PALLIATIVE CARE
RESEARCH COOPERATIVE

Collaborating with the PCRC

- Scientific Review of a proposed project
  - Letter of Support as a member
- PCRC Collaboration with an upcoming grant

Need help with multi-site research?

The PCRC was established in large part to help overcome the many challenges of multi-site research because we know this research matters, and is necessary to advance the field of palliative care.

STEPS OF THE PROCESS:

- submit a Letter of Intent (LOI) to the PCRC Scientific Review Committee (SRC).
- Approval of the LOI at the PCRC Steering Committee
- Budget Development (after LOI approval)

SUMMARY / Overview

LOI

LOI Approval

Budget Development

Grant Submission

Grant Award

Site Selection

Study Conduction

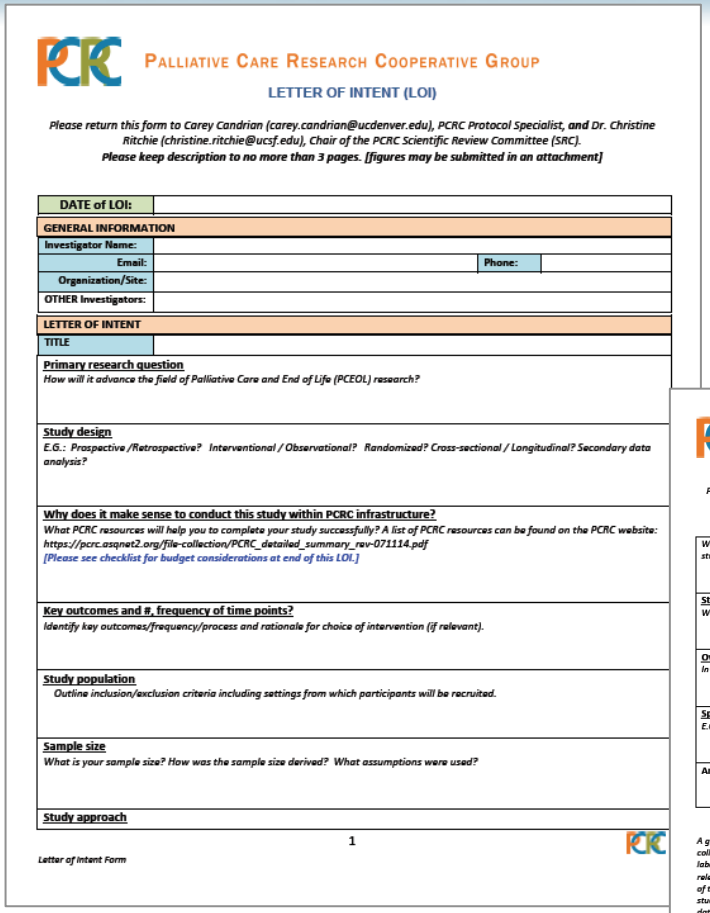
Need help with multi-site research?

FIRST STEP: submit a LOI to the SRC

- For the PCRC, the LOI means you have a study idea that you think would align well with the PCRC, benefit from multi-site infrastructure, and are planning to submit a grant.
- Submission of the LOI is a pivotal step for the PCRC because it gives the SRC a comprehensive understanding of your study in order to evaluate the science, and enough information to allow the Steering Committee to evaluate the study in light of the strategic goals of the PCRC.
- Approval of the LOI at the Steering Committee level ultimately influences whether the PCRC is able to provide a letter of support stating that it has the necessary infrastructure to successfully implement your study and start budget development (if requested)

Process starts with the PCRC LOI…

- Provide details of the project for SRC to evaluate the science, and enough information to allow the Steering Committee to evaluate the study in light of the strategic goals of the PCRC.



PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

LETTER OF INTENT (LOI)

Please return this form to Carey Candrian (carey.candrian@ucdenver.edu), PCRC Protocol Specialist, and Dr. Christine Ritchie (christine.ritchie@ucsf.edu), Chair of the PCRC Scientific Review Committee (SRC).
Please keep description to no more than 3 pages. [figures may be submitted in an attachment]

DATE of LOI:			
GENERAL INFORMATION			
Investigator Name:			
Email:		**Phone:**	
Organization/Site:			
OTHER Investigators:			
LETTER OF INTENT			
TITLE			

Primary research question
How will it advance the field of Palliative Care and End of Life (PCEOL) research?

Study design
E.G.: Prospective /Retrospective? Interventional / Observational? Randomized? Cross-sectional / Longitudinal? Secondary data analysis?

Why does it make sense to conduct this study within PCRC infrastructure?
What PCRC resources will help you to complete your study successfully? A list of PCRC resources can be found on the PCRC website: https://pcrc.asqnet2.org/file-collection/PCRC_detailed_summary_rev-071114.pdf
[Please see checklist for budget considerations at end of this LOI.]

Key outcomes and #, frequency of time points?
Identify key outcomes/frequency/process and rationale for choice of intervention (if relevant).

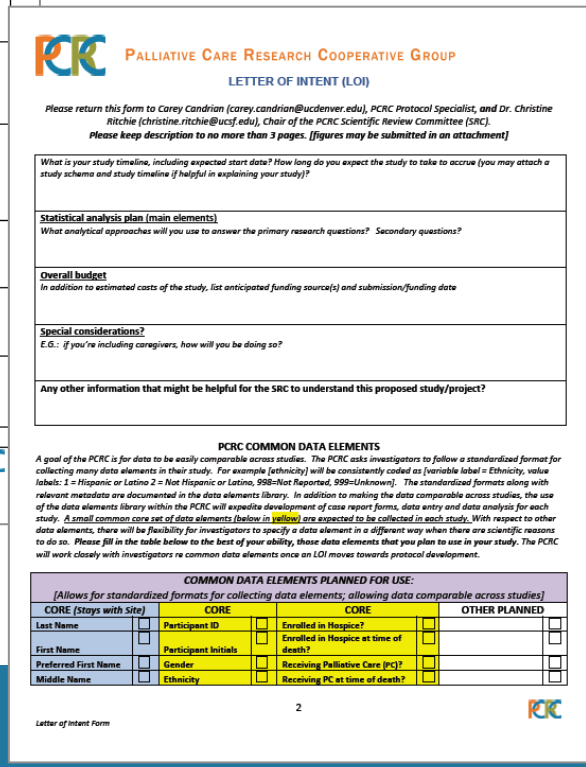
Study population
Outline inclusion/exclusion criteria including settings from which participants will be recruited.

Sample size
What is your sample size? How was the sample size derived? What assumptions were used?

Study approach

1

Letter of Intent Form



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What is your study timeline, including expected start date? How long do you expect the study to take to accrue (you may attach a study schema and study timeline if helpful in explaining your study)?

Statistical analysis plan (main elements)
What analytical approaches will you use to answer the primary research questions? Secondary questions?

Overall budget
In addition to estimated costs of the study, list anticipated funding source(s) and submission/funding date

Special considerations?
E.G.: if you're including caregivers, how will you be doing so?

Any other information that might be helpful for the SRC to understand this proposed study/project?

PCRC COMMON DATA ELEMENTS

A goal of the PCRC is for data to be easily comparable across studies. The PCRC asks investigators to follow a standardized format for collecting many data elements in their study. For example [ethnicity] will be consistently coded as [variable label = Ethnicity, value labels: 1 = Hispanic or Latino 2 = Not Hispanic or Latino, 998=Not Reported, 999=Unknown]. The standardized formats along with relevant metadata are documented in the data elements library. In addition to making the data comparable across studies, the use of the data elements library within the PCRC will expedite development of case report forms, data entry and data analysis for each study. A small common core set of data elements (below in yellow) are expected to be collected in each study. With respect to other data elements, there will be flexibility for investigators to specify a data element in a different way when there are scientific reasons to do so. Please fill in the table below to the best of your ability, those data elements that you plan to use in your study. The PCRC will work closely with investigators re common data elements once an LOI moves towards protocol development.

COMMON DATA ELEMENTS PLANNED FOR USE:
[Allows for standardized formats for collecting data elements; allowing data comparable across studies]

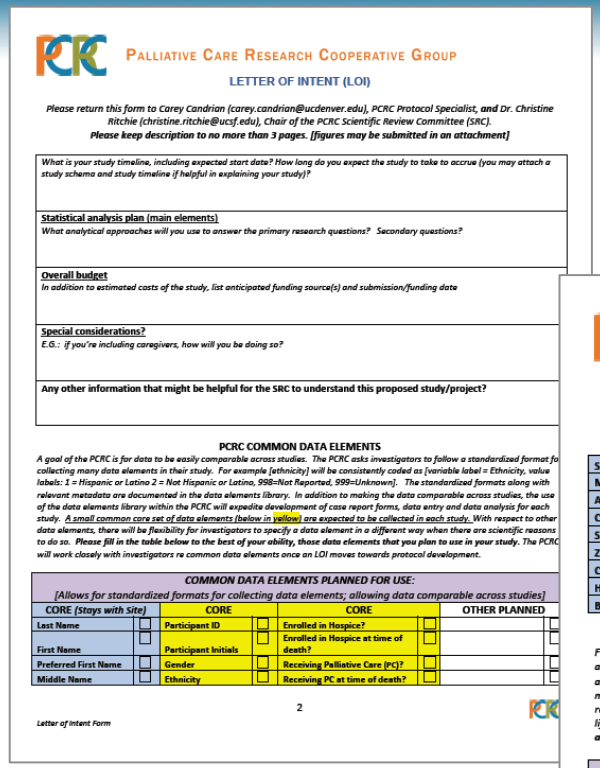
CORE *(Stays with Site)*		CORE		CORE		OTHER PLANNED	
Last Name	☐	Participant ID	☐	Enrolled in Hospice?	☐		☐
First Name	☐	Participant Initials	☐	Enrolled in Hospice at time of death?	☐		☐
Preferred First Name	☐	Gender	☐	Receiving Palliative Care (PC)?	☐		☐
Middle Name	☐	Ethnicity	☐	Receiving PC at time of death?	☐		☐

2

Letter of Intent Form

Process starts with the PCRC LOI…

- Specify the measures and instruments [e.g.: PROs] you plan to use in your proposed study



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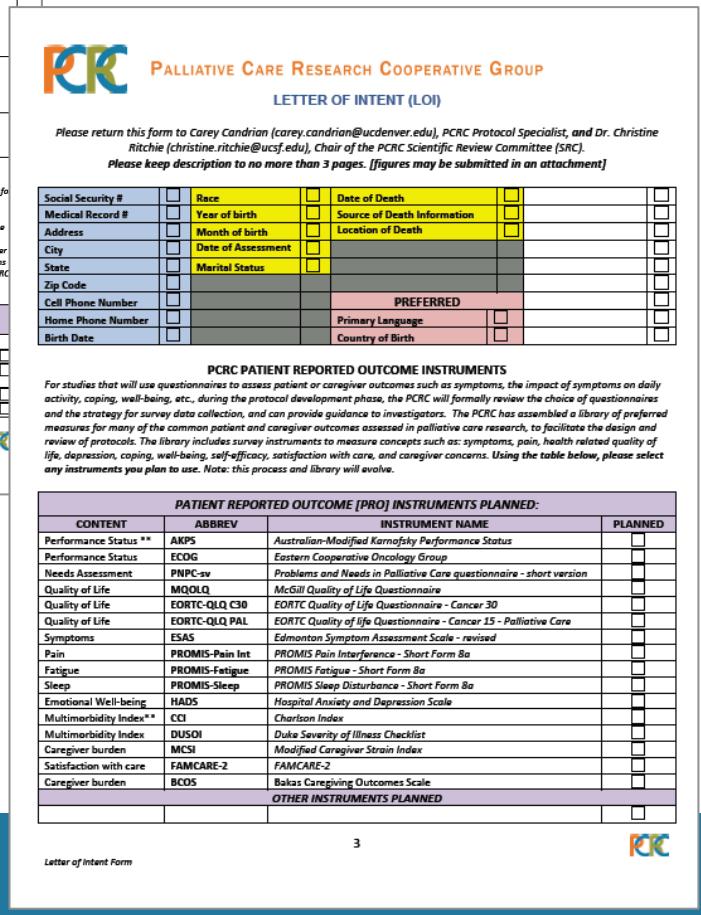
2

Letter of Intent Form



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Social Security #	☐	Race	☐	Date of Death	☐		☐
Medical Record #	☐	Year of birth	☐	Source of Death Information	☐		☐
Address	☐	Month of birth	☐	Location of Death	☐		☐
City	☐	Date of Assessment	☐				☐
State	☐	Marital Status	☐				☐
Zip Code	☐						☐
Cell Phone Number	☐			PREFERRED			☐
Home Phone Number	☐			Primary Language	☐		☐
Birth Date	☐			Country of Birth	☐		☐

PCRC PATIENT REPORTED OUTCOME INSTRUMENTS

*For studies that will use questionnaires to assess patient or caregiver outcomes such as symptoms, the impact of symptoms on daily activity, coping, well-being, etc., during the protocol development phase, the PCRC will formally review the choice of questionnaires and the strategy for survey data collection, and can provide guidance to investigators. The PCRC has assembled a library of preferred measures for many of the common patient and caregiver outcomes assessed in palliative care research, to facilitate the design and review of protocols. The library includes survey instruments to measure concepts such as: symptoms, pain, health related quality of life, depression, coping, well-being, self-efficacy, satisfaction with care, and caregiver concerns. **Using the table below, please select any instruments you plan to use.** Note: this process and library will evolve.*

PATIENT REPORTED OUTCOME [PRO] INSTRUMENTS PLANNED:

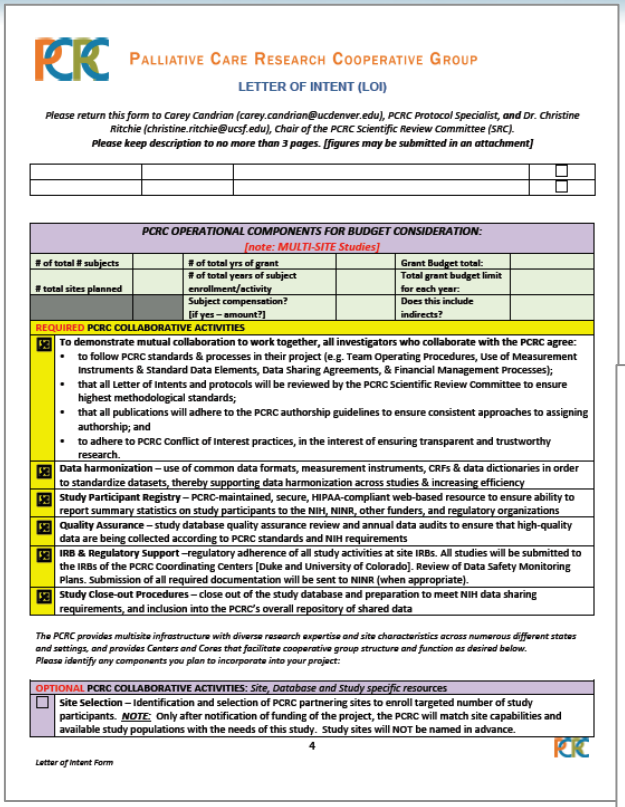
CONTENT	ABBREV	INSTRUMENT NAME	PLANNED
Performance Status **	AKPS	*Australian-Modified Karnofsky Performance Status*	☐
Performance Status	ECOG	*Eastern Cooperative Oncology Group*	☐
Needs Assessment	PNPC-sv	*Problems and Needs in Palliative Care questionnaire - short version*	☐
Quality of Life	MQOLQ	*McGill Quality of Life Questionnaire*	☐
Quality of Life	EORTC-QLQ C30	*EORTC Quality of Life Questionnaire - Cancer 30*	☐
Quality of Life	EORTC-QLQ PAL	*EORTC Quality of life Questionnaire - Cancer 15 - Palliative Care*	☐
Symptoms	ESAS	*Edmonton Symptom Assessment Scale - revised*	☐
Pain	PROMIS-Pain Int	*PROMIS Pain Interference - Short Form 8a*	☐
Fatigue	PROMIS-Fatigue	*PROMIS Fatigue - Short Form 8a*	☐
Sleep	PROMIS-Sleep	*PROMIS Sleep Disturbance - Short Form 8a*	☐
Emotional Well-being	HADS	*Hospital Anxiety and Depression Scale*	☐
Multimorbidity Index**	CCI	*Charlson Index*	☐
Multimorbidity Index	DUSOI	*Duke Severity of Illness Checklist*	☐
Caregiver burden	MCSI	*Modified Caregiver Strain Index*	☐
Satisfaction with care	FAMCARE-2	*FAMCARE-2*	☐
Caregiver burden	BCOS	Bakas Caregiving Outcomes Scale	☐
		OTHER INSTRUMENTS PLANNED	
			☐

3

Letter of Intent Form

Process starts with the PCRC LOI…

- Describe collaborations requested which will align with future budget development
- Describe the study details that will effect budget *[e.g.: # sites, # subjects,* ***study schema****, etc.]*



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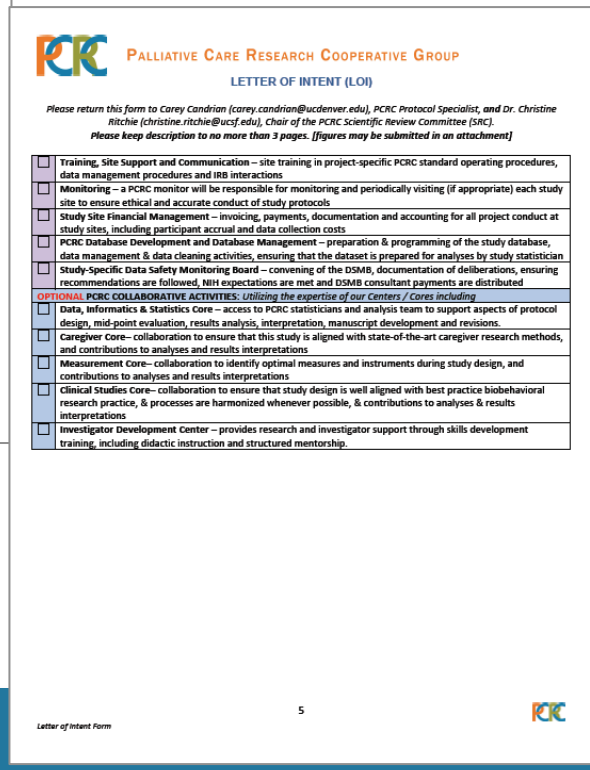
			☐
			☐

PCRC OPERATIONAL COMPONENTS FOR BUDGET CONSIDERATION: *[note: MULTI-SITE Studies]*					
# of total # subjects		# of total yrs of grant		Grant Budget total:	
# total sites planned		# of total years of subject enrollment/activity		Total grant budget limit for each year:	
		Subject compensation? [if yes – amount?]		Does this include indirects?	

