



Research Proposals & Processes

FHS Research Collaborative & Publications Committees

October 21, 2022

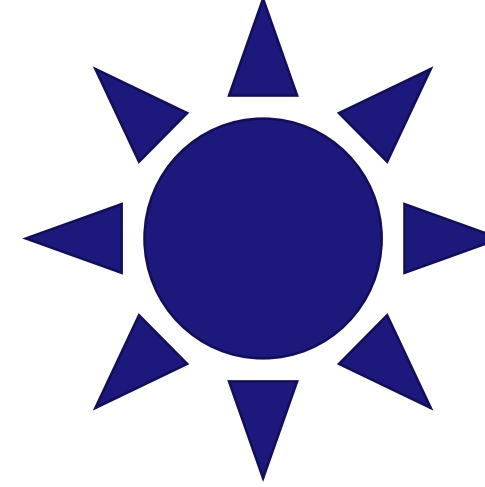
Timelines

Study Type	Concept Proposal Acceptance to Full Proposal Submission (2wks before RCC meets)	RCC Full Proposal Approval to PI site IRB Approval & Database Opening	Time from IRB and Database Finalization at Primary Site(s) to ALL Site IRB Completion	RCC Full Proposal Approval to Data Entry Completed	Data Entry Completion to Data Cleaning & Analysis*	Data Entry Completion to Manuscript Submission to Pub Committee	Total from RCC Full Proposal Approval to Manuscript Submission
Retrospective Chart Review	3-6 mos	3 mos	3-6 mos	6-12 mos	3 mos	6-9 mos	12-21 mos
Retrospective Chart and Central Image Review	3-6 mos	3 mos	3-6 mos	6-18 mos based on complexity & patient numbers	3 mos	6-9 mos	36 mos maximum Timeline based on complexity & patient Numbers
Prospective	6-12 mos	6 mos	6 mos	3 mos from last patient data end point	6 mos	9-12 mos	Timeline based on complexity & patient numbers

These are meant to be guidelines for research proposal timelines. In developing a proposal, changes from the above should be justified based on complexity of the study, retrospective vs prospective, and case volumes for any given institution. Volumes and complexity of echo analyses will also need to be considered. *Would expect abstract development and submission immediately after data analysis. NOTE, SURVEY-BASED PROPOSAL DETAILS IN SLIDES 9 & 10.



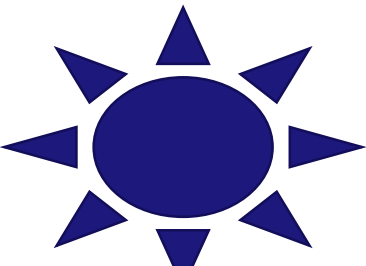
Submitting a Concept Proposal

- Concept proposals can only be submitted by a FHS Active Member who would be the Principal Investigator (PI)
- Concept proposals are to be generated using the  [CONCEPT RESEARCH PROPOSAL](#) form
- Deadline for submission to the Research Collaborative Committee (RCC) Research Chair: **2 weeks prior** to the quarterly RCC meeting
- Proposals are approved by the RCC based on scientific merit, feasibility, and study goals aligned with the mission of the FHS with a vote.
- Decision possibilities:
Move forward to full proposal - Revise concept proposal - Reject
- With RCC approval, the RCC Research Chair will seek approval from the Board of Directors
- The PI will be notified within 10 days of the FHS RCC decision
- With approval from the RCC and Board, the RCC chair will assign an RCC Advisor



Developing & Submitting a Full Proposal:

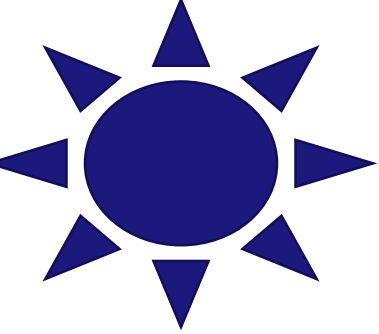
The Study Working Group

- Once a concept proposal is approved, notification of approval will be sent out to FHS Active & Affiliate Members with a request for Members seeking to be included in the Study Working Group to reach out to the PI
- Study Working Group - a group of FHS Active & Affiliate Members actively participating in a study
- Based on responses, the PI will arrange at minimum one conference call or in person meeting to discuss the proposal
 - To define who will be members of the Study Working Group
 - Determine study authors and author roles (see authorship & publication guidelines) – Complete a study  [FHS AUTHORSHIP ATTACHMENT](#) form and submit to the PC chair
 - To assist with developing the full concept proposal
 - To plan study timelines which should be included (with dates) in the proposal



Developing & Submitting a Full Proposal:

Submitting the Proposal

- To create a full research proposal
 - use the most updated  [FULL PROPOSAL](#) form
 - should not exceed 7 pages
- A full research proposal must be submitted within 6 months for retrospective and within 12 months for prospective studies from acceptance of the concept proposal
- Submission to the RCC Research Chair should be at least 14 days prior to the quarterly RCC meeting to be distributed and reviewed by the RCC members
- The full proposal will be reviewed by the RCC and decision will be by majority vote
 - *accept as is
 - *accept with minor revisions
 - *reconsider after revisions
 - *reject
- Once a proposal has been approved by the RCC, the RCC chair will notify the Board of Directors



Developing & Submitting a Full Proposal:

Submitting the Proposal

- Decisions by the RCC for full research proposal:
 - “Accept without revisions”
 - “Accept with minor revisions” - revisions should be submitted to the designated RCC Research Advisor within 30 days following which the RCC will review and accept revisions or make further recommendations
 - “Reconsider after revisions” - the PI should meet with the Study Working Group to address revisions and then resubmit through the original submission process

**Note, if the submission with revisions does not occur within 1 year, the RCC will consider the study withdrawn*



Developing & Submitting a Full Proposal: *After Approval*

- The RCC Chair will send a letter of commitment from the FHS for participation in the study
- The Publications Committee (PC) Chair will elect a PC advisor for the research

NOW THE WORK BEGINS!

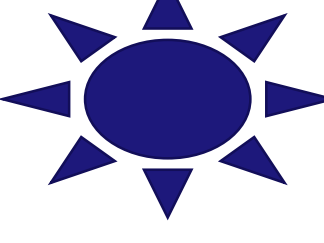


Study Implementation

- Once a study has received approval by the the RCC and the Board of Directors has been notified, the FHS will distribute the proposal to the FHS membership by email and posting on the FHS website to notify of the start of the study
- The PI and Study Working Group will be responsible for moving the study forward including Institutional Review Board approval at their sites, Data Use Agreements, database development, creating timelines for data entry and closure, and uploading of images
 - FHS will host a regular workshop night one day per month for groups to meet virtually and to update. Participation at least every 6 months, up to monthly, encouraged
- The Research (RCC) & Publications (PC) Advisors can assist with setting up and adherence to realistic timelines as outlined in the FHS guidelines

[Please see the FHS MOO for additional details](#)

Developing a Survey-Based Study

- Complete FHS  [SURVEY SUBMISSION](#) form to request distribution to the FHS membership. Send finalized form and draft of questionnaire to the FHS Research Collaborative Committee (RCC) for review and possible revisions.
Note, for surveys that are not meant to result in a publication, the workflow will differ and approval will come from the executive committee.
- Following final survey approval by the FHS RCC, the PI submits for institutional IRB approval.
- Once IRB approval is obtained, the FHS RCC should be notified and then the survey can be distributed to the FHS membership.
- The Research (RCC) & Publications (PC) Advisors will assist with setting up and adherence to realistic timelines based on expected survey responses/time for analysis.



Survey-Based Study Timeline

Study Type	RCC Survey Proposal Approval to PI site IRB Approval & Survey Distribution	Time duration from Survey Distribution to Survey Closure	Completion of Data Collection, Data Cleaning & Analysis	Manuscript Submission to Pub Committee	Total from RCC Survey Proposal Approval to Manuscript Submission
Survey-based study	4 mos	3 mos	3 mos	6-8 mos	14-16 mos