GroupHealth COOPERATIVE
Center for Health Studies

IMPACT OF DIFFERENT IRB PROCESSES IN A MULTI-SITE MAILED SURVEY

Sarah M. Greene MPH, Ann M. Geiger, PhD, for the CRN PROTECTS Project

The HMO CRN Cancer Research Network

SIGNIFICANCE

- Collaborative studies appropriately require IRB approval from every participating site
- Sites vary in interpretation of complex regulations, possibly resulting in:
  - Iterative reviews with the potential to impact project timelines and resources
  - Variation in site-specific project protocols that may compromise the consistency that characterizes high quality science

GOALS

- Characterize how various IRB review processes affected the conduct of a multi-site study
- Provide guidance to researchers and IRBs to optimize this important aspect of research

METHODS

Setting

- IRB processes were assessed for a study of patient outcomes following prophylactic mastectomy
- Six Cancer Research Network Sites
  - Group Health Cooperative
  - Harvard Pilgrim
  - HealthPartners
  - KP Northern California
  - KP Northwest
  - KP Southern California
- Each site has its own IRB

Nature of Study Data

- *MODE:* mailed patient survey
- *SURVEY CONTENT:* psychosocial impact of prophylactic mastectomy; some potentially sensitive questions
  - Depression, Body Image, Sexuality (single item)
- *MATERIALS:*
  - Introductory letter
  - Physician notification letter
  - 7-page questionnaire
  - Incentive valued at $5.00
  - Scripted reminder phone call

METHODS *(continued)*

Data Collection Process

Each site using the centralized survey firm enacted a Business Associate Agreement with the firm

Sites sent contact data directly to survey firm

Introductory letter, $5 incentive and questionnaire mailed

2nd letter & questionnaire mailed to non-responders three weeks after 1st mailing

Reminder calls to non-responders three weeks after 2nd mailing

(no phone administration of survey)

IRB Review Process

- Full IRB Committees performed initial review of study protocol
  - 3 of 6 sites required draft study materials with initial review
- All subsequent modifications and amendments received expedited review by the IRB
- Lead site prepared model IRB application for other sites to adapt
- Each site PI completed and shepherded own review with assistance from lead site
- Lead site maintained log of IRB submission types, dates and approvals
- IRB developments & challenges documented using minutes from biweekly conference calls

OUTCOMES

Outcomes of IRB Review

	Site A	Site B	Site C	Site D	Site E	Site F
# of IRB submissions	4	8	9	5	3	8
Type of incentive allowed	Cash	Cash	Coupon	Cash	Cash	Cash
Signature(s) on invitation letter	Site PI + subject's own MD	Site PI	Site PI + subject's own MD	Site PI	Site PI	MD with breast care program
Type of MD consent required before contacting subjects	Active/ Passive	None	Active	None	Passive	Passive
Contact materials edited by IRB	Yes	No	No	Yes	No	Yes
Protocol deviations resulting in additional costs	Data collection handled locally	Site-specific phone script for reminder calls	3rd wave of letters, one done by site not vendor	None	None	None
Response Rate	84.6%	75.4%	60.7%	76.0%	70.2%	73.7%

Notable Features of IRB Review Process

- Five IRBs agreed to centralizing data collection with an outside firm; Site A's IRB required procedures that precluded use of the survey firm—data collection was handled locally
- Five IRBs allowed the use of a $5 cash incentive; Site C's IRB required use of a coupon valued at $5
- Two sites required that subject's MD sign invitation letter in addition to the Site Principal Investigator
- Site F stipulated that the physician leader of the breast cancer screening program was the appropriate signatory, though this person was not involved in the project
- Requirement for physician notification/consent varied by IRB
- During reminder calls by survey firm, five sites' IRBs were acknowledged: "This study has been approved by {SITE} IRB." Site B IRB did not want the IRB mentioned in reminder call

DISCUSSION

Did these changes impact participation?

- Future research should address the possibility that protocol variations could result in differential participation
  - Signatories on introductory letters
    -Would women be more likely to participate if their own MD signed invitation letter?
  - Previous research has has shown that cash is more effective than coupons; could be a factor in our site specific response rates
  - Acknowledging IRB endorsement of study during reminder call
  - Timing of mailings & calls by one site handling data collection locally

Recommendations

- Researchers on multi-site studies should incorporate knowledge of site-specific IRB requirements into project planning & timeline
- Crucial for each site investigator to anticipate potential site-specific IRB issues during protocol development
- Dialogue is needed between HMORN researchers & IRBs to discuss possibilities for streamlining, centralization, reciprocity, especially for lower-risk studies
- IRB process should be re-evaluated given the evolution of the research climate

CONCLUSIONS

- In a multi-site environment, different IRB requirements can result in marked protocol variations, affecting consistency and efficiency of research
- As projects increase in complexity and number, the burden on IRBs will only increase
- With multi-site collaborations increasing, a systematic evaluation of the review process is needed
- Scientific and IRB communities should seek opportunities to develop strategies that will both facilitate the research review process and maintain scientific integrity

Poster design & layout by Kelly-Jane H. Denke, CHS Graphic Services