REQUIRED PCRC COLLABORATIVE ACTIVITIES	
☒	**To demonstrate mutual collaboration to work together, all investigators who collaborate with the PCRC agree:** • to follow PCRC standards & processes in their project (e.g. Team Operating Procedures, Use of Measurement Instruments & Standard Data Elements, Data Sharing Agreements, & Financial Management Processes); • that all Letter of Intents and protocols will be reviewed by the PCRC Scientific Review Committee to ensure highest methodological standards; • that all publications will adhere to the PCRC authorship guidelines to ensure consistent approaches to assigning authorship; and • to adhere to PCRC Conflict of Interest practices, in the interest of ensuring transparent and trustworthy research.
☒	**Data harmonization** – use of common data formats, measurement instruments, CRFs & data dictionaries in order to standardize datasets, thereby supporting data harmonization across studies & increasing efficiency
☒	**Study Participant Registry** – PCRC-maintained, secure, HIPAA-compliant web-based resource to ensure ability to report summary statistics on study participants to the NIH, NINR, other funders, and regulatory organizations
☒	**Quality Assurance** – study database quality assurance review and annual data audits to ensure that high-quality data are being collected according to PCRC standards and NIH requirements
☒	**IRB & Regulatory Support** –regulatory adherence of all study activities at site IRBs. All studies will be submitted to the IRBs of the PCRC Coordinating Centers [Duke and University of Colorado]. Review of Data Safety Monitoring Plans. Submission of all required documentation will be sent to NINR (when appropriate).
☒	**Study Close-out Procedures** – close out of the study database and preparation to meet NIH data sharing requirements, and inclusion into the PCRC's overall repository of shared data

The PCRC provides multisite infrastructure with diverse research expertise and site characteristics across numerous different states and settings, and provides Centers and Cores that facilitate cooperative group structure and function as desired below. Please identify any components you plan to incorporate into your project:

OPTIONAL PCRC COLLABORATIVE ACTIVITIES: *Site, Database and Study specific resources*	
☐	**Site Selection** – identification and selection of PCRC partnering sites to enroll targeted number of study participants. ***NOTE:*** Only after notification of funding of the project, the PCRC will match site capabilities and available study populations with the needs of this study. Study sites will NOT be named in advance.



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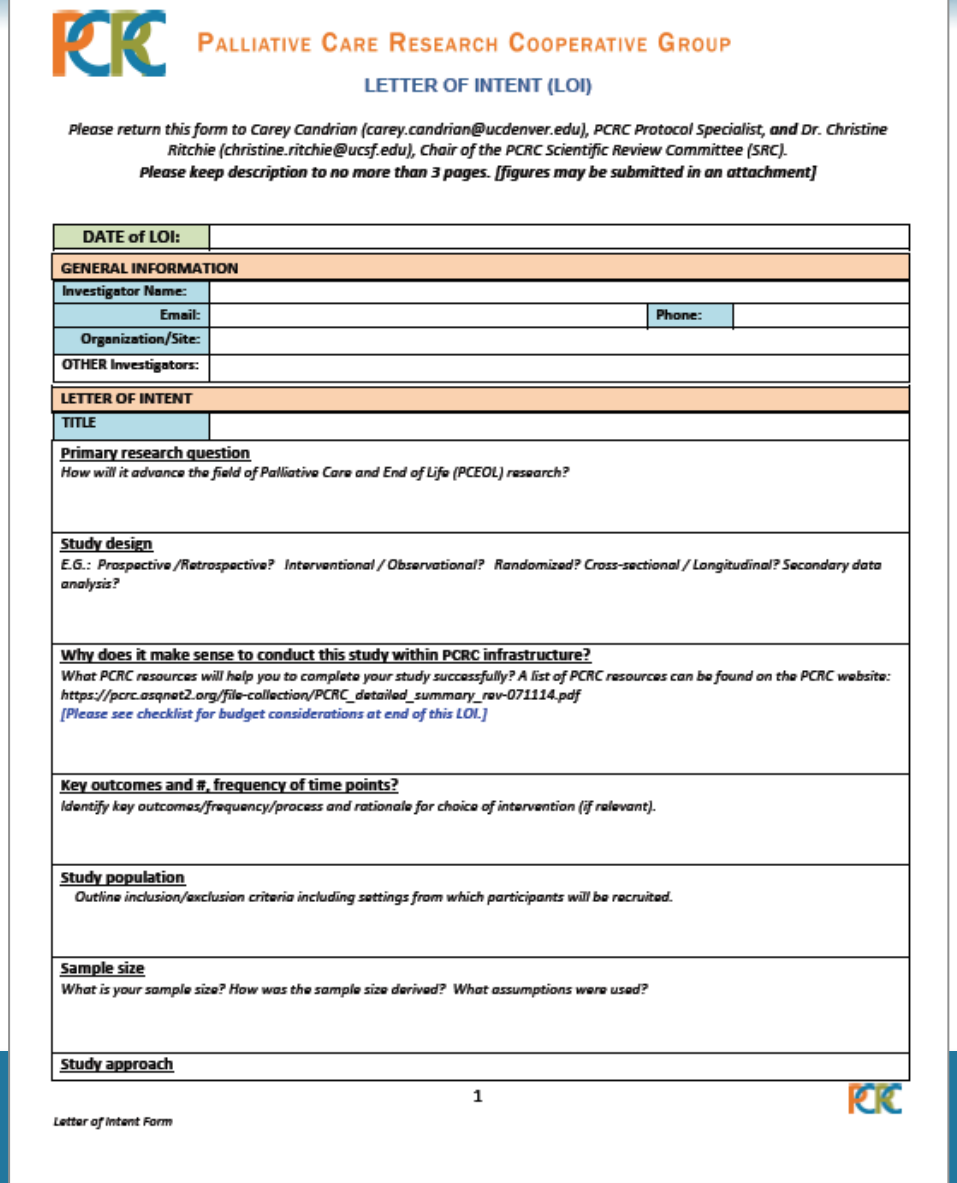
☐	**Training, Site Support and Communication** – site training in project-specific PCRC standard operating procedures, data management procedures and IRB interactions
☐	**Monitoring** – a PCRC monitor will be responsible for monitoring and periodically visiting (if appropriate) each study site to ensure ethical and accurate conduct of study protocols
☐	**Study Site Financial Management** – invoicing, payments, documentation and accounting for all project conduct at study sites, including participant accrual and data collection costs
☐	**PCRC Database Development and Database Management** – preparation & programming of the study database, data management & data cleaning activities, ensuring that the dataset is prepared for analyses by study statistician
☐	**Study-Specific Data Safety Monitoring Board** – convening of the DSMB, documentation of deliberations, ensuring recommendations are followed, NIH expectations are met and DSMB consultant payments are distributed
OPTIONAL **PCRC COLLABORATIVE ACTIVITIES**: *Utilizing the expertise of our Centers / Cores including*	
☐	**Data, Informatics & Statistics Core** – access to PCRC statisticians and analysis team to support aspects of protocol design, mid-point evaluation, results analysis, interpretation, manuscript development and revisions.
☐	**Caregiver Core**– collaboration to ensure that this study is aligned with state-of-the-art caregiver research methods, and contributions to analyses and results interpretations
☐	**Measurement Core**– collaboration to identify optimal measures and instruments during study design, and contributions to analyses and results interpretations
☐	**Clinical Studies Core**– collaboration to ensure that study design is well aligned with best practice biobehavioral research practice, & processes are harmonized whenever possible, & contributions to analyses & results interpretations
☐	**Investigator Development Center** – provides research and investigator support through skills development training, including didactic instruction and structured mentorship.

