Unique IRB issues and other types of approval processes encountered in conducting disparities intervention research

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Topics

- IRB approval process
- Participant contact
- Data Use
- Social media

Map of Kaiser Permanente Northern California (KPNC) Service Areas

IRB approval process at KPNC

- KPNC's 2 IRB meetings have monthly face-to-face meetings.
- Meeting materials deadlines about a month prior to meeting
- Expedited reviews by single IRB reviewers conducted between monthly meetings
- KPNC is a single HIPAA entity so that IRB approval of a study application can apply to a single or multiple facilities.
- IRB applications for new research studies or for the addition of KPNC study sites require the following approvals for each facility:
  - Local research chair
  - Chief of Service
  - Physician In Chief
  - Area manager

Participant contact in intervention studies

- **Collaborative effort between researchers and clinical settings**
- **Political context of institution: Leadership / institutional buy-in and approval**
- **Role of the participant's physician.**
  - **Traditional clinical trial**
  - **Pragmatic trial**

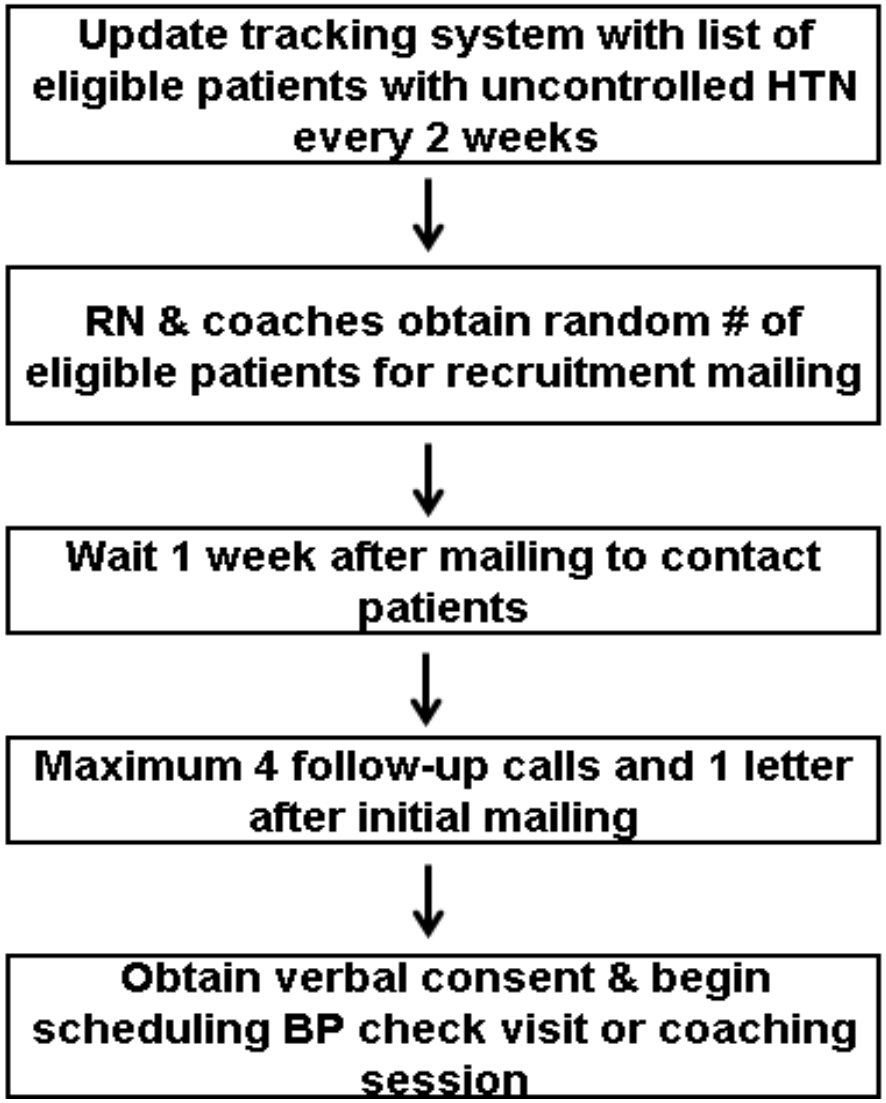
Data Use

- EHR data typically approved for IRB use:
  - Data-only studies with no participant contact
  - Studies in which participant has specifically consented to EHR review.
- Pragmatic trial creates new challenges because of the desirability of using data from individuals who do not respond to any contact efforts or decline to participate in the study.

