How to establish milestones in your HSSA grant

The following is meant as a guide to negotiating and finalizing your milestones and timeline with HSSA. Milestones serve as unambiguous indicators of progress and are used to satisfy Washington state requirements that grants are paid on a reimbursement basis against agreed-upon work. Generally, milestones measure concrete, discrete outcomes such as a deliverable. There needs to be a sufficient number of milestones so progress is not measured against abroad indicator spanning a considerable period and to make reimbursement logical, but not so many that they become trivial or burdensome to manage.

Research grant milestones must include both scientific and business tasks, even if all or some of the business tasks are funded through non-HSSA sources.

Milestones are reported on in quarterly grant progress reports by the principal investigator (PI), and are cited on reimbursement requests submitted as frequently as monthly. Milestones do not have to be completed for payment to be made, but progress towards milestone completion must be clear and definite.

Failure to meet milestones can result in renegotiation of the milestones to more realistically predict progress; acceleration of effort to catch up; and, when particularly critical milestones are missed and/or the work will not be completed as originally proposed, termination of the grant.

The following are hypothetical examples using a one-year grant term. The "acceptable" format is not a required template. The **bolded milestones** are mandatory milestones.

Unacceptable:

Year 1: Synthesize inhibitor

Hire two new members for our group

Buy new hypervariator

Initiate recruitment efforts for clinical study

Acceptable:

Milestone #	**Milestone**	**Completion Date**	**Criterion/Deliverable**
1	Recruit staff for clinical study	Start Date	Post job descriptions & ads for study coordinator and research nurse. Study coordinator requires PhD and 5 years relevant experience; research nurse must be RN w/10 year relevant experience
2	Request FDA approval for clinical study	Start date	IND/IDE application submitted to FDA
3	Obtain FDA approval for clinical study	Month 2	FDA approval of IND/IDE application received. Go/no-go point, i.e., if FDA approval is denied or significantly delayed, project stops for HSSA review
4	Hire staff for clinical study	Month 2	One study coordinator and one research nurse hired
5	Request institutional approval for animal/human subjects studies	Month 2	Animal/human subjects protocol(s) submitted to IACUC/IRB at ABC University
6	Receive institutional approval for animal/human subjects studies	Month 3	ABC University IACUC/IRB protocol approval letter received. Go/no-go point, i.e., if IACUC/IRB approval is denied or significantly delayed, project stops for HSSA review
7	Synthesize inhibitor against protein XYZ3	Month 3	Produce 100 mg of inhibitor using grantee's validated GMP synthesis protocols. Go/no-go point, i.e. if inhibitor yield significantly lower, project stops for HSSA review
8	**First quarterly update meeting**	**Month 3**	**In-person meeting between project team and HSSA staff/Grants Comm.**

			representative(s)
9	Distribute information on first-in-human clinical study of an XYZ3 inhibitor for treatment of early-stage breast cancer	Month 4	In-Person visits & consultations by study coordinator & research nurse (including presentation of study goals, procedures, and inclusion criteria) completed with 10 oncologists in the statewide ABC Hospital & Clinic Network
10	Freedom-to-operate analysis	Month 4	Commercial partner, Company X, performs FTO as cost-sharing with the project
11	Identify patients for the study of XYZ3 inhibitor for breast cancer	Month 6	15 eligible patients consented and enrolled from the 100 ABC oncologists contacted. Go/no-go point, i.e. if recruitment is fewer than 5 patients, project stops for HSSA review
12	**Collaboration agreements executed**	**Month 6**	**Collaboration agreements specifying IP rights & disposition signed among grantee, co-applications, service providers, & collaborators.**
13	**Semi-annual progress report**	**Month 6**	**Progress report submitted to HSSA. Represents second quarterly update meeting.**
14	Order new hypervariator	Month 6	Purchase agreement signed.
15	Management committee meeting	Month 6	Co-investigators & at least one additional lab member meet for hours.
16	Complete dose-escalation study with 15 patients	Month 8	Administer 3 doses XYZ3 inhibitor to 5 patients each and monitor for toxicity as detailed in the FDA- and IRB-approved protocol. Go/no-go point, i.e., if significant toxicity is observed, project stops for HSSA review.
17	Install new hypervariator	Month 9	Receive hypervariator, install in B2-243
18	Company funding	Month 9	Commercialization partner completes two meetings with angel investment groups.
19	**Third quarterly meeting**	**Month 9**	**In-person meeting between project team and HSSA staff and Grant Comm.**

			representative(s)
20	**Develop method for submission of post-award progress reports**	**(One month before end of grant term)**	**Agree on the schedule and mechanism for post-award progress reports with HSSA staff**
21	Analyze data from dose-escalation study	Month 12	Select optimal dose(s) for follow-on studies based on toxicity profile.
22	Apply for follow-on funding to continue work after HSSA grant term ends	Month 12	One NIH SBIR proposal submitted
23	Semi-annual progress report	Month 12	Progress report submitted to HSSA. Represents fourth quarterly update meeting.
24	Intellectual property meeting (meeting occurs every year of grant term)	Month 12	In-person meeting with HSSA to discuss intellectual property prosecution and protection