

# Research/QI/Letters of Support Feasibility Checklist

This checklist outlines the criteria for administrative approval for conducting Research/QI and requests for Letters of Support.

<b>Principal Investigator/Project Lead:</b>	
<b>Protocol Title:</b>	
<b>Protocol IRB# (if applicable):</b>	
<b>Clinical Research Coordinator or Administrative Contact:</b>	
<b>Project Lead Affiliation &amp; Department:</b>	
<b>Date of the Request:</b>	
<b>Proposal Purpose:</b>	<input type="checkbox"/> Research <input type="checkbox"/> QI Project <input type="checkbox"/> Letter of Support
<b>Proposed Start and End Date:</b>	Dates:        to

<b>Project Information</b>	
<p><b>Summary/abstract - please briefly address each of the following topics:</b></p> <ul style="list-style-type: none"> <li>-Background and significance of the problem/issue</li> <li>-Project purpose statement</li> <li>-Project objectives</li> <li>-Population/setting/participants</li> <li>-Key stakeholders</li> <li>-Methods/implementation plan</li> <li>-Outcome measures and data analysis plan</li> <li>-Harris Heath resources needed</li> <li>-Potential financial implications to Harris Health</li> <li>-State if your project will interrupt or make a change in operational work flow</li> </ul>	
<p><b>List expected project outcomes:</b></p>	
<p><b>Identify the Strategic Pillar this project fits into:</b></p>	<p><b>Harris Health’s Strategic Plan is supported by 6 strategic pillars that serve as its foundation &amp; Harris Health’s plan forward:</b></p> <p><input type="checkbox"/> <b>Quality and patient safety:</b> Harris Health will become a high-reliability organization (HRO) with quality and patient safety as a core value where zero patient harm is not only a possibility but an expectation.</p> <p><input type="checkbox"/> <b>People:</b> Harris Health will enhance the patient, employee and medical staff experience and develop a culture of respect, recognition and trust by actively listening to feedback and developing strategies to address high-impact areas of opportunity.</p>

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	<input type="checkbox"/> <b>One Harris Health System:</b> Harris Health will act as one system in its approach to the management and delivery of healthcare.  <input type="checkbox"/> <b>Population health management:</b> Harris Health will measurably improve patient health outcomes by optimizing a cross-continuum approach to health that is anchored in high-impact preventive, virtual and community-based services, deployed in coordination with clinical and social services partners, and underwritten by actionable population health analytics and technology.  <input type="checkbox"/> <b>Infrastructure optimization:</b> Harris Health will invest in and optimize infrastructure related to facilities, information technology (IT) and telehealth, information security, and health informatics to increase value, ensure safety and meet the current and future needs of the patients we serve.  <input type="checkbox"/> <b>Diversity, Equity and Inclusion:</b> Harris Health will ensure equitable access to high-quality care for patients, foster a diverse and inclusive workplace, cultivate and sustain strategic relationships with supplies and community partners, and broaden its reach and understanding of the communities it serves.
<b>Indicate at which location(s) the project will be implemented, include the specific health center/clinic or hospital and unit.</b>	

1.) <b>Participant Recruitment:</b> (Check all that apply) <input type="checkbox"/> N/A	Comment
How many Harris Health patients?	
How many other types of participants (e.g., nurses, physicians, students, other employees)	

2.) <b>Financial Information</b> (Check all that apply) <input type="checkbox"/> N/A	Comment
Are there budgeted funds to pay for Harris Health resources to be used for project?	<input type="checkbox"/> Yes <input type="checkbox"/> No If not, please explain:
Are there Patient billable charges?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Are there Research billable charges?	<input type="checkbox"/> Yes <input type="checkbox"/> No

3.) <b>Study Requirements:</b> (Check all that apply) <input type="checkbox"/> N/A	Comment
Project/Study requirements performed in another location additional to the recruitment area (ex: study required EKG & blood draws performed in main Operating Room)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Surveys, questionnaires (such as quality of life), dosing diaries will be utilized? Who will conduct or collect the surveys or QOLs?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes, name the surveyor:
Will project/study specific labs be drawn? (Do not include standard of care labs)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Who will draw the labs?	<input type="checkbox"/> Harris Health Staff Member? <input type="checkbox"/> Or Other: List Title

