Updated on Friday, February 12, 2016

PCORI INTERIM PROGRESS REPORT

Use continuation pages as needed. Limit 20 pages, not including the Certification page.

Date (mm/dd/yyyy): 7/31/2016	
Title of Project: Sensitivity Analysis Tools for Clinical Trials with Missing Data	
Period Covered by this Report: 2/1/2015 to 7/31/2016	
Iteration of Progress Report: ☐ 6-month ☐ 12-month ☐ 18-month ☐ 24-month ☒ 30-month ☐ Other (specify here)	
Principal Investigator & Institution Updated Contact Information:	
PI First Name:	Daniel
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Telephone:	410-955-3067
Key Patient and Other Stakeholder Partner Contact Information (up to three):	
Name:	
Telephone/Email:	
Name:	
Telephone/Email:	
Name:	
Telephone/Email:	

MILESTONES UPDATE

Record each milestone label, name, description, and projected completion date (columns A-D), as shown in Attachment B (Milestone Schedule) of your Contract. Complete Columns E, F, and G for milestones due or completed during the current reporting period.

Column E: Check appropriate box indicating milestone completion status during reporting period. Additional information on milestones that were not completed is required and should be provided in the section below this table.

Column F: Select actual date of milestone completion.

Column G: If applicable, select appropriate reason for delay/non-completion of projected milestone during the specified reporting period.

Column A	Column B	Column C	Column D	Column E	Column F	Column G
Milestone Label *(e.g., B-1, etc.)*	**Milestone Name**	**Description**	**Projected Completion Date**	**Completed? (Yes/No)**	**Date Completed**	**If Not Completed, Reason for Delay**
B-1	Website	Expand registration on website to include PCO researchers	7/31/2014	☒Yes☐No	10/31/2014	Choose an item.
B-2	Advisory Board	Convene Meeting	7/31/2014	☒Yes☐No	7/21/2014	Choose an item.
C	Submit Interim Progress Report	Interim Progress Report	7/31/2014	☒Yes☐No	7/31/2014	Choose an item.
D-1	Case studies/training materials	Create PCO-centered case study and training materials	1/31/2015	☒Yes☐No	1/31/2016	Choose an item.
D-2	Short courses	Facilitate two short courses	1/31/2015	☒Yes☐No	1/12/2015	Choose an item.
D-3	Adobe connect session	Adobe connect session with users	1/31/2015	☒Yes☐No	1/12/2015	Choose an item.

Column A	Column B	Column C	Column D	Column E	Column F	Column G
Milestone Label *(e.g., B-1, etc.)*	**Milestone Name**	**Description**	**Projected Completion Date**	**Completed? (Yes/No)**	**Date Completed**	**If Not Completed, Reason for Delay**
D-4	Manuscript for monotone missing data	Submit case study to PCOR focused journal	1/31/2015	☐Yes☒No	10/31/2016	Choose an item. Technical Issues
E	Submit Interim Progress Report	Interim Progress Report	1/31/2015	☒Yes☐No	2/2/2015	Choose an item.
F	Advisory Board	Convene Meeting	7/31/2015	☒Yes☐No	11/31/2015	Choose an item.
G	Submit Interim Progress Report	Interim Progress Report	7/31/2015	☒Yes☐No	8/21/2015	Choose an item.
H1	Case studies/training materials	Create PCO-centered case study and training materials	1/31/2016	☐Yes☒No	9/30/2016	Choose an item. Technical Issues
H2	Short courses	Facilitate two short courses	1/31/2016	☒Yes☐No	7/26/2016	Choose an item.
H3	Adobe connect session	Adobe connect session with users	1/31/2016	☒Yes☐No	5/24/2016	Choose an item.
H4	Manuscript for non-monotone missing data	Submit case study to PCOR focused journal	1/31/2016	☐Yes☒No	11/30/2016	Choose an item. Drafted, Waiting for main manuscript to be accepted
I	Submit Interim Progress Report	Interim Progress Report	1/31/2016	☒Yes☐No	2/19/2016	Choose an item.
J	Advisory Board	Convene Meeting	7/31/2016	☒Yes☐No	Click here to enter a date.	Choose an item.
K	Submit Interim Progress Report	Interim Progress Report	7/31/2016	☒Yes☐No	Click here to enter a date.	Choose an item.

