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this user's guide is a resource for investigators and stakeholders who develop and review observational comparative effectiveness research protocols it explains how to 1 identify key considerations and best practices for research design 2 build a protocol based on these standards and best practices and 3 judge the adequacy and completeness of a protocol eleven chapters cover all aspects of research design including developing study objectives defining and refining study questions addressing the heterogeneity of treatment effect characterizing exposure selecting a comparator defining and measuring outcomes and identifying optimal data sources checklists of guidance and key considerations for protocols are provided at the end of each chapter the user's guide was created by researchers affiliated with ahrq's effective health care program particularly those who participated in ahrq's decide developing evidence to inform decisions about effectiveness program chapters were subject to

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