Shake Rattle & Roll Trial - recruitment

- 3 arms
  - Usual care – IRB did not require participant contact or consent. Treated this arm as data only study.
  - Enhanced monitoring & lifestyle arms – standard IRB contact protocol (introductory letter, opt-out postcard, follow-up recruitment calls).

Recruitment workflow



Data Use Issues and IRB - Shake Rattle and Roll Trial

Postcard (submitted 1/23/2013)

[ ] Yes, I am interested in participating in the study

[ ] I am unsure about participating in this study, and may have some questions. Please call me; I have filled out the best way to reach me, below.

Best phone numbers: (__ __ __) __ __ __-__ __ __ __ [CIRCLE ONE]: home work cell other

(__ __ __) __ __ __-__ __ __ __ [CIRCLE ONE]: home work cell other

The best times in general to reach me are: _____

Times of day and days of the week

****

[ ] No, I do not wish to participate in the study.

[ ] No, I do not wish to participate in the study, but the study investigators may look at information relating to the management of my blood pressure.

Data Use Issues and IRB - Shake Rattle and Roll Trial

Data Use – those returning follow-up postcard after initial recruitment letter

- **1/24/2013:** IRB approved postcard with removal of choice to not participate in study, but to review health records for information relating to blood pressure
- **2/15/2013:** Appeal letter #1 to reinstate this choice, because of need to do "intention-to-treat" analysis
- **2/28/2013:** Appeal denied because allowing use of medical record is participation in the study, use of medical record data is not explained to participant, and revised postcard did not meet HIPAA PHI use and disclosure standards
- **3/14/2013:** Appeal letter #2 along with changes in the study participant contact letter and the IRB application to address the IRB concerns
- **3/28/2013:** Appeal denied because IRB still felt that active consent was required for health record review as a research activity and that it should be separated out in introductory letter and on postcard
- **4/25/2013:** Appeal accepted with revised letter and postcard

Data Use Issues and IRB - Shake Rattle and Roll Trial

Postcard (approved 4/25/2013)

[ ] Yes, I am interested in participating in the study.

[ ] Yes I am interested in participating in this study but have more questions. Please call me; I have filled out the best way to reach me below.

[ ] I am unsure about participating in this study and may have questions. Please call me; I have filled out the best way to reach me below.

Best phone numbers: (__ __ __) __ __ __-__ __ __ __ [CIRCLE ONE]: home work cell other

(__ __ __) __ __ __-__ __ __ __ [CIRCLE ONE]: home work cell other

The best times in general to reach me are: _____
Times of day and days of the week

****

[ ] While I do not wish to participate in the other study activities, the study researchers may review my medical record for blood pressure measurements, and for information that is related to blood pressure control including behaviors (such as smoking and physical activity), medications, and health conditions (such as stroke and heart disease).

[ ] No, I do not wish to participate in any of the study activities and do not give my permission to the study researchers to review my medical record. Don't call me

Enrollment report (as of 6/1/15)

	Usual Care	Enhanced	Lifestyle
Participants with high BP – ever	3599	3940	3475
Participants contacted	n/a	794	685
Participants enrolled	731	349	304
Unable to reach	n/a	272 (34%)	215 (31%)
If reached, consented	n/a	349/522 (67%)	304/470 (65%)
If reached, declined -- No EMR	n/a	93 (18%) 67 (72%)	110 (20%) 55 (50%)

Data Use Issues and IRB - Shake Rattle and Roll Trial

Data Use – those returning follow-up postcard after initial recruitment letter

- **4/1/2013:** **IRB denied inclusion of sentence in follow-up letter to non-responders to SRR recruitment efforts (>30%) that their medical records would be reviewed for hypertension-related information if they did not indicate that they didn't want health record review**
- **11/21/2013:** **Appeal #1, based on problems that would occur resulted to "intention to treat" type analysis**
- **12/19/2013:** **Appeal denied**
- **5/13/2014:** **Appeal #2, including reference to PAC report stating that absence of these data would be an "extremely serious threat to validity" of the study**
- **5/29/2014:** **Appeal accepted**

