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| 1. **Problem Statement / Need to be met by this study**

What is the problem being experienced? What need is this study addressing? Be specific in identifying the “pain point” to provide a basis for doing this study. Talk about problem statement – why is that important? i.e., if it takes too long, “how long”?If there is an unknown, how does that unknown affect progress towards patient care?**Discussion Questions for Problem Statement/ Potential Benefits** * Does the statement give a good description of what the project is addressing?
* Is the issue or theme stated as it relates to the customer/stakeholder?
* Include quantitative data where available – something that will quantify why this is a problem – not just a one-time occurrence.

**Questions to be answered:****Brief introduction to project:****Benefits that will be realized from project:** | **B. Customers/End Users****(**I.e. patients, students, researchers, community members, special populations…)What is their role in the study? Will they be engaged throughout; are their milestones where they will be engaged? What is the method of communication? Meetings/frequency. Emails/updates, etc. |
| 1. **Funding Organization Objectives Supported by this Study**
 | **D. Team Participants/ Selection/ Roles*** Is team member selection realistic and will members be able to contribute accordingly?
* Are key stakeholders and pertinent partners represented?
* Who is not at the table

***Who Knows?******Who Cares?******Who Can Act?**** Are the necessary subject matter experts included (statistical plan and support, cohort identification, study support)?
* What are the roles of the team members? Are all members involved to the same degree or will some be engaged at different points of the study?
* How will communication with the team occur? Meetings, minutes, shared drives, news bulletins..
* How will decisions be made and conflict be addressed?
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| **E. Current State Definition** Description of the current process or state of knowledge-. Include information and data to show why it is a problem or what knowledge is lacking to help support your problem statement.  |
| **F. Included in Scope*** Where the process starts and where does it end (bookends)?
* Does the scope clearly define what is included in the study?
 | **F. Excluded from Scope*** What is specifically not in scope (off the table)?
* Are the items and/or areas out of scope clearly spelled out?
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| **G. Objectives/Outputs** **/Deliverables/*** Aims
* Sub Aims
* Outputs for each aim
* Outcomes for the study
* Is a publication one output for this study? If so, what are the topics of the publication (s) and plan for what will be needed to publish?
* How will your team address primary and secondary authorship?
 | **H. Evaluation*** Are the metrics measurable, meaningful scorecard metrics that would support more focus and attention on attaining this goal?
* Do the metrics align with objectives?
* Are the metrics within the scope of this study?
* Are there appropriate qualitative data that should be collected?
* What outcomes are you seeking and how will you know those outcomes were achieved?
* If outcomes have a long lead-time in showing achievement are there leading indicators?
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| **I. Approach & Critical Path Milestones & Time Frames** * What is the approach?
* Do the milestones and timelines define what needs to happen to move us to the end of the study (are all deliverables contained in the milestones)?
* Has each activity in the plan been specified as to when and outcome?
* Is the plan realistic and achievable?
* Is the scope of proposed work realistic for the time assigned?
 | **J. Risks** * Are risks clearly outlined and identify what needs to be addressed for study completion and success?

 **Dependencies*** + Are dependencies well defined within/across area of the study, i.e. all ITHS and institutions?
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| 1. **Resources**
* What are the anticipated resources to design/ implement the study? (estimated FTE, costs, equipment, etc)
* What is needed to sustain the effort once implemented? (How will the effort be sustained?) (if applicable)
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**TEAM CHARTER DEFINITIONS ROLES**

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| **Problem Statement/ Potential Benefits*** + What is the problem being experienced? Do not include direct or assumed solutions or causes in statement.
	+ Include quantitative data where available. If not available, consider including a place marker until data is gathered.

**Don’t do this:** Problem with assumed cause.* + What are the potential benefits of achieving the study objective?

**Current State Description**Where appropriate include:* Process flow( include number of people, departments and roles), Diagram of workflow (spaghetti diagram)
* Related data), Identify various data collection and reporting systems

**Scope*** + Where does the process start and stop? Where does the study begin and end?
	+ What areas/ stakeholders are involved?
	+ What is not in our scope of work (though others might think it is)?
	+ Are key partners included or excluded in scope (FHCRC, Seattle Children’s, UW, WWAMI, etc)?