Column A	Column B	Column C	Column D	Column E	Column F	Column G
Milestone Label *(e.g., B-1, etc.)*	**Milestone Name**	**Description**	**Projected Completion Date**	**Completed? (Yes/No)**	**Date Completed**	**If Not Completed, Reason for Delay**
			Click here to enter a date.	☐Yes ☐No	Click here to enter a date.	Choose an item.
			Click here to enter a date.	☐Yes ☐No	Click here to enter a date.	Choose an item.

RECRUITMENT, ENROLLMENT, AND RETENTION UPDATE

Instructions for completing recruitment, enrollment, and retention Table 1 and Site Information

- **Complete recruitment tables and site information at every reporting period. Report cumulative information at each reporting time period.** Complete a separate Table 1 and requested site information for each distinct project activity that involves recruitment and enrollment of study participants. Each of the following may be distinct:
    - Prospective trials
    - Observational studies
    - Focus groups
    - In-depth interviews
    - Surveys
    - Recruitment of different participant populations (e.g., patients, providers, caregivers) for any of the above activities

Example:
If your project conducts in-depth interviews with clinicians, then conducts surveys with patients, and then conducts a randomized-controlled trial enrolling patients, then you need to complete three tables and provide the requested Site Information for each project activity.

Table 1 Cumulative Recruitment, Enrollment, and Retention of Study Participants

Project Activity (e.g., in-depth interviews, patient focus groups, prospective trial): _____
Participant population (e.g., patients, caregivers, clinicians): _____

		Column A	Column B	Column C	Column D	Column E	Column F	Column G
Interim Progress Report	**Project months**	**Date of update**	**Planned Sample Size**	**Total Screened (N)**	**Total Eligible (N)**	**Total Enrolled (N)**	**Total Lost to Follow-up (N)**	**% Lost to follow-up**
6-month	0 – 6 months							
12-month	7-12 months							
18-month	13-18 months							
24-month	19-24 months							
30-month	25-30 months							
36-month	31 – 36 months							

KEY

Column A: Date of update

Column B: Sample size (number of individuals you plan to enroll) in your approved research plan. For group-level data such as a focus group, enter the numbers of groups, not the number of participants for each group.

Column C: Total number of individuals screened for eligibility to date. This is the number approached and/or tested (e.g., lab tests, review of medical history, survey, etc.) to determine potential eligibility for the project.

Column D: Of the screened individuals, total number of individuals who met the eligibility criteria to date

Column E: Of the eligible individuals, total number of participants enrolled to date

Column F: Number of participants that have been lost to follow-up (enter N/A if not applicable to your project)

Column G: Percent lost to follow-up = Number lost to follow-up/total number enrolled * 100

Site Information

- Number of sites, clinics and/or practices from which you will recruit study participants? _____. If you are recruiting study participants from sources that are not site specific (e.g., websites, newspapers), please provide the number and names of those sources:

  _____

  - **Total** number of sites, clinics, and/or practices that have enrolled at least 1 participant: _____
  - **Names** of sites, clinics, and/or practices that have enrolled at least 1 participant: _____

Please describe the following:

1. Describe your systematic effort to identify potentially eligible individuals to enroll in your project (i.e., how are you finding potentially eligible individuals for your project?).
   a. Describe any significant changes from your approved research plan.

2. Describe your systematic effort to screen individuals who appear eligible. Refer to Methodology Standard, PC-2, and describe how this standard is being met (i.e., of the individuals identified, how are you approaching and/or testing them to determine potential eligibility?).
   a. Report reasons for ineligibility and the number of individuals for each reason.

3. Describe your systematic effort to document information about eligible individuals who decline to enroll in the project.
   a. Report reasons for declining and the number of individuals for each reason.

4. Describe your systematic effort to reduce attrition of participants enrolled in your project (as applicable).

5. Report the time points at which participants are lost to follow-up (e.g., mid-way through the intervention, after the intervention, specific follow-up time points) and the number of participants for each time point.

Complete Table 2 by listing the Racial/Ethnic and Gender breakdown of the participants enrolled in your study to date. Ensure totals are calculated and appropriately recorded. If you have not collected these data, please explain why. Add a separate table for each type of participant recorded in Table 1 above.

Table 2 Racial/Ethnic and Gender Enrollment Table*

Race	**Male (N)**	**Female (N)**	**Total (N)**
American Indian/ Alaska Native			
Asian			
Black/ African American			
Hawaiian/ Pacific Islander			
White			
Multi-race			
Other			
Ethnicity	**Male (N)**	**Female (N)**	**Total (N)**
Hispanic (Latino/Latina)			
Non-Hispanic			

*If more detailed information is available regarding racial/ethnic subgroups for the participants in your study, please share a separate table with this information in the Additional Documents section.

ACCOMPLISHMENTS AND CHALLENGES

Discuss and document study progress and all significant events for the current reporting period. In particular, please discuss:

- Any significant change from the funded application, including changes in the study protocol, engagement plan, endpoints, sample size, etc. Include reasons for these changes. Please note that you should discuss changes with PCORI program staff prior to implementation and some change require prior approval from PCORI (see your executed funding contract for changes that require PCORI prior approval and notice thirty (30) days in advance of the proposed change).

  No significant change.

- Progress and accomplishments achieved during the current 6-month reporting period, with reference to planned project activities, milestones, and planning for dissemination. (Please include the specific milestone label as relevant.)

  Submitted manuscript to the *Biometrics* on 6/1/2016. Gave ASA webinar on 5/24/16. Gave short course at Johns Hopkins on 6/22/16 at the University of Washington on 7/26/16.. Gave talk at Brown University on 4/4/16.

  A foundational manuscript describing how to analyze randomized trials with death and intermittent missing data has been accepted at *Biometrics.* An R package called idem has been posted on CRAN. A translational version of this work has been submitted to the *British Medical Journal*.

- Challenges with project progress including anticipated upcoming challenges (e.g., delays in IRB approval, delays in recruitment of sites, participant retention issues). How have you overcome these challenges? What is your continued plan for overcoming these challenges? (Please include the specific milestone label as relevant.)

  The software development aspect of this project is funded by the FDA. We have been battling technical issues regarding constructing confidence intervals with proper coverage. In part, this is due to sensitivity of our methods to outliers. We have not yet found a way to "robustify" our procedures. Right now, our best recommendation is to identify outliers and remove them from the analysis. After removal, our procedures work well. Within the next month, we plan to release software that extends SAMON (our software for monotone missing data) to handle non-monotone missing data.

  The manuscripts planned under this contract are of a more applied nature; they cannot be submitted until the more foundational articles have been accepted. Right now, the foundational article underlying SAMON is under review at *Biometrics*. The more applied PCOR-focused version of SAMON has been drafted and will be submitted once the foundational article has been accepted. The same issue applies to the non-monotone missing data manuscript. We expect that Milestone D-4 will be completed by 10/31/16, Milestones H1 will be completed by 9/30/16 and

we will have software for non-monotone missing data by 8/31/16.

Methodology Standards to address	Report how these Methodology Standards are being met
Upon Study Protocol Completion	
Data Integrity and Rigorous Analysis (IR-1, IR-2 IR-3, IR-4)	**N/A**
Missing Data (MD-1, MD-2, MD-3, MD-4)	**N/A**
Heterogeneity of Treatment Effects (HT-1, HT-2)	**N/A**
Causal Inference, if applicable (CI-1-6)	**N/A**
Data Registries, if applicable (DR-1-3)	**N/A**
During Each Interim Progress Report	
Data Integrity and Rigorous Analysis (IR-1, IR-2 IR-3, IR-4)	**N/A**
Adaptive Trials, if applicable (AT-1-5)	**N/A**
Missing Data (MD-1, MD-2, MD-3, MD-4)	**N/A**

- A summary of any reports submitted to the sponsor, a DSMB, an IRB, the FDA, or other regulatory or oversight body about unanticipated problems involving risks to subjects or others relating to the research project (e.g., adverse events, deviation from approved protocol that places subjects at increased risk of harm, data breach, procedural or medication error) that were reported during the reporting period. **N/A**

- A summary of any significant decisions, findings, recommendations, actions and directions of a DSMB, an IRB, the FDA or any other regulatory or oversight body relating to the research project during the reporting period. **N/A**

- Please report how your project meets **PCORI's Methodology Standards** that apply to your ongoing research (enter N/A if appropriate). The following Standards should be addressed at the appropriate study phases (see table below):

ENGAGEMENT REPORT

The end-users of our methods and software are: (1) those who use our technology to analyze and report the results of clinical trials and (2) those who review the results of clinical trials to make decisions about treatments.

- Describe progress on your approved **engagement plan** during the current 6-month reporting period, relative to the activities outlined in your application. Refer to Methodology Standard PC-1 and describe how this standard is being met.

  In the last six months, we have been disseminating our methods and software to researchers, practitioners and policy makers. We have given short courses at the Johns Hopkins University and University of Washington.

- Describe challenges with **patient and stakeholder engagement**. How have you overcome these challenges? What is your continued plan for addressing these challenges?

  The key challenge is access to illustrative datasets and getting stakeholders to use our methods and software. A key stakeholder is the FDA. We speak with them monthly. This summer they hired an intern to test our software. As we have indicated to our PCORI project officers, we would welcome the opportunity to implement the methods and software on PCORI sponsored trials.

- **For the 6-month time intervals** (i.e., 6 months, 18 months, 30 months, etc. but not at 12 months or 24 months), provide specific examples of the impact of engagement on project activities during the reporting period. Include examples of all relevant stakeholders in each phase of research – planning the study, conducting the study, and dissemination where applicable – per the PCORI Engagement Rubric.

- For each **annual** report (i.e., at year 1, year 2, etc. but not at 6 months or 18 months), additional descriptive information on engagement of patients and/or other stakeholders should be reported below. This report is intended to capture the perspective of the research team. Patient and stakeholder partners will have additional opportunities to provide input.

Use the link below to complete this report. Your Username is your PCORI contract number *(no letters, dashes, or spaces)*.

Provide your engagement report here: https://live.datstathost.com/PCORI-Collector/Survey.ashx?Name=Engagement_Report_Login

When you have completed the questions, record your confirmation code: **N/A**

FINANCIAL STATUS UPDATE

Describe any significant deviations in costs and budget, how those deviations affected the study progress (e.g., staffing and cost estimates), and any anticipated need for budget modifications. Significant deviations are considered any adjustment that exceeds 25% of a budget category.

There have not been any significant deviations in costs and budget.

KEY PERSONNEL EFFORT UPDATE

Key Personnel changes must be reported (see your executed funding contract for changes in key personnel that require prior PCORI approval or advance written notification). Report the individual's role, change in percentage effort, and an explanation for changes. If you have more than five changes to report, please include additional information under "Explanation of Changes." Send PCORI a biosketch for all new key personnel at fundedpfa@pcori.org.

☒ No changes in key personnel

Name (First, Last)	Title	Contracted Percentage Effort	Actual Percentage Effort
		%	%
		%	%
		%	%
		%	%
		%	%

Explanation of Changes:

Note any **proposed** changes to key personnel in the next 6 months, if applicable, and provide an explanation for changes, below. Add rows as necessary. If you have more than five proposed changes to report, please include additional information under "Explanation of Changes." Send PCORI a biosketch for all new key personnel at fundedpfa@pcori.org.

☒ No changes in key personnel

Name (First, Last)	Title	Contracted Percentage Effort	Actual Percentage Effort
		%	%
		%	%
		%	%
		%	%
		%	%

Explanation of changes:

PUBLICATIONS UPDATE

REMINDER: Please make sure that all publications/communication/media pieces contain the following acknowledgement of PCORI funding and required disclaimer:

> *"Research reported in this [work, publication, article, report, presentation, etc.] was [partially] funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (##-###-####)."*

> *"The [views, statements, opinions] in this [work, publication, article, report] are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee."*

In the tables below, record information regarding publications and presentations (scientific and non-scientific) related to your PCORI-funded research that occurred as of the reporting date. Retain information submitted in previous reports.

Publications and/or presentations by any member of the research team, including patient and stakeholder partners, should include those:

- In preparation to be submitted.
- That have been submitted to a publication.
- That have been accepted to a publication.
- That are in-press.
- That have been published.

Please send any submitted or published manuscripts, other publications, and conference abstracts, as described in the Additional Documents section.

Please review the public abstract posted on your project's summary page on PCORI's website here and confirm that it is accurate or note whether changes are needed. If changes are needed, please attach your updated abstract to your progress report submission (use tracked changes).

Scientific Manuscripts

Title	Type	Status	Journal *	URL, if applicable
On the Analysis of Tuberculosis Studies with Intermittent Missing Data	Methods	Published	Annals of Applied Statistics	
Inference in Randomized Trials with Death and Missingness	Methods	Accepted	Biometrics	
Global Sensitivity Analysis for Repeated Measures Studies with Informative Drop-out: A Semi-Parametric Approach	Methods	Under Review	Biometrics	
Global Sensitivity Analysis of Clinical Trials with Missing Patient Reported Outcomes	Methods	In Preparation	Clinical Trials	
Accounting for Mortality and Missing Data When Comparing Clinical Outcomes Across Treatment Groups in Randomized Trials	Methods	Under Review	British Medical Journal	

***target journal for papers in preparation**

Scientific Manuscripts, con't:

Please provide this additional information for **accepted or published manuscripts**.

For ACCEPTED or PUBLISHED manuscripts					
Title	**Authors ****	**Publication date**	**Volume (issue)**	**Page #s**	**PMID**
Inference in Randomized Trials with Death and Missingness	Wang, Chenguang; Scharfstein, Daniel; Colantuoni, Elizabeth; Girard, Timothy; Yan, Ying				
On the Analysis of Tuberculosis Studies with Intermittent Missing Data	Scharfstein, Daniel; Rotnitzky, Andrea; Abraham, Maria; McDermott, Aidan; Chaisson, Richard; Geiter, Lawrence	12/2015	9	2215-2236	

**** Include all authors, using format: Last name 1, First name 1; Last name 2, first name 2; etc.**

Other Publications (e.g., book chapter, report, organizational journals, newsletters, blogs, other lay press)

Title	Publication Type	Status	Name of publication	Authors **	Publication date	URL, if applicable
Survival Analysis	Book Chapter	Under Review	Handbook of Statistical Methods for Randomized, Controlled Trials	Scharfstein, Daniel; Zhu, Yuxin; Tsiatis, Anastasios		
Prospective EHR-Based Clinical Trials: The Challenge of Missing Data	Editorial	Published	Journal of General Internal Medicine	Kharazzi, Hadi; Wang, Chenguang; Scharfstein, Daniel	4/16/2014	

**** Include all authors, using format: Last name 1, First name 1; Last name 2, first name 2; etc.**

Peer-Reviewed Presentations

Title	Status	Presentation Date	Presenter(s) Name*	Presenter(s) role in the project (Select all that apply)	Conference or Meeting Name	Meeting Location (City, State)	URL, if applicable	Intended Audience (Select all that apply)

***Last, First**

Other presentations (e.g., invited talk, local provider meeting, webinar, YouTube video)

Title	Presentation Type	Presentation Date	Presenter(s) Name*	Presenter(s) role in the project (Select all that apply)	Conference or Meeting Name, if applicable	Presentation Location **	URL, if applicable	Intended Audience (Select all that apply)
Global Sensitivity Analysis of Repeated Measures Studies with Informative Dropout: A Semi-Parametric Approach	Oral	8/3/2014	McDermott, Aidan	Researcher	Joint Statistical Meetings,	Boston, MA		Researchers
Global Sensitivity Analysis of Repeated Measures Studies with Informative Dropout: A Semi-Parametric Approach	Oral	9/18/2014	Scharfstein, Daniel	Researcher	Andrei Yakovlev Colloquium, University of Rochester	Rochester, NY		Researchers
Inference in Randomized Trials with Death and Missingness	Oral	9/24/2014	Wang, Chenguang	Researcher	ASA Biopharmaceutical Section FDA-	Rockville, MD		Researchers, Practitioners

					Industry Workshop			
Global Sensitivity Analysis of Randomized Trials with Missing Data: Recent Advances	Short Course, In-Person	12/8/2014	Scharfstein, Daniel	Researcher	Deming Conference	Atlantic City, NJ		Researchers, Practitioners
Standards in the Prevention and Handling of Missing Data for Patient-Centered Outcomes Research	Oral	12/16/2014	Li, Tianjing	Researcher	Journal Club, Johns Hopkins	Baltimore, MD		Students
Analysis of Randomized Trials with Missing Data	Short Course, In-Person and Adobe Connect	1/12/2015	Scharfstein, Daniel; McDermott, Aidan; Wang, Chenguang	Researchers	Johns Hopkins University	Baltimore, MD		Researchers, Practitioners
Global Sensitivity Analysis of Randomized Trials with Missing Data	Poster	4/27/2015	Scharfstein, Daniel	Researcher	FDA ORSI Symposium	Rockville, MD		Researchers, Practitioners, Policy Makers
Global Sensitivity Analysis of Randomized Trials with Missing Data	Short Course, In-Person	5/17/2015	Scharfstein, Daniel	Researcher	Society of Clinical Trials	Arlington, VA		Researchers, Practitioners

Analysis of Prospective Studies with Missing Data	On-Line Lecture	7/31/2015	Scharfstein, Daniel; Li, Tianjing	Researchers	Johns Hopkins University	Baltimore, MD		Researchers, Practitioners, Policy Makers
Global Sensitivity Analysis of Randomized Trials with Missing Data: A Frequentist Perspective	Oral	11/6/2015	Scharfstein, Daniel	Researcher	FDA – Center for Tobacco Products	Rockville, MD		Researchers, Practitioners, Policy Makers
Missing Data and Sensitivity Analyses in Randomized Trials	Oral	11/12/2015	Scharfstein, Daniel	Researcher	GlaxoSmithKline	Valley Forge, PA		Researchers, Practitioners
Global Sensitivity Analysis of Randomized Trials with Missing Data: From the Software Development Trenches	Oral	11/13/2015	Scharfstein, Daniel	Researcher	National Institute of Statistical Sciences	Washington, Dc		Researchers
Analysis of Randomized Trials with Missing Data	Short Course, In-Person and Adobe Connect	11/30/2015	Scharfstein, Daniel; McDermott, Aidan; Wang, Chenguang	Researchers	FDA	Rockville, MD		Researchers, Practitioners, Policy Makers
Inference in Randomized	Oral	4/4/2016	Scharfstein, Daniel	Researcher	Brown University	Providence, RI		Researchers, Practitioners.

Trials with Death and Missingness								
Analysis of Randomized Trials with Missing Data	Webinar	5/24/16	Scharfstein, Daniel	Researcher	American Statistical Association			Researchers, Practitioners
Analysis of Randomized Trials with Missing Data	Short Course, In-Person and Adobe Connect	6/22/2016	Scharfstein, Daniel; McDermott, Aidan; Wang, Chenguang	Researchers	Johns Hopkins University	Baltimore, MD		Researchers, Practitioners
Analysis of Randomized Trials with Missing Data	Short Course, In-Person	7/26/2015	Scharfstein, Daniel	Researcher	University of Washington	Seattle, WA		Researchers, Practitioners,

*** Last, First**

****City, State or online (e.g., webinar)**

PROGRESS STATEMENT FOR PUBLIC USE

Describe notable progress to date, preliminary results, (if applicable) and engagement/stakeholder experiences using nontechnical language that is ready for public use. (Note: This information may be publicly disseminated by PCORI.) *Limit 250 words.*

We posted R and SAS versions of the software SAMON on the www.missingdatamatters.org website.

ADDITIONAL DOCUMENTS

All attachments should be combined with this document and submitted to PCORI as one PDF to fundedpfa@pcori.org.

Any documents that you feel are relevant and noteworthy can be shared, such as:

- Copies of drafts of instruments, data dictionaries, educational materials, manuals, or other project deliverables, if not already delivered
- Abstracts from presentations made to professional groups or associations
- Manuscripts submitted or in press
- Summaries of preliminary data
- Minutes or summaries from patient and/or stakeholder meetings
- Bibliographies
- Summaries from DSMB meetings
- Final study protocol
- Other communications efforts
- Copies of reports from any consultants or advisors, where applicable
- Other documents or materials, as appropriate
- Websites, blogs, or other Internet-based links
- Public affairs or popular press coverage of the study online, on television, radio, etc.
- New and continuing IRB approvals

CERTIFICATION

This document must be certified by the Principal Investigator and the designated Administrative Official (AO).

Principal Investigator:

☒ I certify that I, as the Principal Investigator, have reviewed and approved this document (and any associated attachments, if applicable) and the information provided in this document is correct.

PI First Name: Daniel
Last Name: Scharfstein
Date: 2/19/2015

Administrative Official:

☐ I certify that I, as the designated Administrative Official, have reviewed and approved this document (and any associated attachments, if applicable) and the information provided in this document is correct.

AO First Name:
AO Last Name:
Date: