Division of General Internal Medicine
SCHOOL OF MEDICINE
UNIVERSITY OF COLORADO **ANSCHUTZ MEDICAL CAMPUS**

June 6, 2017

Palliative Care Research Cooperative Group
2400 Pratt St.
Durham, NC 27705

Re: Request for PCRC Data to Conduct Secondary Analyses

To: Data, Informatics, and Statistics Core

I am formally requesting data from the Statin Discontinuation Study to complete a research projected to partially fulfill my training goals as a Palliative Care & Aging Research Fellow at the University of Colorado, School of Medicine (NIH T32AG044296, PI: Jean Kutner, MD, MSPH). I have outlined a succinct description of my study below:

Although there are studies that demonstrate improved symptom management, improved quality of life, and increased satisfaction, there remains no consensus on methodology for measuring effectiveness in the *economic evaluation* of palliative care or a study that quantifies the relationship between palliative care effectiveness in a value equation measure. The research goal for this project is to answer: *Will an alternative reimbursement model provide financial sustainability for a palliative care program?*

Aim 1: Evaluate the association between palliative care interventions and cost of care.
Hypothesis: Palliative care interventions are associated with significantly lower Medicare cost. Extrapolated cost from Medicare claims data will provide evidence of cost-savings for patients receiving palliative care interventions compared to patients who did not receive palliative care interventions.

Aim 2: Evaluate an alternative reimbursement model for palliative care services.
Hypothesis: A global/capitated (per member per month) alternative reimbursement model for palliative care services will pay for palliative care operating and service delivery costs while demonstrating a return on investment for 3rd party payers.

This study utilizes data collected from the Statin Discontinuation Study to develop and test a theoretical model for alternative reimbursement in the delivery of palliative care services. The Statin Discontinuation Study adds strength to this secondary data analysis because it was a multicenter, parallel-group, unblended, randomized, pragmatic clinical trial in the palliative care setting. Study participants were randomized into two study groups: discontinue statin therapy (palliative care group) or continue statin therapy. Patients were enrolled from 15 academic and community Palliative Care Research Cooperative Group clinical member sites. Utilizing data originating from geographically diverse locations coupled with randomization will contribute to this study's validity.

Measures. Computation of cost and cost variances between the discontinue statin group and the continued statin group will be calculated from a *third party payer source perspective*. The data points utilized from the Statin study include: demographics, patient's payer source, primary diagnosis, comorbidities, polypharmacy, hospital, ED visits, and cardiovascular procedures. Costs will be extrapolated and lend to total population and individual costs. Then, using the research engagement data points with the discontinue statin group (in-person baseline, follow-up calls, and monthly supportive telephone calls beyond the end of scheduled data collection) a calculation cost for "palliative care services" will be extrapolated. The cost variances between the discontinue and continue statin therapy groups will be calculated. Cost for the discontinue therapy groups will also include the cost of palliative care services. The modeling for alternative reimbursement for the discontinue therapy group will be computed and analyzed.

Analysis. Data analysis will be conducted with R programming language. Calculation of frequencies by study group, payer source, primary and secondary diagnosis, polypharmacy, hospitalizations, procedures, ED visits, patient out of pocket costs will be computed. *Payer cost* will be extrapolated using *Medicare Geographic Variation Data*. Cost differences between the two study groups will be compared based on the distribution of cost. Median cost metrics will be compared using Wilcoxon rank-sum test. Alternative reimbursement model calculations for best fitness in return for investment for 3rd party payers will be assessed.

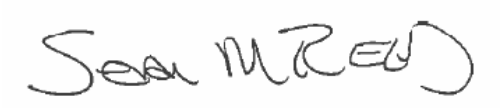
Timeline.

2017							2018		
JUN	**JUL**	**AUG**	**SEP**	**OCT**	**NOV**	**DEC**	**JAN**	**FEB**	**MAR**
IRB Submission	IRB Approval	Data Scrubbing	Data Scrubbing	Cost Extrapolation	Cost Extrapolation	Analysis	Analysis	Manuscript Prep	Manuscript Submission

Requested Data Points (.csv format):
All variables collected from the following datasets: REGISTRATION, FORMATOT, FORMZ, FORMBAB, FORMBCTOT, FORMBD, FORMBEF, FORMBGH, FORMWX, FORMFEVNTTOT, FORMFTOT, FORMHSUMMARY, FORMI, FORMJ, ENROLLMENT, BASELINE, WITHDRAWALS, DEATHS, IMPORTANTEVENTS, MQOLQ, AKPS, PRIMARYENDPOINT, POLYPHARMACY, ESAS, RECOMMEND, and AES.

Thank you for your consideration and please feel free to contact me as questions arise.

Sincerely,



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PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

REQUEST FOR PCRC DATA TO CONDUCT SECONDARY ANALYSES

Please fill out the form and return it to Kathryn.Colborn@ucdenver.edu and Rachael.Kendrick@ucdenver.edu. Your request will be reviewed by the Data, Informatics, and Statistics Core (DISC) within 7 days. If further information is required, a DISC representative will contact you.

GENERAL INFORMATION			
Investigator Name:	Sean M. Reed, PhD, APN, ACNS-BC, ACHPN		
Email	sean.reed@ucdenver.edu	**Phone:**	303-724-0735
Organization/Site:	University of Coloardo, School of Medicine		
Date of request:	6/26/2017	**Need by:**	7/26/2017
Please indicate all of the following reasons for your request that are relevant:	☒ **Research** Target journal for manuscript (e.g., JPM, etc): J Palliat Med Target submission date: March 31, 2018 Target conference for abstract / poster/ presentation: AAHPM Target submission date: 2019 Do you already have IRB approval? No If yes, IRB number: ☐ **Grant proposal background** Funding organization (e.g.: NIH, AHRQ, etc): Target submission date: ☒ **Other** Palliative Care and Aging T32 Fellowship NIH: T32AG044294-04		
Data:	From which study or studies are you requesting data? Statin Discontinuation Study In what format would you like the data? (e.g. csv, Excel, etc.) .csv **Please submit a separate list of variables you would like us to include along with this form**		

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 all 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 OPS use only:

Approval of Study PI		
Approval of EC:		
Assigned DISC representative:		
DUA needed:	Yes ☐ No ☐	Comment:
PCRC Member:	Yes ☐ No ☐	Comment: