Guide) 3rd edition