Feasibility Resources:

Feasibility Checklists:

- Industry Sponsored/Initiated Drug/Device Protocol Feasibility Checklist (attached)–
    - Check for updated versions regularly at OCTRI Policies, Forms and Templates https://www.ohsu.edu/octri/policies-forms-and-templates
- Knight Cancer Institute- Study Feasibility Tools
    - Knight Bridge Site
- OHSU Department of Dermatology – Pre-Feasibility Questionnaire for Sponsors (attached)
- Comprehensive Protocol Feasibility Questionnaire – University of Alabama at Birmingham
    - https://www.uab.edu/ccts/images/Comprehensive__FEASABILITY_FORM_1-21-15.pdf

OHSU Patient Identification Tools (require IRB approval required to access identifiable data)

- Cohort Discovery – Self reporting tool. Contact OCTRI Research Navigator
- OCTRI Research Data Warehouse Contact OCTRI Research Navigator
- Epic Reporting Workbench – See EPIC For Research Bridge site

Budget Resources

- RATE Clinical Trials I – Pre-Award Class
- Industry Sponsored/Initiated Drug/Device Protocol Feasibility Checklist –Budget Section
    - OCTRI Policies, Forms and Templates https://www.ohsu.edu/octri/policies-forms-and-templates

Industry Sponsored/Initiated Drug/Device Protocol Feasibility Checklist

This tool can be used to assist investigators evaluate the feasibility of conducting an industry sponsored study at OHSU. For the best results, you should have the final study protocol, the sponsor's consent template, Case Report Forms (CRFs), questionnaires, lab manuals, drug brochure/device manual available for evaluation. Re-evaluate the study as new information becomes available. You may need to contact your department administrator, members of the study team, and/or other departments to determine if the appropriate resources are available to conduct the study.

Conducting a thorough feasibility analysis is important for financial reasons and to protect your reputation as a valuable research site. It is generally better to turn down a study that isn't a good fit, than to participate in a trial as an underperforming site.

Study Population:

	Yes	No	Unk
Does OHSU have the patient population described in the inclusion/exclusion criteria? A Cohort Discovery search can give you a count of potential subjects at OHSU. Complex inclusion/exclusion criteria may require a Research Data Warehouse (RDW) query. Contact OCTRI@ohsu.edu if you have questions about the tools, need access, or a cost estimate.			
Do you see these patients in your clinic at OHSU? If not, can you get a collaborator or use another means of recruitment? Epic options may include MyChart recruitment, Epic alerts, Epic workbench reporting. You can contact the EpicResearchTeam@OHSU.edu to discuss electronic recruitment options and associated costs. You can also contact octrirecrutiment@ohsu.edu for a comprehensive recruitment consultation.			
Will you need to recruit participants from external sources (Community, VAPORHCS, OHSU Partners)? If so, will the sponsor provide funding for recruitment costs? Consider time for phone screening, and advertising costs in your budget. Recruitment from other sites may require additional approvals and considerations. Contact Kitt Swartz swartzk@ohsu.edu, if you plan to recruit or see participants at OHSU partner sites.			
Is the proposed enrollment period realistic? If enrollment is expected to close in the next 6-12 months consider the likelihood of meeting enrollment expectations. Note: start-up can take approximately 4 months from the time of IRB submission.			
Are inclusion/exclusion criteria overly restrictive? Consider the likely screen failure rate and the number of screen failures for which the sponsor is willing to pay. Consider co-morbidities that may impact the ability to recruit this population.			
Are there logistical issues that will impact recruitment/implementation? Consider time and arrangements for special populations. ☐ Will participants need to travel? ☐ Can these considerations be overcome with time/budget/personnel?			

	Yes	No	Unk
Will this study compete with other studies seeking the same patients? □ Is the competing study expected to end soon? □ Is it enrolling well? □ Are there enough eligible patients to meet enrollment in both trials?			