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Who will provide the lab kits?	If yes, document:
Who will handle the specimen (e.g., transport, shipping)?	If yes, document:
Will normal operational flow of the area for recruitment, treatment, clinic visits, etc., be impacted (e.g., research study activities may increase patient time in waiting area or clinic room that may potentially create bottlenecks, delays and patient and/or healthcare team members frustration)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Can the project/protocol be adequately integrated with routine standard of care?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the project/study being conducted in patient care areas?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will this affect other non-research patients?	<input type="checkbox"/> Yes <input type="checkbox"/> No
What is the duration of the visit(s)?	
Will the visit impact staff hours?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is this an inpatient project/study/trial or does this involve some inpatient requirements?	Document:
Will there be a PI/Co-I on call and will there be a call tree for questions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Who will be on call?	Document:
<input type="checkbox"/> Will special procedures require evaluations or tests outside of regular clinic hours? <input type="checkbox"/> Evening after 5 pm? <input type="checkbox"/> Weekends?	Document:
What's required and who is involved?	Document:
How will the patient and project/study be managed during weekends or holidays?	Document:
What's required and who will be involved?	Document:
Who will in-service the Harris Health staff explaining the roles & responsibilities for all shifts if needed / day / night / weekend?	Document:

<b>4.) <u>IT Data Requests: Data Security and IT/EPIC Information</u></b> <b>(Check all that apply) <input type="checkbox"/> NA</b>	<b>Comment</b>
<b><i>If you need IT assistance in identifying eligible patients and/or data abstraction, please complete the IT Report Request form and submit to <a href="mailto:QIprojects@harrishealth.org">QIprojects@harrishealth.org</a>.</i></b>	
<b>Please check the following IT services you require:</b>	
Database Development?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Custom Epic build?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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	<p>If Yes,          1.) Order          2.) Order details (frequency, instructions, dose, dose strength, etc.)          3.) Order Set          4.) Nursing documentation          5.) Physician documentation          6.) Clinical Decision Support Alert (Best Practice Advisory)          7.) Discharge Instructions          8.) Patient Education</p>
<p>External Data Transfer?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No          If yes, then select mode of data transfer  <input type="checkbox"/> Secure FTP  <input type="checkbox"/> Email  <input type="checkbox"/> Data Interface  <input type="checkbox"/> Other</p>
<p>EPIC Access needed for project team?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No          If Yes to EPIC access, Document the First, Last Names and Titles:</p>

<p><b>5.) <u>Department Services Requested</u></b>  <b>(Check all that apply)</b> <input type="checkbox"/> N/A</p>	<p><b>Comment</b></p>
<p><input type="checkbox"/> IDS Pharmacy              Beacon Required? <input type="checkbox"/>Yes <input type="checkbox"/>No              Study drug(s): <input type="checkbox"/>Yes <input type="checkbox"/>No              Name: <input type="checkbox"/>SOC or <input type="checkbox"/>Research              Name: <input type="checkbox"/>SOC or <input type="checkbox"/>Research              Name: <input type="checkbox"/>SOC or <input type="checkbox"/>Research  <input type="checkbox"/> Clinical Lab/Pathology Services              Supplies provided by project? <input type="checkbox"/>Yes <input type="checkbox"/>No  <input type="checkbox"/> Radiology/Imaging              Will a CD be required? <input type="checkbox"/>Yes <input type="checkbox"/>No  <input type="checkbox"/> Cardiology Requirements? <input type="checkbox"/>Yes <input type="checkbox"/>No              EKGs? <input type="checkbox"/>Yes <input type="checkbox"/>No  <input type="checkbox"/> Nursing Services  <input type="checkbox"/> Agreements/Contracts Review (DUA, FTA, Reliance)              List Agreements(s): _____  <input type="checkbox"/> Biomed Review  <input type="checkbox"/> Compliance Review  <input type="checkbox"/> Patient Education Committee Review (Only for QI Projects using patient education materials)</p>	

<p><b>6.) <u>Harris Health Employee Assistance Requested</u></b>  <b>(Check all that apply)</b> <input type="checkbox"/> N/A</p>	<p><b>Comment</b></p>

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<input type="checkbox"/> Participant identification & pre-screening (recruitment) <input type="checkbox"/> Screening <input type="checkbox"/> Laboratory specimen collection <input type="checkbox"/> Laboratory process <input type="checkbox"/> Medication administration <input type="checkbox"/> Other (please describe)	

<b>7.) <u>Special Considerations:</u></b> <b>(Check all that apply)</b>	<b>Comment</b>
<input type="checkbox"/> Does project/study require a device?  <input type="checkbox"/> Is the study providing the special equipment and/or supplies?  <input type="checkbox"/> Will the special equipment and/or supplies require storage space at Harris Health facilities?  <input type="checkbox"/> Space needed (e.g., conference rooms, office space, etc. Please describe)	<div style="text-align: center;"><input type="checkbox"/> N/A</div>          Document:

<b>8.) <u>Additional Information:</u></b>	<b>Comment</b>