**Study Objectives/ Outputs/ Target metrics*** + What will be accomplished by this study? Quantify where possible. If data is not currently available, use place holders until data is gathered and quantitative goal is defined.
* Outputs include (as needed).

**Critical Path Milestones & Time Frames*** Includes dates and incremental deliverables.

**Risks/Dependencies*** List all dependencies associated with study. Examples include: development of data systems, funding source identified, processes providing input to process under study. Requires data be obtained from ABC organization.
* Risks include all factors that may negatively impact the success of the study (on time meeting of study objective). Examples include: simultaneous study that may negatively impact available support resources, funding for solution that may disappear, additional studies that could impact solutions of this study.
* List all study constraints and requirements.

**Planning for Article (Research & Science on Science studies)*** Include research question (s) in Problem Statement.
* Plan for co-authorship.
* Consider methods that will substantiate findings (these should be mapped in the timeline).
* Identify potential journals for publication.
* Include production of article (s) in study objectives, as milestones and in the time line.
* During data collection, create needed charts and graphs that can be used in article.
 | **PI and Aim** ResponsibilitiesRepeatedly Communicate value of study to team. Keep team abreast of organizational perceptions and changes relating to project. Ensures resource availability. Remove obstacles from team as they arrive.Approve Charter. Ensure team is meeting milestones. Recognize and reward team progress. Review team dynamics, achievement of desired effect, problems encountered. Meet with Team Lead, LPM to review progress and ensure alignment- identify derailments early.Support team’s solutions or provide reasons for differing opinions. If solutions cannot be accepted due to a previously improperly identified constraint, ensure team is made aware of oversight. Accountable for team achievement of objectives and outputs. Ultimate owner of study.Clearly defines roles and division of responsibilities with co-PIs.Responsible for effectively utilizing time of team members. Responsible for keeping team on schedule with milestones and deliverables (this responsibility may be delegated to LPM.**Lean Project Manager (LPM)//Facilitator**Works with PI and team in creation of charter.Facilitates all work and follow up. Works with team to develop project plan, meeting agendas, and minutes. Facilitates team dynamics. Work with PI in meeting management, communication skills, team dynamics and problem-solving tools. Coordinate with team on responsibilities for minutes, follow up on action items, ensuring team is on track to completion. Communicates any issues or stumbling blocks with PIPlan for organize and conduct team meetings. **Process Owner- is there an element of the study that extends the life of the study (i.e. curriculum development, training, dissemination studies)**Ongoing responsibility for managing process. For new processes ownership determination and ongoing management may be part of the project. Accountable for ongoing implementation of solutions. Ensures measures are in place and use measures to monitor ongoing success of work. Ensure adherence to meeting ground rules, creating a psychologically safe environment for the team.Will be project manager/team lead for implementation unless otherwise designated to LPM.Ensure stakeholders are updated on progress and any barriers, etc. Keep clear communication with sponsor.**Subject Matter Experts (SME)**Have specialized area of knowledge pertinent to the project or Individuals that carry influence and authority (official or unspoken influence) to affect the success of the project and have a vested interest in the project. Can include management, key stakeholder or partner groups. Help define charter, objectives, outputs and milestone deliverables, scope, and constraints as requested. Support and participate in implementation of change. Responsible to stay abreast of project, ensuring timely feedback on course and direction. Ensure prompt and timely solutions are carried through and followed. Assist team as requested.**Team Members**Selected based on who knows, who cares and who can act. Representatives include key partners/ process customers where applicable. Understand reason for selection and contribute accordingly. If representing others in department, keep them informed and bring their input to meetings.Attend and actively participate in meetings (if applicable). Question others input if not clearly understood. Complete agreed upon action items. Assist lead in maintaining focus.Responsible for information and feedback on all meetings where attendance is requested (whether present or not).**Customers/ Communities and Special Populations**Represent areas that will be impacted by changes. Provides customer input into protocol where appropriate. . **Yoketen**Identify other opportunities to share learnings (publications, conferences, talks, posters, etc.). |