Protocol:

	Yes	No	Unk
Is the study question important to the OHSU PI? Does the PI/study team feel that participation is in line with the PI's/ study teams research goals/study portfolio? Consider whether Phase IV or other post marketing trials are asking an important research questions if the drug/device is otherwise available.			
Is the protocol well designed?			
Are there ethical issues that need to be considered in the protocol? Will there be issues that could delay IRB approval (e.g. withholding treatment, sham interventions)			
Is this the final version of the protocol? If not consider the following: □ How many amendments can be expected? Consider waiting to submit the study to the IRB until the protocol is final. □ Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written?			
Can other departments/services meet the protocol requirements? Consider the timing of visits/procedures, available equipment, and local lab tests.			
If the protocol indicates some of the procedures are standard of care does it match the current OHSU standard of care? If not, can the protocol be integrated/implemented with our standard of care?			
Are study visits complex, presenting possible scheduling difficulties? Consider whether there are special procedures that require evaluations or testing by specific individuals or testing outside of regular clinic hours. □ Are the required visits and assessments feasible with the resources currently available? □ If multiple clinics/service units are needed for visits is the scheduling compatible with the study requirements?			

	Yes	No	Unk
Are the procedures/study design likely to cause compliance problems or patient drop-outs? Consider the burden of compliance with study procedures in projecting recruitment and retention: □ Are procedures painful and generally not needed for standard of care? □ Will frequent or long visits require participants to miss work/school? □ Are procedures difficult for this population to complete? (medication compliance/ hard to swallow pills)			
Are data collection forms complex, lengthy, and time consuming? Include staff time in the budget. If the protocol/contract require specific turnaround times, determine if these are reasonable.			
Is this a late phase therapeutic trial? Drop-outs may be more likely if the study drug becomes commercially available while the study is underway.			
Is this study similar to previous studies conducted at OHSU? □ Did those studies meet enrollment? □ Were they completed with the proposed budget?			

Staff:

	Yes	No	Unk
Does the PI have adequate time to devote to the study? Will the PI be at OHSU for the duration of the study? If not, consider a different PI who is interested in the study.			
Do you have adequate research staff for the study required activities including but not limited to: □ Regulatory tasks (IRB submissions, regulatory binder maintenance) □ Study coordination (scheduling visits, obtaining diaries, recruiting patients, completing CRFs, responding to queries, etc.) □ Consenting □ Clinical tasks □ PI/MD Co-I time to review study CRFs, AEs, imaging, labs, etc.			
Are additional specialists needed to conduct the study? Are they available and interested in participating?			
Are the staff identified above qualified (and credentialed if applicable), trained, and available (enough FTE) to complete the protocol required activities? Clinical activities conducted for research purposes require the same OHSU credentialing as a clinical care. If you have any questions about credentialing requirements see https://o2.ohsu.edu/medical-affairs/credentialing/index.cfm			
If training is needed is it available? If the protocol requires training for specific equipment/procedures: □ Will the sponsor provide training? □ Compensation for training time (include costs in your budget)?			

Space:

	Yes	No	Unk
Do you have adequate space for the study visits and protocol required equipment?			
Is the study visit space adequately supplied/equipped?			
Is the space available when needed? Review protocol required scheduling timelines.			
Where will study staff reside? Is the space adequately resourced (computers, phones, document storage)?			

Sponsor/Clinical Research Organization (CRO):

	Yes	No	Unk
Has your previous experience with this sponsor/CRO been satisfactory? If you don't have experience with this sponsor/CRO, check with your colleagues, department or CTO contracting to see if there are any issues.			
Will the sponsor agree with the OHSU subject injury and liability position? If you haven't worked with the sponsor before you can direct them to the OHSU CTO contracting page which documents OHSU required provisions http://www.ohsu.edu/xd/research/administration/clinical-trials-office/. If there are questions about the policies, contact your OHSU CTO Contract Officer.			

Budget/Payment Terms:

The PI/Department are responsible for developing, negotiating, and finalizing the budget and payment terms. Look at the overall budget while considering enrollment, clinical costs, and expenses over the life of the trial to see if costs are covered in the sponsor's offer. At a minimum, the budget should cover the cost of all tests and procedures, salary support for all study team members, professional fees (if not covered by salary), and invoiceable costs such as (but not limited to) IRB, pharmacy, shipping, subject reimbursement, advertising, long term storage and consent translation fees. You should contact the involved departments to make sure that use are using the correct procedure codes and account for other costs that may not be specified in the protocol. There is additional guidance available in the Industry Funded Clinical Trial Budget and Payment Term Guidelines (https://o2.ohsu.edu/upload/Industry-Funded-Clinical-Trial-Budget-and-Payment-Term-Guidelines-and-Information.pdf)

	Yes	No	Unk
Does the proposed budget cover clinical costs? Research rates can be found in eCRIS or the Research Rates Search. Questions about the CPT codes and other associated procedure costs should be directed to the appropriate department contact. For OCTRI Cost estimates contact OCTRI@ohsu.edu or complete the OCTRI Resource Request form https://octri.ohsu.edu/redcap/surveys/?s=jKxNzqKq3p For Advanced Imaging Research Center (AIRC) estimates contact the AIRC at 503-418-1505			

	Yes	No	Unk
Does the budget cover staff time?			
Is the participant compensation appropriate for the participant time commitment and potential discomfort?			
Is the sponsor willing to pay for advertising/recruitment costs?			
Do you need to consider providing or paying for travel, childcare, etc? If yes, add this as an invoiceable cost in the budget.			
Are proposed payment intervals/conditions reasonable? - Payments should be made at least quarterly unless there are special circumstances - Holdbacks on study visits should not be more than 20% (try to negotiate lower) - Try to negotiate late payment fees if the sponsor doesn't pay on time			
Is the study using imaging? - Does the budget cover additional CPT codes for extra views/slices? - Data/image transfer? - Are they read locally? Send the protocol and any imaging instructions to the radiology to determine if additional fees apply.			
If the budget/contract require that OHSU bill insurance for study required procedures, do the procedures match current OHSU standard of care? If not ask the sponsor to pay, if they won't contact the CRBO to see if it is allowable to bill to insurance.			
Does the sponsor agree to our current F&A rate and any departmental assessments?			
Will the sponsor agree to pay for monitoring visit fees and time to complete queries?			
If applicable, does the sponsor agree to pay for pharmacy start-up and storage fees? (http://www.ohsu.edu/xd/health/services/pharmacy/research-pharmacy/) Consider whether there are after hours or on-call Pharmacist needs. Send the pharmacy the protocol and drug manual to get an accurate estimate.			
Does the sponsor require OHSU purchase the study device(s)? If so, complete the device form in the eIRB to start the purchasing review process. This can be submitted prior to completing the full IRB application.			

OHSU Dermatology Pre-Feasibility Questionnaire for Sponsors

BASIC INFORMATION

1. Sponsor name:

2. CRO and start-up contact information:

STUDY DETAILS

3. Title of study:

4. Indication/Population:

5. Provide a brief description of study (2-3 sentences max). *Include timeframe for treatment and name(s) of study drug(s)*:

6. Optional portions of the protocol *(if any, i.e., PK draws, photography)*:

7. Does the study require both blinded and unblinded study staff?

ENROLLMENT

8. Number of participants planned for study-wide enrollment:
    - Number planned for OHSU enrollment:

9. Are other sites already enrolling? How many sites currently open and/or planned to open? If other sites are open, how many subjects have been screened and enrolled study-wide?

10. Estimated end date of enrollment *(date and # driven to stop enrollment):*

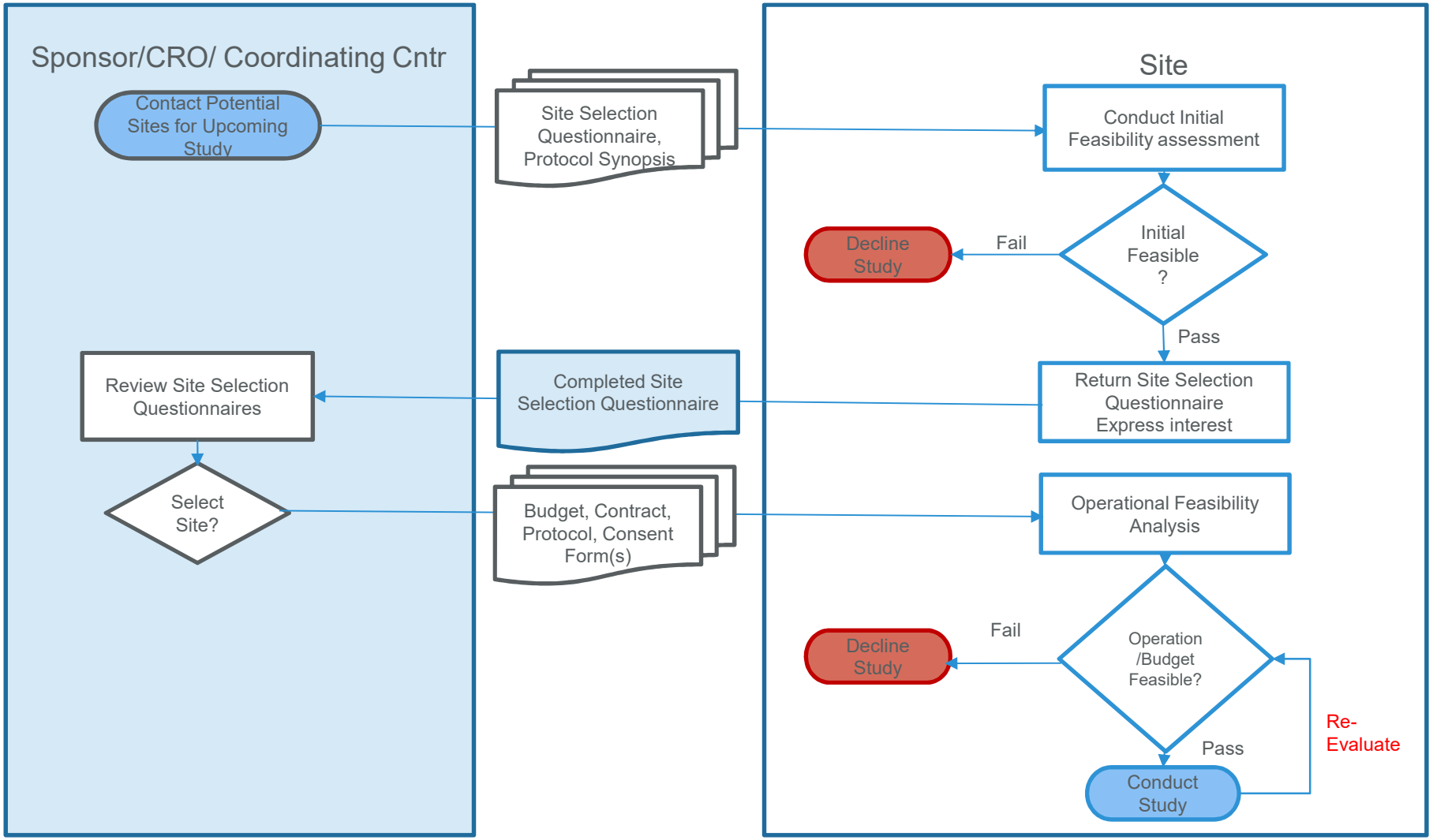
11. Funding available from sponsor?

