

**IRB Signature**

Signature Jean Taylor-Woodbury By Jm 8/21/2019  
 Jean Taylor-Woodbury, RN, MS, ANP-BC, Chair Teresa Majors, CIP Date

**Review and Approval Information**

E&I Study Number 19123 - 01 Approval Date Wednesday, August 21, 2019  
 Review Process Expedited 7 Expiration Date Thursday, August 20, 2020 at 11:59 PM

This document certifies the IRB's approval, per 45 CFR 46, of the bolded items identified under "Documents Approved" to be conducted by the named Principal Investigator.

**NOTE: Subjects must be asked for their consent using the most recently approved, stamped version(s). All IRB approved consent documents are version controlled and may not be modified in any way without prior IRB approval. Use of an unapproved document may constitute non-compliance.**

**Study**

Virtual Focus Groups with Primary Care Physicians and OBGYNs: Attitudes about Proposed Hepatitis C Screening Guidelines DVH 2019 Client The Henne Group  
 Sponsor Centers for Disease Control and Prevention

**Grant Number and/or Title**

Contract - HHSD2002015M88164B: Task Order: 200-2016-F-90427; Viral Hepatitis National Educational Campaigns and Communication Support

**Principal Investigator**

Mark David Richards, PhD

E&I PI Number 17094 - 001

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**Performance Sites**

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Reckner Healthcare, 1600 Manor Drive, Suite 100, Chalfant, PA 18914

**Documents Approved**

Documents Approved	Document #	Version	Date
Protocol	KRC19123		August 9, 2019
Consent Form for Participation in a Physician Focus Group	E&I 08/21/2019		August 21, 2019
Discussion Guide	Appendix A		August 9, 2019
Recruitment Screener	Appendix B		August 9, 2019
Physician Inclusion Criteria	Appendix C		August 9, 2019
Initial Recruitment Email	Appendix D		August 9, 2019
Focus Group Recruitment Spreadsheet	Appendix H		August 9, 2019
Focus Group Participation Confirmation Letter	Appendix I		August 9, 2019

**Stipulations of Approval**

1. No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. Investigators and sponsors are responsible for initiating Continuing Review proceedings.
2. All protocol modifications must be IRB approved prior to implementation. This includes any addition or change of recruitment materials, change of investigator, or performance site address. (Exception: If

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- necessary to eliminate apparent immediate hazard to subjects.)
3. Report to E&I within five working days of learning if any of the following occur:
    - Unanticipated problems involving risk to human subjects or others;
    - Unanticipated Serious Adverse Events and Safety Reports;
    - Protocol deviations, violations, and exceptions that impact subject welfare or safety or study integrity including changes intended to reduce immediate risk to subjects;
    - Use of an investigational product in an emergency situation; and
    - Claims for compensation or for medical care for research-related injury.
  4. Advertising and recruitment materials must be approved by E&I prior to use or publication.

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**END**



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