Process starts with the PCRC LOI…

- LOI Form located on the PCRC website,
- Tab "Studies"
- Section "Guideline for new investigators"
- Complete and send to: carey.candrian@ucdenver.edu (PCRC Protocol Specialist)



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Email:		**Phone:**	
Organization/Site:			
OTHER Investigators:			
LETTER OF INTENT			
TITLE			

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Study design
E.G.: Prospective /Retrospective? Interventional / Observational? Randomized? Cross-sectional / Longitudinal? Secondary data analysis?

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Key outcomes and #, frequency of time points?
Identify key outcomes/frequency/process and rationale for choice of intervention (if relevant).

Study population
Outline inclusion/exclusion criteria including settings from which participants will be recruited.

Sample size
What is your sample size? How was the sample size derived? What assumptions were used?

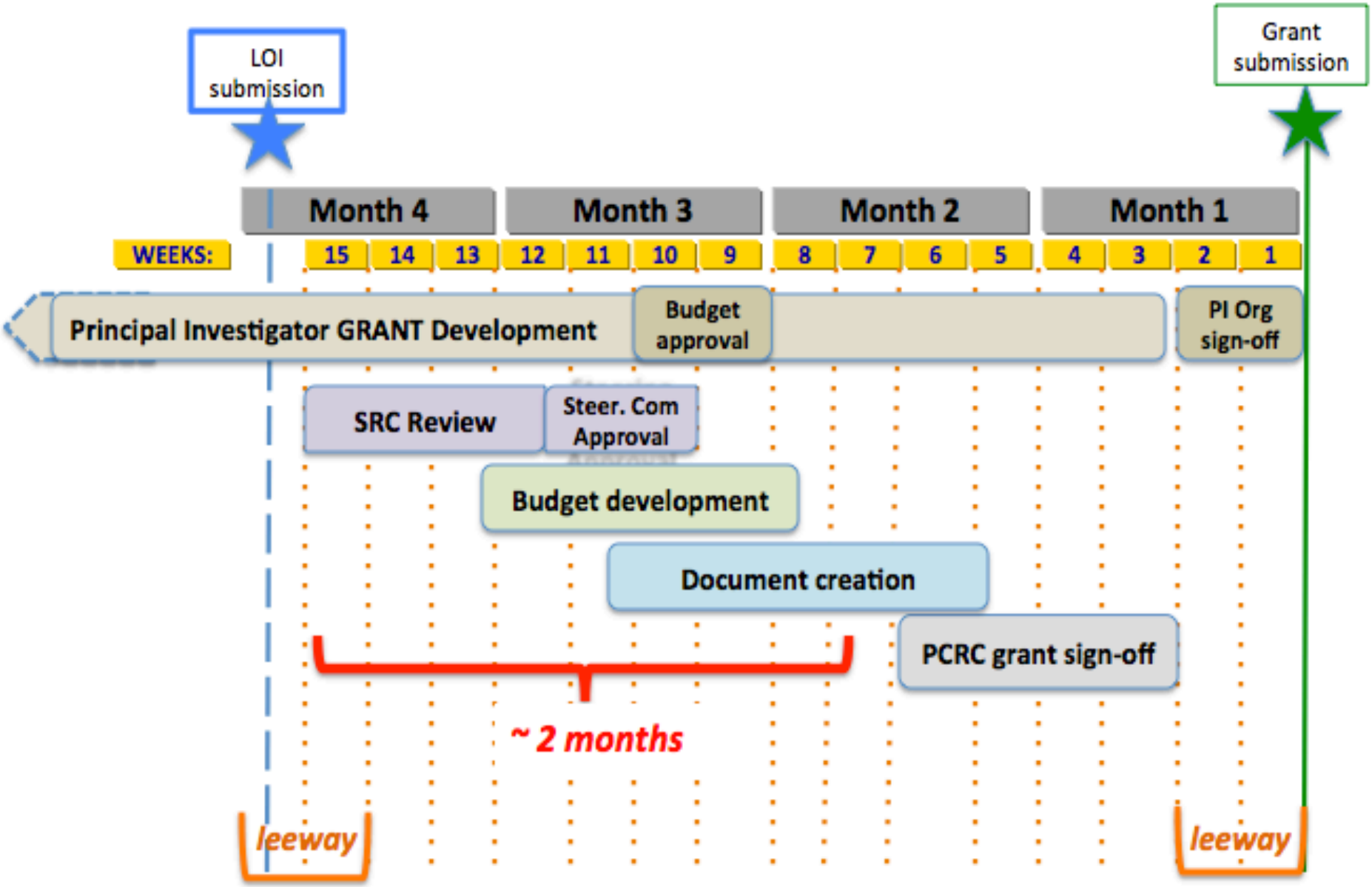
Study approach

Budget Development

AFTER LOI is approved, the PCRC will work with you on budgeting.

- Once budget is approved, the PCRC will provide based upon your LOI and collaboration request all the necessary documents (described on later slides)
- It can take a significant amount of time to route grants through universities, as such it is a VERY good idea to give yourself ample time for the entire process of sub-contracting with the PCRC, which again starts with the LOI. [Ideal time is ~15 weeks]

Process / Timeline



Relationships Between Grant PI and PCRC

GRANT: PI ORGANIZATION

- **Research Plan**
- **PI Activities / staff**
- **Key personnel**

Possible other sub-contracts

SUB-CONTRACT: PCRC

{Grant Specific} Data / Informatics / Site Finance / Cores [e.g.: CG, Measurement, Clin. Studies, Stats]

Sub-contracts to Multi-Sites
[TBD locations]

Grant PI *Responsibilities*

- *Annual non-competing renewals*
- *Sub-contract invoices*
- *Rebudgeting (if any)*
- *Publications (My NCBI policy)*
- *ClinTrials.gov registration*