IRB – Use of Social Media

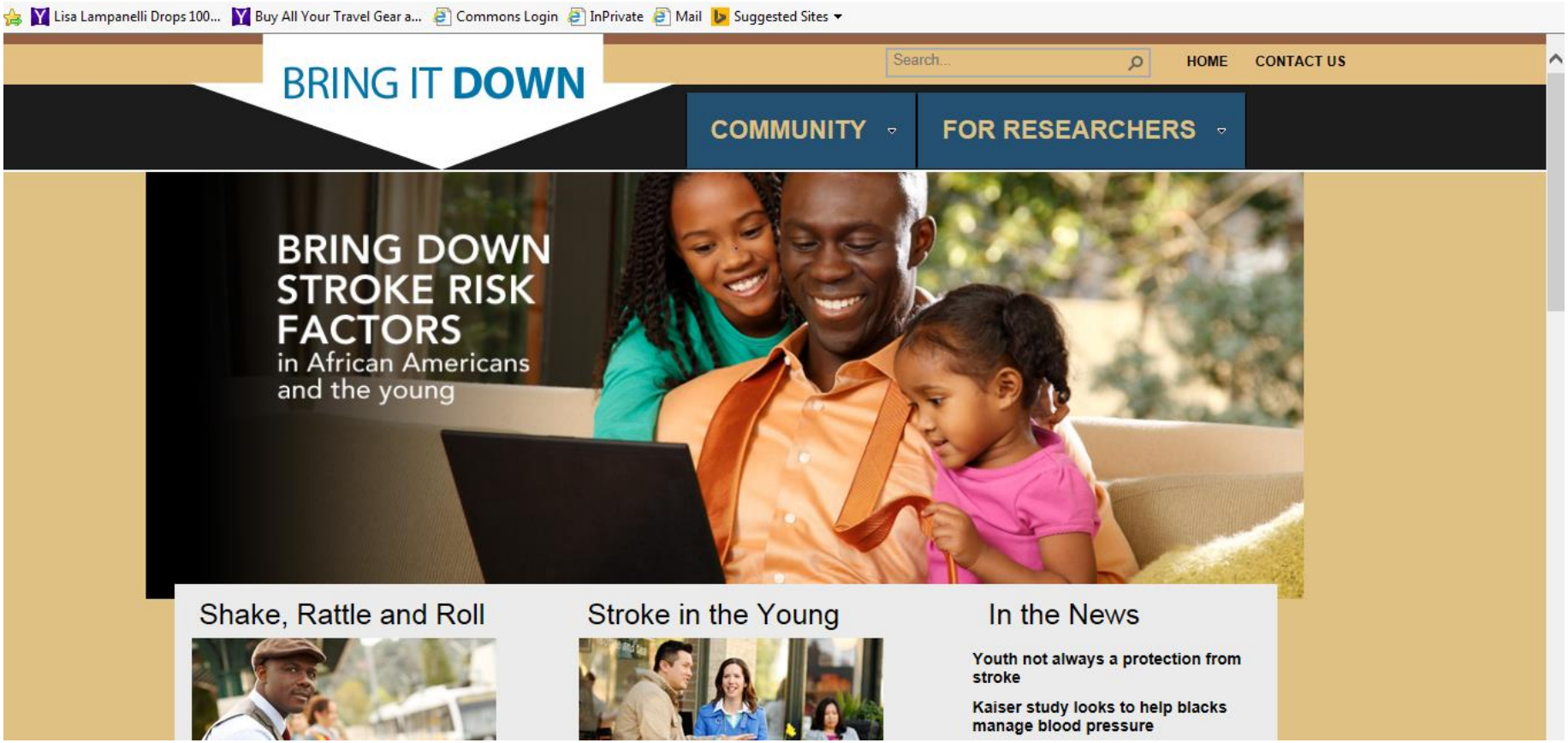
- 8/28/2013:
  - Presentation to IRB by Maureen McInaney, Associate Director of Communications at the DOR, regarding the use of social media for dissemination of research findings
  - Presentation educated and primed the IRB to approve our website and for the use of Twitter
  - Twitter had not been previously used in KPNC research studies

Using Social Media for Research That Requires Dissemination

Maureen McInaney
Associate Director Communications
Kaiser Permanente Division of Research

BRING IT DOWN website

http://www.bringitdownstudy.org/



Summary & Conclusions

- IRB negotiations, particularly about newer research practices, can be frustrating and require considerable time and patience.
- It is essential to educate the IRB about newer research practices.
  - Pragmatic trials have different data use requirements than traditional clinical trials.
  - Use of social media in research is relatively new and evolving.
- Input from external groups associated with a study (e.g., Community Advisory Board, Program Advisory Committee) may be helpful with problematic IRB issues.
- It is helpful to collaborate with the IRB to develop best practices regarding conduct of procedures that are common to many studies.