Ethics and Regulatory Core

Strategies and Opportunities to Stop Colorectal Cancer (STOP CRC)

Gloria Coronado, PhD

Meeting Participants (May 29, 2013):

☒	Jeremy Sugarman (Johns Hopkins)	☒	Jerry Menikoff (OHRP)	☒	Wendy Weber (NIH)	☐	
☒	Rob Califf (Duke)	☒	Ivor Pritchard (OHRP)	☒	Josephine Briggs (NIH)	☐	
☒	Gloria Coronado (Kaiser Permanente)	☒	Russ Glasgow (NIH)	☒	Jonathan McCall (Coord Center)	☐	
☒	Sandy Heinz (Kaiser Permanente)	☒	Stephen Taplin (NIH)	☒	Tammy Reece (Coord Center)	☐	
☒	Amanda Petrik (Kaiser Permanente)	☒	Dave Wendler (NIH)	☒	Cheri Janning (Coord Center)	☐	
☒	Julie Kaneshiro (OHRP)	☒	Catherine Meyers (NIH)	☐		☐	

The minutes from the May 29, 3013 meeting were circulated to all participants on the call for two rounds of review and they reflect all corrections that were received.

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AGENDA ITEMS	DISCUSSION May 29, 2013	PROPOSED ACTION May 29, 2013	CURRENT STATUS as of June 9, 2015
Review of Demonstration Project	• Dr. Coronado gave an overview of the STOP CRC project, a 2-year, pragmatic, cluster-randomized trial to assess the effectiveness of an automated data-driven, EHR-linked program for mailing fecal immunochemical test (FIT) kits (with linguistically appropriate pictographic instructions and return postage) to patients who are due for colorectal cancer (CRC) screening. • Participating research sites: Kaiser Permanente Center for Health Research (CHR); Group Health Research Institute, and OCHIN. • Participating clinic sites (26) from several community health center organizations affiliated with OCHIN. • Clinics will be randomized to either an intervention or usual care (UC) condition. Intervention clinics will be offered training to deliver the STOP CRC program and track patient outcomes using EHR tools. • Costs and cost-effectiveness of the intervention relative to control (usual care) will be assessed. Secondary outcomes assessed by the study will include differences in CRC screening outcomes (e.g., for Hispanic ethnicity, primary language, poverty, and insurance status). The project will also assess adoption, implementation, potential maintenance, and spread of the program using a mixed-methods rapid assessment process, field notes, and other ethnographic data.		The project is using a shared IRB; all participating sub-contracts with partnering organizations including Group Health (Bev Green – Co-PI) and OCHIN have ceded to the KPNW IRB. All participating clinics maintain an active federal-wide assurance (FWA).

	• Kaiser Permanente NW IRB is the IRB of record for the pilot study and will be the IRB of record for the phase 2 study. All participating organizations have agreed to cede to KPNW IRB through an authorization agreement. • No concerns were raised regarding the study or the use of a single IRB of record.		
Minimal risk	• The first phase of the research is approved by the IRB as minimal risk (as of October 2012). • The FIT is part of standard clinical care. There are no harms or risks anticipated with increasing screening rates through the proposed intervention. Research data will consist of patient EHR data and information on clinics and providers. All data will be obtained with automated data extractions. Thus, the risk to subjects is minimal and limited to breach of patient confidentiality. Processes have been put in place to minimize this possibility. The study will not constrain the choice of tests or treatments offered to patients. • No concerns were raised about a minimal risk determination for the study.		
Consent (patient and physician)	• Interested in patients' responses to a low-intensity outreach program and limiting the sample to patients who have consented would diminish the generalizability of the findings. • Justification for waiver of consent reviewed and no concerns were raised.		The study team obtained approval for a waiver of informed consent. The plan did not change.

HIPAA	• The potential study population is large and it is not feasible to obtain HIPAA authorization on all participants. To obtain such authorizations, each patient would have to be contacted. Gathering and retaining contact information poses greater risk to potential participants than does access to EHRs, given the precautions in place. • Only study personnel who have signed a confidentiality agreement will have access to EHR data. Links to identifiers will not be transferred or stored at CHR. • Link to identifiers will be maintained only at OCHIN and will be destroyed after data analysis and manuscript writing is complete. No identifiers or links will be transferred to CHR other than limited data set elements including dates of service. • Dr. Coronado believes that the criteria for 45 CFR 164.512 are satisfied and the waiver of HIPAA is acceptable; no concerns about this were mentioned.		The study team obtained approval for a waiver of HIPAA authorization. The plan did not change.
Monitoring and oversight	• Currently, there is no official DSMB. • NCI does not require a fully appointed DSMB for this type of project. • There is currently no monitoring plan in place.	• The study will require a Data and Safety Monitoring Plan, which will be developed by the study team, and approved by NCI prior to study implementation. Although a DSMB would not be required for the trial, independent monitoring of the trial would likely be appropriate, and NCI staff will work with the study team to finalize the Plan.	The project has an official Data and Safety Monitoring Plan (DSMP) consisting of semi-annual review of study progress and adverse events by two independent monitors: a biostatistician and a retired gastroenterologist. Both monitors were approved by NCI staff.

Issues beyond the STOP CRC trial	• None voiced.		None.
Conclusion of meeting	• Follow-up needed as noted in action items.	• Case study will be written up to provide guidance for others planning similar trials to facilitate navigation of the ethics and regulatory issues.	
Additional regulatory or ethics issue(s) that arose after the meeting			None noted.
Additional follow-up information			None noted.