ADDITIONAL VALUE:

PCRC Activities funded by U24 mechanism

- *Scientific Review & Guidance*
- *Consultative expertise (Clinical Trials, Behavioral Science, Measurement & Statistics)*
- *Grant review & feedback*
- *Investigator Development*
- *Mentoring*
- *Networking Opportunities*
  - *Research Experts*
  - *PCRC Investigators*
- *Grant opportunities / Vouchers*

NOTE: Final Sites are NOT selected until grant award

Documents provided for grant submission

- PCRC scientific resources / facilities general overview
- More specific details on the targeted resources / facilities within our PCRC community [focused for your project]
  - More specific details on the targeted-like SITES if using PCRC locations [focused for your project]
- Biosketches of PCRC Co-Chairs
- Letter of Support signed by the PCRC Executive Committee outlining your detailed planned PCRC involvement.
- Signed grant packages for the PCRC sub-contract from Duke Office of Grants Management *[home site for the PCRC grant]*

NOTE: Final Sites are NOT selected until grant award

Documents provided (cont)

- Budget to include the following ***required / mandatory elements***: **
  - Data Harmonization
    - PI to approve created data dictionary of CDEs
  - Subject Registry
  - Dataset Quality Assurance
  - Dataset Study Closeout and data transfer

- Budget justification for all of the above

** whether or not PCRC sites are involved

NOTE: Final Sites are NOT selected until grant award

Documents provided (cont)

- Budget to include the following ***if requested***:
  - Site Payment budget on a per ”subject” or a “per dyad” model
    - Includes start up fees, study conduct, patient remuneration, etc.]
    - **Please note, this is the “bulk” of the budget**
  - Database / data management development
  - Small administrative fee (if PCRC multi-site study)
    - Site selection *(with PI approval)*
    - Site finance / grant management (contracts, invoicing, payments, etc.)
    - Site management (site training, support, communications, enrollment tracking, etc.)

