NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory

Ethics and Regulatory Core

Pragmatic Trial of Population-Based Programs to Prevent Suicide Attempt

Gregory Simon, MD, MPH

Meeting Participants (May 17, 2013):

☒	Jeremy Sugarman (Johns Hopkins)	☒	Jerry Menikoff (OHRP)	☒	Wendy Weber (NIH)	☐	
☒	Rob Califf (Duke)	☒	Irene Stith-Coleman (OHRP)	☒	Tammy Reece (Coord Center)	☐	
☒	Greg Simon (Group Health)	☒	Jane Pearson (NIH)	☒	Cheri Janning (Coord Center)	☐	
☒	Barbara Young (Group Health, IRB)	☒	Dave Chambers (NIH)	☐		☐	
☒	Tonya Matthews (Group Health)	☒	Catherine Meyers (NIH)	☐		☐	
☒	Julie Kaneshiro (OHRP)	☒	Josephine Briggs (NIH)	☐		☐	

The minutes from the May 17, 2013 meeting were circulated to all participants on the call for two rounds of review and they reflect all corrections that were received.

AGENDA ITEMS	DISCUSSION May 17, 2013	PROPOSED ACTION May 17, 2013	CURRENT STATUS as of May 11, 2015
Review of Demonstration Project	• Dr. Simon gave an overview of the Suicide Prevention project. All eligible patients will be randomly assigned in equal proportions (1:1:1) to either of the two prevention intervention conditions or to continued usual		

	care (control). Following a modified Zelen design, participants will be assigned automatically at the time that eligible participants are identified prior to obtaining consent; those assigned to either of the active intervention conditions will be asked to consent to participation. Outcomes will be analyzed according to original treatment assignment, regardless of willingness to accept either intervention and regardless of level of intervention participation. • The study will enroll approximately 16,000 adults whose responses to item 9 of the PHQ depression scale (regarding thoughts of death or suicide) indicate elevated risk. • Centers involved include: Group Health Cooperative, the University of Washington, the University of Pittsburgh, Health Partners, and Kaiser Permanente Colorado. • Trial design: Participants will be randomly assigned to one of three arms: usual care (UC); UC plus online interactive program and coaching; or UC plus systematic outreach for structured risk assessment. • Primary endpoint: Suicide attempt (fatal or nonfatal) in the year following enrollment. • IRB approval has been obtained for UH2 and UH3 phases. • No concerns were raised about the trial design.		
Minimal risk	• Regarding the use of medical records information to identify participants, Dr. Simon indicated that this falls within the definition of		

	minimal risk, as these data are collected and recorded during healthcare encounters. • Dr. Simon stated that none of the interventions are believed to expose participants to greater than minimal risk. Although the interventions differ in intensity and mode of delivery, each is based on best available evidence regarding the prevention of suicide attempts. • For participants assigned to the UC control group, treatment will be identical to what would have been delivered had the study not occurred. • No treatment or intervention will be restricted or withheld, and treating providers will still be responsible for any assessment and follow-up care they would normally provide. • No concerns were raised about a minimal risk determination for this study.		
Consent (patient and physician)	• The project is requesting waivers of consent for: assignment to usual care or one of the intervention groups; participation in the usual care group; and access to health records to ascertain outcomes. In addition, the project is requesting a waiver of documentation of consent for participation in either of the intervention groups. • These waivers or alteration will not adversely affect the rights or welfare of the subjects. Study participants (in the UC group or either intervention group) will be free to receive any treatment or services that are normally available.	• Additional information regarding the consent process will be sent to OHRP to help clarify consent issues.	The project involves multiple stages, with specific procedures for those stages: 1) Identification of participants from electronic medical records: waiver of informed consent 2) Assignment of participants to intervention or usual care groups: waiver of informed consent 3) Offer and delivery of intervention programs: alteration or partial waiver of consent (abbreviated online consent process) 4) Use of records data to ascertain outcomes: waiver of consent.

	• In each of the intervention conditions, the initial contact with each participant will clearly identify this as a research activity and will clearly state that participation is voluntary. Participants assigned to the UC group will not be contacted. For this group, after-the-fact notification that the study occurred would offer no additional protection, and attempting to contact participants would increase the risk of violating confidentiality. • The research could not practicably be carried out without the waiver or alteration. • No concerns were raised regarding the planned waivers of consent or waivers of documentation of consent.		
HIPAA	• The study is using a closed data system. • Dr. Simon believes that criteria for 45 CFR 164.512 are satisfied and that a waiver of HIPAA is acceptable. No concerns were mentioned.		
Monitoring and oversight	• Study intervention is one and the same with safety monitoring. • The study will not have much power until enrollment is halfway completed; this would probably be an appropriate point to start systematically reviewing safety data. • Concerns were raised about the need for a systematic and objective review for safety.	• The study will require a Data and Safety Monitoring Plan, which will be developed by the study team, and approved by NIMH prior to study implementation. NIMH will determine the level of independent oversight appropriate for the project, and whether a DSMB will be appointed for trial oversight.	The study is monitored by the NIMH Data and Safety Monitoring Board. Negotiating the terms and procedures for DSMB monitoring (via the NIMH DSMB) was a major barrier leading to significant delay and extra expense.

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Issues beyond the Suicide Prevention Trial	• None voiced.		None noted.
Conclusion of meeting	• Follow-up needed as noted in action items.	• A case study will be drafted to provide guidance for others on the process and value of open dialogue with regulators.	
Additional regulatory or ethics issue(s) that arose after the meeting			
Additional follow-up information			None noted.