

Division of Research Updates & Demystifying Proposal Writing

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July 8, 2020

Agenda

- FM faculty Research interest updates and needs assessment
- On writing a research proposal – start with a pilot
- Next round of pilot project application timeline
- Discussion

Research Interest and Needs Assessment

Update faculty research profile

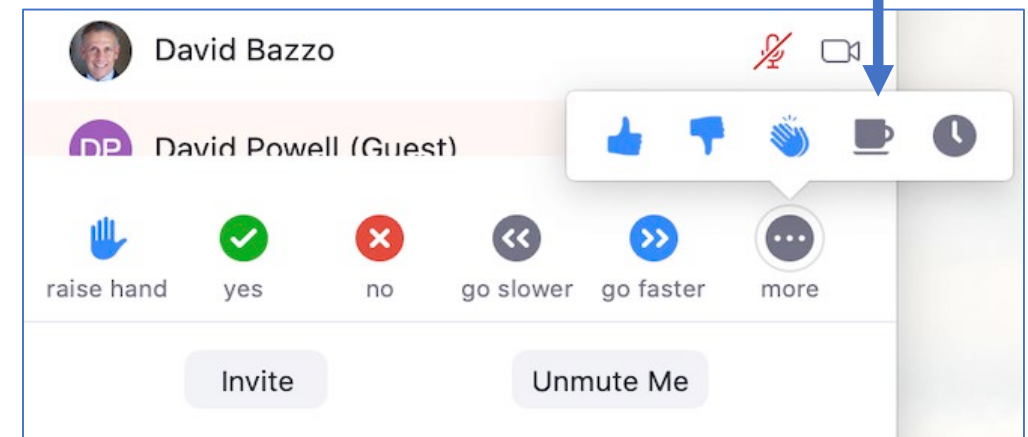
<https://medschool.ucsd.edu/som/fmph/divisions/family-medicine/research/Pages/Research-Interests.aspx>

Guide planning

https://ucsd.co1.qualtrics.com/jfe/form/SV_2uAM16gb6un4f8V



When done, show the cup under “Participants”



Writing a Research Proposal

Start with a pilot



Form Approved Through 8/31/2015 OMB No. 0925-0001

Department of Health and Human Services Public Health Services		LEAVE BLANK—FOR PHS USE ONLY	
Grant Application <i>Do not exceed character length restrictions indicated.</i>		Type	Activity
		Review Group	Number
		Council/Board (Month, Year)	Formerly
1. TITLE OF PROJECT (Do not exceed 81 characters, including spaces and punctuation.) Advance Care Planning Practices in Caring for Vulnerable Elders with MCC		Date Received	
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES (If "Yes," state number and title)			
Number: Title: HMORN-OAIC Aging Initiative Pilot Project			
3. PROGRAM DIRECTOR/...			
3a. NAME (Last, first, middle) Tai-Seale, Ming			
3c. POSITION TITLE Senior Investigator			
3e. DEPARTMENT, SERVICE			
3f. MAJOR SUBDIVISION			
3g. TELEPHONE AND FAX TEL: 650-853-4779			
4. HUMAN SUBJECTS REVIEW <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes			
4b. Federal-Wide Assurance 00000089			
5. VERTEBRATE ANIMALS			
6. DATES OF PROPOSED SUPPORT (month, day, year)			
From: 04/01/2015 To: _____			
9. APPLICANT ORGANIZATION Name: Palo Alto Medi Research, Inc Address: 795 El Camino Palo Alto, CA 94301			
12. ADMINISTRATIVE OFFICE Name: Jane A. Risser Title: Director of Adr Address: Palo Alto Medi 795 El Camino Palo Alto, CA 94301 Tel: (650) 853-4827 E-Mail: risserj@pamf.c			
14. APPLICANT ORGANIZATION (the statements herein are true, or accept the obligation to comply will is awarded as a result of this application or claims may subject)			

What a finished product looks like

• https://grants.nih.gov/grants/funding/phs398/398_forms.pdf

Abstract

**Title: Advance Ca
HMORN Co-Princ
OAIC Pepper Cer**

Patients with multi teams in various lc that the medical re documentation of j teams to honor the team which demor wide variation in t documentation wa there has been a t Foundation (PAMF) will be a collabora Independence Cer characterize ACP documentation pre explore barriers ar health care teams serious illness (e.g additional chronic frequencies and lo identified in the Et cardiology, pulmor ACP conversation the documentation practice patterns, i intervention study beyond.