NOTE: Final Sites are NOT selected until grant award

Documents provided (cont)

- Budget to include the following ***if requested (cont)***:
  - Core consulting effort (study specific)
    - Statistics
    - Caregiver
    - Measurement
    - Clinical Studies
    - Statistical Support
  - DSMB set up / management
  - Site Monitoring
  - Site Auditing (separate independent group)
- Budget justification for all of the above

Site Selection

NOTE: **Site selection is performed AFTER grant award in order to…..**

- Match studies with sites to optimize accrual
- Number of sites always growing, so the match might improve over time
- Since we don't know which studies / grants are going to get funded when, allows us to balance the number of studies at any particular site (and reduce the chance that a single site gets overwhelmed
- This enhances prioritization of your study at a site

Exception: Study PI's site

PCRC Standards

Adherence to PCRC standards is critical for high quality data that is comparable across studies.

In order to achieve this, as an Investigator working with the PCRC, is expected that you will incorporate the following ** into your project:

- Common Data Elements
- Use of Questionnaires to assess outcomes
- Study Participant registration
- Data Sharing
- Standard Operating Procedures
- Data Audit

*** See details on next few slides*

PCRC Standards (cont)

- ***Data elements ("variables"):***
  - Investigators will follow a PCRC standardized format for collecting many of the data elements in their study.
  - As an example, the data point, "ethnicity" will be consistently coded as [variable label = Ethnicity, value labels: 1 = Hispanic or Latino 2 = Not Hispanic or Latino, 998=Not Reported, 999=Unknown].
  - The standardized formats along with relevant metadata are documented in the PCRC data elements library and study data dictionary available to all investigators collaborating with the PCRC. In addition to making the data comparable across studies, the use of a data elements library within the PCRC will expedite development of case report forms, data entry and data analysis for each study when applicable.
  - There will be flexibility for investigators to specify data elements when there are scientific reasons to do so.
  - A small common core set of data elements will be collected for each study conducted with the PCRC.

PCRC Standards (cont)

- ***Use of questionnaires***
  - For studies using measurement instruments to assess patient or caregiver outcomes such as symptoms, the impact of symptoms on daily activity, coping, well-being, etc., the PCRC Measures Core (and Caregivers Core when applicable) will formally review the choice of measures and the strategy for data collection, and will be available to provide guidance to investigators.
  - The PCRC Measures Core and Caregivers Core are assembling a library of preferred measures for many of the common patient and caregiver outcomes assessed in palliative care research, to facilitate the design and review of protocols. The library will include study instruments to measure concepts such as: symptoms, pain, health related quality of life, depression, coping, well-being, self-efficacy, satisfaction with care, and caregiver burden.

PCRC Standards (cont)

- ***Study Participant registration***
  - The PCRC has a responsibility to report summary statistics on study participants enrolled in PCRC-related studies to the NIH, NINR, other funders, and regulatory organizations.
  - All PCRC studies will record study participants in the PCRC Participant Registry in order to ensure that this criterion can be made.
  - The PCRC will maintain a secure, HIPAA compliant web-based resource for study participant registration.
- ***Data Sharing***
  - The PCRC fully supports the Final NIH Statement on Sharing Research Data and will provide assistance to all investigators and personnel for compliance. Consistent with OMB Circular A-110 and subsequent NIH Grants Policy Statements, the PCRC will provide access to data collected as part of PCRC-supported investigations, insofar as access is consistent with IRB/CHR rules, local, state, and Federal laws and regulations, and the HIPAA Privacy Rule.

PCRC Standards (cont)

- ***Team Operating Procedures [TOPs]***
  - The PCRC maintains team operating procedures to ensure ethical, consistent and efficient conduct of multi-site clinical trials. Consistent conduct of clinical trials is critical in order to collect high quality data.
  - All PCRC sites are expected to conduct PCRC-related studies in accordance with these standards. When applicable, a monitor will visit / audits sites to ensure compliance.
  - Investigators conducting studies at sites other than PCRC sites have the option to use these operating procedures in order to improve the quality of data collection within their studies.
- ***Data Audit***
  - All PCRC studies will be subjected to an annual data audit to ensure that high quality data are being collected according to the actions outlined above.

SUMMARY / Overview

LOI

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Grant Submission

Grant Award

Site Selection

Study Conduction