PCORI Methodology Standards Checklist

Follow the instructions provided below. Upload the completed template as an Excel file into PCORI Online. Detailed instructions are included in the Submission Instructions for this PCORI Funding Announcement (PFA). Refer to the PCORI Methodology Report for explanations about the standards.

In the checklist below, you will see a complete list of the PCORI Methodology Standards. In column D, using the drop-down menu options, indicate whether or not each methodology standard applies to your research. If the standard applies, in column E, provide the page number of your research plan where the text illustrates how you addressed the standard. Lastly, in column F, indicate whether your study may deviate from the standard and provide a rationale. Repeat the sequence for each standard. **Note: Do not add or delete columns or rows in this template.**

Application ID	**Contract No. 75Q80120D00009**
PI Name	**Susanne Hempel**
Application Title	**Systematic Review – ADHD Diagnosis and Treatment in Children and Adolescents**

Standard Category	Abbrev.	Standard	Have you addressed how you plan to adhere to the standard in your application?	List page numbers	Notes
Cross-Cutting Standards for PCOR					
Standards for Formulating Research Questions	RQ-1	Identify gaps in evidence	Yes	1	Introduction
	RQ-2	Develop a formal study protocol	Yes	See notes	Available on the AHRQ website and registered in PROSPERO
	RQ-3	Identify specific populations and health decision(s) affected by the research	Yes	7	Methods
	RQ-4	Identify and assess participant subgroups	Yes	8 and 9	KQs1c
	RQ-5	Select appropriate interventions and comparators	Yes	9 and 11	Methods
	RQ-6	Measure outcomes that people representing the population of interest notice and care about	Yes	9 and 11	Methods
Standards Associated with Patient-Centeredness	PC-1	Engage people representing the population of interest and other relevant stakeholders in ways that are appropriate and necessary in a given research context	Yes	vi and vii	Frontmatter (KI and TEP)
	PC-2	Identify, select, recruit, and retain study participants representative of the spectrum of the population of interest and ensure that data are collected thoroughly and systematically from all study participants	Yes	7	Methods
	PC-3	Use patient-reported outcomes when patients or people at risk of a condition are the best source of information for outcomes of interest	Yes	See notes	Results
	PC-4	Support dissemination and implementation of study results	Yes	See notes	Accompanying manuscipt(s)
Standards for Data Integrity and Rigorous Analyses	IR-1	A priori, specify plans for data analysis that correspond to major aims	Yes	See notes	Published protocol
	IR-2	Assess data source adequacy	Yes	13	Risk of bias assessment
	IR-3	Describe data linkage plans, if applicable	Yes	See notes	Data will be published in SRDRPlus
	IR-4	Document validated scales and tests	Yes	See notes	Evidence tables in the appendix
	IR-5	Provide sufficient information in reports to allow for assessments of the study's internal and external validity	Yes	14, 15, 16	Methods
	IR-6	Masking should be used when feasible	N/A	N/A	Standard does not apply
	IR-7	In the study protocol, specify a data management plan that addresses, at a minimum, the following elements: collecting data, organizing data, handling data, describing data, preserving data, and sharing data.	Yes	See notes	Published protocol
	MD-1	Describe methods to prevent and monitor missing data	Yes	18 and 19	Methods

Standard Category	Abbrev.	Standard	Have you addressed how you plan to adhere to the standard in your application?	List page numbers	Notes
Standards for Preventing and Handling Missing Data	MD-2	Use valid statistical methods to deal with missing data that properly account for statistical uncertainty due to missingness	Yes	18 and reported in the Results chapter by each KQ	SoE assessment, result section
	MD-3	Record and report all reasons for dropout and missing data, and account for all patients in reports	Yes	Reported in the Results chapter by each KQ	Results
	MD-4	Examine sensitivity of inferences to missing data methods and assumptions, and incorporate into interpretation	Yes	Reported in the Results chapter by each KQ	Results
Standards for Heterogeneity of Treatment Effect (HTE)	HT-1	State the goals of HTE analyses, including hypotheses and the supporting evidence base	Yes	Reported in the Results chapter by each KQ	Results
	HT-2	For all HTE analyses, provide an analysis plan, including the use of appropriate statistical methods	Yes	14, 15	Methods
	HT-3	Report all prespecified HTE analyses and, at minimum, the number of post-hoc HTE analyses, including all subgroups and outcomes analyzed	Yes	Reported in the Results chapter by each KQ	Results
Standards for Specific Study Designs and Methods					
Standards for Data Registries	DR-1	Requirements for the design of registries	N/A		Standard does not apply
	DR-2	Documentation and reporting requirements of registry materials, characteristics, and bias	N/A		Standard does not apply
	DR-3	Adapting established registries for PCOR	N/A		Standard does not apply
	DR-4	Documentation requirements when using registry data	N/A		Standard does not apply
Standards for Data Networks as Research-Facilitating Structures	DN-1	Requirements for the design and features of data networks	N/A		Standard does not apply
	DN-2	Selection and use of data networks	N/A		Standard does not apply
Causal Inference Standards	CI-1	CI-I: Specify the causal model underlying the research question ***CROSS-CUTTING STANDARD***	N/A		Standard does not apply
	CI-2	Define and appropriately characterize the analysis population used to generate effect estimates	Yes	Reported in the Results chapter by each KQ and in Appendix C	Results and evicence table
	CI-3	Define with the appropriate precision the timing of the outcome assessment relative to the initiation and duration of exposure	Yes	Appendix C	Evidence tables
	CI-4	Measure potential confounders before start of exposure and report data on potential confounders with study results	Yes	Reported in the Results chapter by each KQ	Results and meta-regressions
	CI-5	Report the assumptions underlying the construction of propensity scores and the comparability of the resulting groups in terms of the balance of covariates and overlap	N/A	See notes	Standard does not apply

Standard Category	Abbrev.	Standard	Have you addressed how you plan to adhere to the standard in your application?	List page numbers	Notes
	CI-6	Assess the validity of the instrumental variable (i.e. how the assumptions are met) and report the balance of covariates in the groups created by the instrumental variable	N/A	See notes	Standard does not apply
Standards for Adaptive and Bayesian Trial Designs	AT-1	Specify planned adaptations, decisional thresholds, and statistical properties of those adaptations	N/A	See notes	Standard does not apply
	AT-2	Specify the structure and analysis plan for Bayesian adaptive randomized clinical trial designs	N/A	See notes	Standard does not apply
	AT-3	Ensure that clinical trial infrastructure is adequate to support planned adaptation(s) and independent interim analyses	N/A	See notes	Standard does not apply
	AT-4	When reporting adaptive randomized clinical trials, use the CONSORT statement, with modifications	N/A	See notes	Standard does not apply
Standards for Studies of Medical Tests	MT-1	Specify the clinical context and key elements of the medical test	N/A	See notes	Standard does not apply
	MT-2	Assess the effect of factors known to affect performance and outcomes	N/A	See notes	Standard does not apply
	MT-3	Focus studies of medical tests on patient-centered outcomes, using rigorous study designs with a preference for randomized controlled trials	N/A	See notes	Standard does not apply
Standards for Systematic Reviews	SR-1	Adhere to National Academy of Medicine (NAM) standards for systematic reviews of comparative effectiveness research, as appropriate	Yes	See notes	Published protocol and report
Standards on Research Designs Using Clusters	RC-1	Specify whether the study objectives, the interventions, and the primary outcomes pertain to the cluster level or the individual level	N/A	See notes	Standard does not apply
	RC-2	Justify the choice of cluster randomization	N/A	See notes	Standard does not apply
	RC-3	Power and sample size estimates must use appropriate methods to account for the dependence of observations within clusters and the degrees of freedom available at the cluster level	N/A	See notes	Standard does not apply
	RC-4	Data analyses must account for the dependence of observations within clusters regardless of its magnitude	N/A	See notes	Standard does not apply
	RC-5	Stratified randomization should be used when feasible	N/A	See notes	Standard does not apply
Standards for Studies of Complex Interventions	SCI-1	Fully describe the intervention and comparator and define their core functions	N/A	See notes	Standard does not apply
	SCI-2	Specify the hypothesized causal pathways and their theoretical basis.	N/A	See notes	Standard does not apply
	SCI-3	Specify how adaptations to the form of the intervention and comparator will be allowed and recorded	N/A	See notes	Standard does not apply
	SCI-4	Plan and describe a process evaluation	N/A	See notes	Standard does not apply
	SCI-5	Select patient outcomes informed by the causal pathway	N/A	See notes	Standard does not apply
	QM-1	State the qualitative approach to research inquiry, design, and conduct	Yes	13	Methods
	QM-2	Select and justify appropriate qualitative methods sampling strategy	Yes	13	Methods

Standard Category	Abbrev.	Standard	Have you addressed how you plan to adhere to the standard in your application?	List page numbers	Notes
Standards for Qualitative Methods	QM-3	Link the qualitative data analysis, interpretations, and conclusions to the study question	Yes	Reported in the Results chapter by each KQ	Results
	QM-4	Establish trustworthiness and credibility of qualitative research	Yes	Reported in the Results chapter by each KQ	Results
Standards for Mixed Methods Research	MM-1	Specify how mixed methods are integrated across design, data sources, and/or data collection phases	N/A	See notes	Standard does not apply
	MM-2	Select and justify appropriate mixed methods sampling strategy	N/A	See notes	Standard does not apply
	MM-3	Integrate data analysis, data interpretation, and conclusions	N/A	See notes	Standard does not apply
Standards for Individual Participant-Level Data Meta-Analysis (IPD-MA)	IPD-1	Specify the research question(s) that will be addressed through the IPD-MA and describe the specific information it will provide that other approaches would not	N/A	See notes	Standard does not apply
	IPD-2	Describe the proposed governance structure for the IPD-MA in the protocol and study reports	N/A	See notes	Standard does not apply
	IPD-3	Use systematic, reproducible methods to identify studies for inclusion in the IPD-MA	N/A	See notes	Standard does not apply
	IPD-4	Specify the design and planned analyses of the IPD-MA in a protocol, document any changes, and report significant amendments and modifications	N/A	See notes	Standard does not apply