Specific Aims

Increasingly patients with multiple chronic conditions (MCC) and serious illnesses are cared for by multiple healthcare teams spanning (ACP) information such as / Treatment (POLST) are eit decreasing the likelihood t understand ACP document: MCC patients. ACP, the act is a critical and underdevel operationalizes patient valu documentation in the EHR r signatures).¹ Poor systems care of patients with serious

The goal of this pilot proj barriers/facilitators to ACI Institute (PAMFRI), a memt Centers (OAIC) investigator contained in electronic heal treatments, and outcomes."

PAMF, a nonprofit multispe serve almost one million pa component of the Welcome Clinicians are sent an auton palliative care initiative was care practices in multiple lo creating a natural experime teams. PC Programs are cc and engage in outreach to i cardiology, and primary car was published in the Journe report "Dying in America."³ Palliative Care Program. He the UCSF OAIC enthusiasti early career investigator.

The pilot will accomplish tw

- To characterize current components of the PC F characteristics on ACP i Hypothesis 1a. The elders with accessb Hypothesis 1b. The documented in the v
- To identify barriers and f MCC, using in-depth int and cardiology who are

The collaborative relationship to plan R01-level proposals discussion and documentat

B. Research Plan Section 1 - Significance

Advance care planning (ACP) has bec documented divergence between patie life places serious burdens on patients, whole. ACP has the potential to anchor honor patient's preferences for future n illness they often navigate care for their various health care teams in different g in which their own values and judgments discuss and document patient preferen actionable when viewed by a range of l

This work builds on earlier studies conc inconsistent documentation of ACP in t describes current ACP practices and id influences ACP documentation in the E depth interviews to explore barriers an ACP documentation variation across s patients with multiple chronic condition: interviews will identify methods to impr ACP documentation in the EHR.

Innovation 1: using EHR data to identifi (in both directions) are identified quanti respect to ACP documentation. The pr made in the last 2 years: ACPs are har team searched EpicCare EHR to identi the IOM report "Dying in America," our 33.5% of patients with an ACP docum (such as an Advance Directive or POL) documentation was variously located ir problem list.¹ This study covered the tir staged rollout of the PC Program. The consider MCC among vulnerable elder: to offer more new insights on the impac

Innovation 2. Leveraging a natural experiment. The staged implementation team-based palliative care program at l since 2011 represents a natural experit giving us the opportunity to determine i what aspects of the Program has made impact on ACP documentation at PAMF addition, the EHR data will be analyzec identify providers with high and low rat ACP documentation. The research tea then target these divergent groups for interview sampling. The in-depth interv will explore practices surrounding ACP discussion and documentation. Intervie also identify other possible contributors ACP documentation in the EHR, such a physician health care team members v

may update or enter medical record information

3. Shovel-Ready pilot w scientists have been st. PAMF colleagues in the product of their on-going paper published in *Med* interview guide similar t in this proposal has air Once approved for fund proposed here. IRB revi immediately. The advan collaboration between tl communicated effective strengths of Drs. Tai-Se great promise for a pro

Section 2 - Overview :
2.1 **Setting.** PAMF is a approximately 1 million 2010. In 2013 it served The palliative care team have completed POLST

One of the primary obje Advance Care Planning National Consensus Pr regular patient and fami ACP and goals of care, healthcare and commur

The PC Program at PAMF complies with most of the NCP guidelines.⁷ (<http://www.pamf.org/palliativecare/>) We anticipate that it contributes to advancing ACP in each of the above-mentioned ways and may impact practices beyond the palliative care department itself. The PC Program at PAMF has dissemina standardization in Octob was added to the defau

Furthermore, PAMF phy each of PAMF's four div other locations. The co-

Section 3 - Research De 3.1 Conceptual model: f conceptual model for the addition to having a direct documentation, the PC Pi hypothesized to affect the patients and non-PC prov also influence clinical dec documentation of ACP. O recognizes that the proce by patients, providers, an potential facilitators and " barriers.

3.2 Aim 1: To characteri documentation practice sequential impact of se of the PC Program, MCC ACP documentation
3.2.1. **Study Design:** The experimental design. We from the years 2005 to 20 following its launch). The hypotheses are:

H1. The staged imple ACP documentati

H2. The number, t the vulnerable

Inclusion criteria: Patie conditions (identified v these patients are MC life care measurement serving these vulnera

Dependent variables: dependent variables: i both (Y3_{it}) for patient and Y2_{it} will be measu appears in the proble accessible. If it appear is in scanned docume actionable. Y3_{it} is 1 if i in Table 2). We will m illustrated in Table 2.

Explanatory variables: MCC profile, i.e., numl health insurance, inco to the co-located PC p distribution of patient ; installed, two binary v SmartSets, and a line: where the patient rece healthcare teams will i

Empirical analyses: A

Coefficients (λ and ϕ reveal the impact of c The effects of the PC I future intervention stu descriptive analysis fo (in both directions) for

3.2.2 Anticipated findir practices, and the pos impact of each compo

3.3. Aim 2: To identifi including the role of 3.3.1 Study Design: Tl to ACP documentation documentation. The in and what enables sor documentation. While teams perceive ACP.⁸ none that use our pro

Recruitment: Healthca of ACP doc

oncology, cardiology, pulm providers within departmen the EHR. We will sample 2 Interviews will be evenly di

The first wave of recruitmei physicians' ACP document documentation status relati other health care team me EHR, and if so these other social workers, medical as: meetings to explain the go: EHR analysis by email and at a time and location conv

Interviews will be conducte research assistant at PAMF transcribed verbatim. Inten for their participation.

Interview Topics: An interv our ongoing research on p: ACP, (2) Clinical experienc Barriers/Facilitators for ACI

Analysis: We will employ st all text will be imported int and a research assistant) v coding, guided by the tenel review the transcripts for er and analysis will begin with and interview questions in data is being analyzed to r then be applied to the entir categories. In this framewo language. Targeted coding research aim, and which w depth qualitative informatio apply established processe organizing themes, to even

Sample size: As stressed i saturation.¹⁵ Although the theoretical saturation, one research question. The sar processes reported or obsa approach saturation. Given locations, but sampling pos practices.

3.3.2 Anticipated findings: may reveal why practices v or health care teams. Inten data. For example, some p them in the EHR or they m

reveal the problems physicians face with respect to ACP and possible solutions or resources to mitigate these problems. This needs assessment element of the interviews is an important step in improving the ACP capabilities of the healthcare organization.

3.4. Strengths and Limitations

Strengths: In response to the HMORN AGING Research Network's call for pilot proposals, we propose a shovel-ready pilot to not only address important research questions on advance care planning, but also to build a meaningful scientific collaboration relationship between PAMFRI and UCSF OAIC scientific investigators. This effort holds promise for future R01-level intervention to remove the barriers and strengthen the facilitators to advance care planning identified in this study. The limitations include, first, the potential omission of information in the EHR that ACP was discussed but patient did not wish or was not able to name a surrogate decision maker or provide documentation. Second, while being able to identify the healthcare team member who documented the ACP in the EHR is a valuable contribution, we cannot rule out the possibility that the discussion was done by a different provider. In the future, we will use Natural Language Processing techniques to identify the healthcare team member(s) who initiated and carried out the ACP discussion prior to its documentation. By expanding the responsibility to the healthcare team, however, rather than individual clinicians, we recognize the importance of teamwork in providing patient-centered care for vulnerable elders with MCC. Lastly, it is necessary to limit the scope of the study. Future efforts built upon this pilot will examine the total use of services and costs.