12. Will sponsor provide resources (i.e., central campaign) for subject recruitment and/or travel?

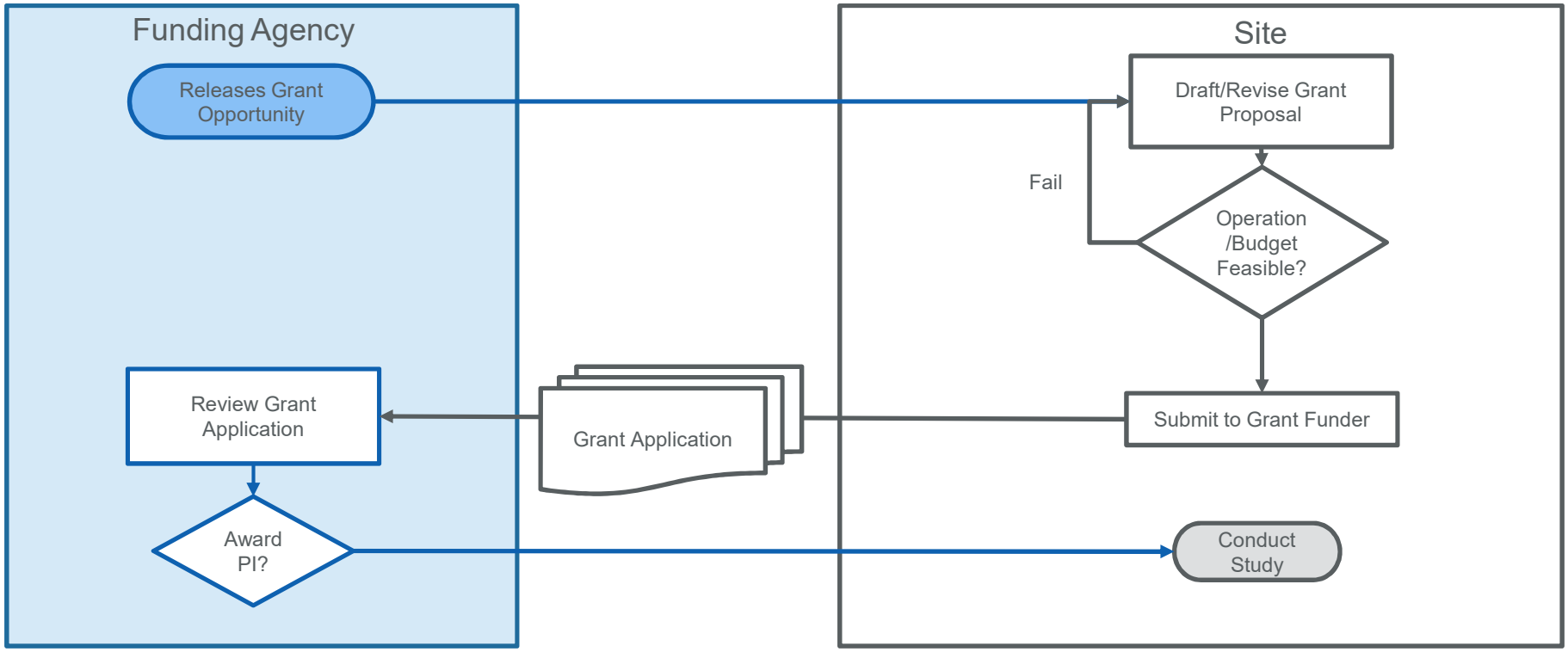
MONITORING

13. Does this study include risk-based monitoring and/or remote monitoring?

Industry Protocol Feasibility Analysis



Grant Feasibility/Protocol Analysis



Feasibility and Operational Analysis should be done during the grant writing process

- Consider Grant Requirements
- Consider Budget Guidelines
- Consider Resources
- Consider Science!
- Consider feedback from Program Officer and peers