3.5 Conclusion

The proposed pilot is responsive to the Call for Proposal because, (1) it is highly relevant to older adults with MCCs as understanding and documenting patient wishes are prerequisites to honoring them in their care. While it is a basic component of palliative care specialists' work, its diffusion into non-palliative care specialists is essential as there are not and will not be enough PC specialists to meet the growing demand as the number of vulnerable elders with MCCs continues to rise. (2) The proposed pilot combines the expertise of researchers and clinicians in two outstanding research institutions to build a meaningful collaborative relationship and to answer important research questions. (3) The EHR data have already been extracted (a non-trivial accomplishment), under IRB approval. We have also developed the key informant interview questions. It is highly likely that the proposed study will be completed within one year. (4) The investigators have a track record in publishing research in high-impact scientific journals. A previous paper on this subject produced by PAMFRI researchers has been referenced heavily in the recent IOM Report *Dying in America*. (5) This work will prepare us well for a large-scale R01 study in the near future. (6) Dr. Ellis Dillon is an early career investigator. She was Dr. Tai-Seale's postdoctoral fellow before being promoted to her current position as an Assistant Medical Sociologist. Dr. Christine Ritchie will also mentor Dr. Dillon, who will lead the work on Aim 2 and manage the project.

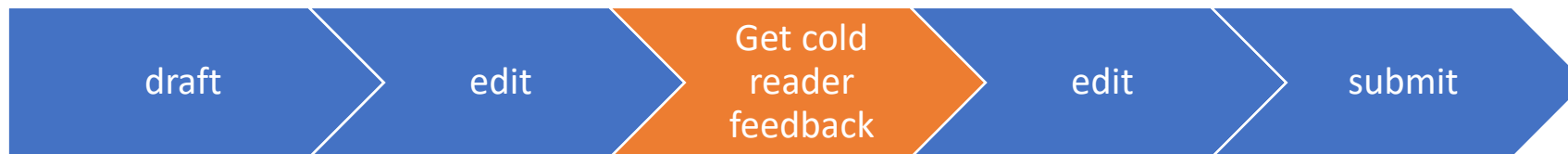
Section 4 – Timeline of Main Tasks

The EHR analysis for the parent project is already underway, with IRB approval. As soon as funding is secured, we will request IRB approval to amend the protocol to include additional key informant interviews.

	Q1	Q2	Q3	Q4
Amend IRB protocol				
Analyze EHR data				
Identify healthcare team outliers (in both directions) in ACP documentation				
Interview key informant				
Analyze interview data				
Write papers/presenting work				
Prepare R01 proposal				

Parts of an Application

- Abstract/summary – 30 lines
 - Research plan
 - Specific aims – 1 page
 - Significance
 - Innovation
 - Approach - how it will be conducted.
- } 6 pages



Specific Aims

1. Start with an overview:

- a) State the goal of your project
- b) State your hypothesis
- c) Summarize the rationale and significance of your project

2. List specific aims:

- a) Each one should be specific and focused.
- b) Each one should test the hypothesis.
- c) As a whole they should synergize (but not be co-dependent on one another)

3. End with important information your project will uncover:

- 1-3 sentences

Example

The pilot will accomplish two **specific aims**:

1. To characterize current ACP documentation practices and evaluate the sequential impact of several components of the Palliative Care Program, multiple chronic conditions (MCC), and other patient and care team characteristics on ACP documentation.

Hypothesis 1a. The staged implementation of the Palliative Care Program increases the percentages of vulnerable elders with accessible and actionable ACP documentations over time.

Hypothesis 1b. The number, type, and severity of MCC are associated with the likelihood that ACP is documented in the vulnerable elders' EHR.

2. To identify barriers and facilitators of ACP conversations and ACP documentation, including the role of MCC, using in-depth interviews with healthcare team members in primary care, oncology, pulmonology, and cardiology who are outliers (in both directions) with respect to ACP documentation.

Research Plan - Significance

1. Summarize the pivotal work before yours.
 - a) Strive for balance and completeness
 - b) Include any controversies and discrepancies your project will address
2. State the key scientific questions that remain and why they need to be answered.
3. Summarize what you propose to do to answer one of these questions or fill an important gap in our understanding.
4. Explain how the research will improve scientific knowledge, technical capability, clinical practice, or health services.

Research Plan - Innovation

1. Explain how your project is innovative and will add significantly to existing knowledge.
2. Don't assume that your reviewers will understand why your project is innovative.

Research Plan - Approach

For each specific aim, describe:

- a. methods (with an explanation for why you chose them)
- b. preliminary data (if available, not required)
- c. a description of any samples (including size, inclusion/exclusion criteria, sampling approach, and proof you have access to them)
- d. measures (and any conceptual frameworks for them)
- e. data collection process (including a description of collection procedures and validation methods)
- f. data management plan (including procedures for data entry, auditing, security and quality control)
- g. data analysis plan (including descriptions of approach, software used, validation methods, and theoretical underpinnings);
- h. study limitations (including potential sources and consequences of bias and strategies to minimize bias; also any confounding variables and strategies for addressing them);
- i. expected results and their interpretation;
- j. strategies for addressing potential problems.

The Budget

- Maximum: \$30,000/year for 1 year
- Match the scope/size of the project
 - Beware of promising to do a 5-year project with the budget of a 1-year project
- Preferred priority:
 - Release time for PI's scholarly activity
 - 10% time



What do reviewers look for

- Overall Impact
- Scored Review Criteria
 - Significance
 - Investigator(s)
 - Innovation
 - Approach
 - Environment

Impact	Score	Descriptor	Strengths/Weaknesses
High Impact	1	Exceptional	
	2	Outstanding	
	3	Excellent	
Moderate Impact	4	Very Good	
	5	Good	
	6	Satisfactory	
Low Impact	7	Fair	
	8	Marginal	
	9	Poor	

Score	Descriptor	Additional Guidance on Strengths/Weaknesses
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

Contents of the proposal

- Face Page (NIH Format- [template](#))
- Abstract/Project Summary (up to 30 lines)
- Specific Aims (One Page)
- Research Plan (Six-Page maximum; Does not include References or Human Subjects)
- Human Subjects Section (If applicable)
- Biosketches for Key Personnel ([NIH format](#))
- Detailed Budget Page**
- Facilities & Administrative/Indirect Costs Checklist ([template](#))
- Budget Justification

****Note:** Budget of up to \$30,000 for the pilot project should be used mainly for salary release for the PI to conduct the pilot research project

- [https://medschool.ucsd.edu/som/fmph/divisions/family-medicine/research/Pages/Division-of-Family-Medicine-\(DFM\)-Pilot-Project.aspx](https://medschool.ucsd.edu/som/fmph/divisions/family-medicine/research/Pages/Division-of-Family-Medicine-(DFM)-Pilot-Project.aspx)

A few Fillable pdf forms

What	Where	By Whom
Form Page 1: Face Page	https://grants.nih.gov/grants/funding/phs398/fp1.pdf	Staff (Maddy/Daisy)
Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, ...	https://grants.nih.gov/grants/funding/phs398/fp2.pdf	Staff (Maddy/Daisy)
Form Page 3: Research Grant Table of Contents	https://grants.nih.gov/grants/funding/phs398/fp3.pdf	Staff (Maddy/Daisy)
Form Page 4: Detailed Budget for Initial Budget Period	https://grants.nih.gov/grants/funding/phs398/fp4.pdf	Fund manager
Continuation Format Page	https://grants.nih.gov/grants/funding/phs398/continuation.pdf	PI & research team



Next round of pilot application timeline

	Key dates (Tentative)
Letter of Intent due	Sept 1, 2020
Invitation for full proposal sent	Oct 1, 2020
Full proposal due	Dec 1, 2020

[https://medschool.ucsd.edu/som/fmph/divisions/family-medicine/research/Pages/Division-of-Family-Medicine-\(DFM\)-Pilot-Project.aspx](https://medschool.ucsd.edu/som/fmph/divisions/family-medicine/research/Pages/Division-of-Family-Medicine-(DFM)-Pilot-Project.aspx)

Additional resources

- <https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm#What%20Peer%20Reviewers%20Look%20For>
- <https://medschool.ucsd.edu/som/fmph/divisions/family-medicine/research/Pages/DFM-Monthly-Research-Meetings.aspx>