

Engaging the Community for Research Success: What Scientists and IRBs Need to Know

Community Engaged Research: Partnerships with Schools

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- Examples of projects within and with schools
 - Ethical considerations
 - Risk levels and categories of review
 - Review by schools and other partner organizations
 - Steps to engage parents and students
 - Steps to engage schools
- Community engaged research support

The Second Chance Club



Key JD, Barbosa GA, Owens VJ. *Journal of Adolescent Health* 28(3):167-169, 2001.

O'Rourke KM, Key JD. *International Quarterly of Community Health Education* 23(3):253-262, 2005.

Key JD, O'Rourke K, Judy N, and McKinnon SA. *International Quarterly of Community Health Education* 24 (3):231-240, 2005-2006.

Key JD, Gebregziabher M, Marsh LD, and O'Rourke KM. *Journal of Adolescent Health* 42(4):394-400, 2008.

- Office of Adolescent Pregnancy Programs, DHHS 2001-2006
- School-based secondary pregnancy prevention program with hospital-based teen-tot clinic
- Located in Title 1 High School
- Data included chart review, surveys, focus groups, birth certificate data (all identified)
- MUSC full IRB review with off campus form from school
- Signed witnessed parental consent, participant assent

The Second Chance Club



- Developed following invitation from the high school
- Existing partnership with the school (school-based health center, school improvement council)
- School participation in planning the program
- >95% enrollment
- About 25% of participants were not previously identified by the school (referred by participants or self-identified)
- **Lesson Learned: Allow unanticipated/alternative methods for recruitment (Build a good program and they will come)**

Best Chance



Beyer C, O'Rourke K, Key J, Evans E, Lewis- Kendrick Z.
Recruitment Issues in Obtaining Written Parental Consent
for an Adolescent School-based Sexuality Education
Program. School Health Conference of the American School
Health Association Conference, Pittsburg, PA, October, 2004.

- Office of Adolescent Pregnancy Programs, DHHS 2002-2007
- Prospective group randomized trial of “Sex Can Wait” with and without teen developmental component
- Located in Title 1 Middle School & developed collaboratively with principal and staff, but moved after grant funded
- Data included identified survey about sexuality knowledge, attitude and behavior
- MUSC IRB full review with off campus forms signed by schools
- Witnessed, signed parental consent, participant assent

Best Chance



Beyer C, O'Rourke K, Key J, Evans E, Lewis- Kendrick Z. Recruitment Issues in Obtaining Written Parental Consent for an Adolescent School-based Sexuality Education Program. School Health Conference of the American School Health Association Conference, Pittsburg, PA, October, 2004.

- Developed with one school then moved to another resulting in 1 year delay
- **Lesson Learned: Relationship with school can be built after project begins but its harder**
- Inadequate enrollment at school events due to low attendance, 90/312 (29%)
- Home visits to enroll participants
- Final enrollment 269/312 (82%)
- Cost of enrollment (employee work + travel) = \$62.95/subject
- Increasing costs of enrollment as approached 80% enrollment
- **Allow for expense of recruitment**

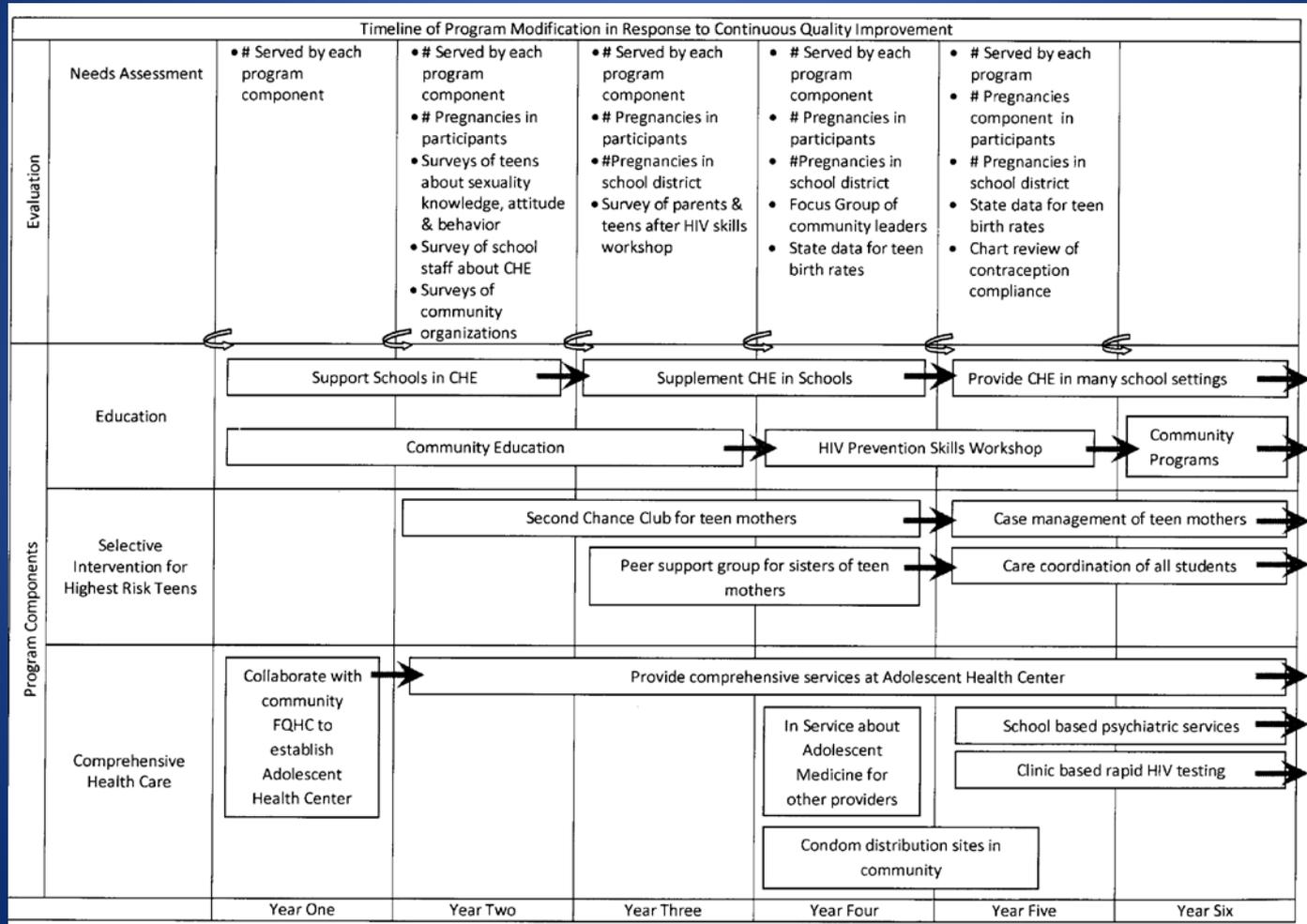
Sea Islands Teen Opportunity for Prevention Programs



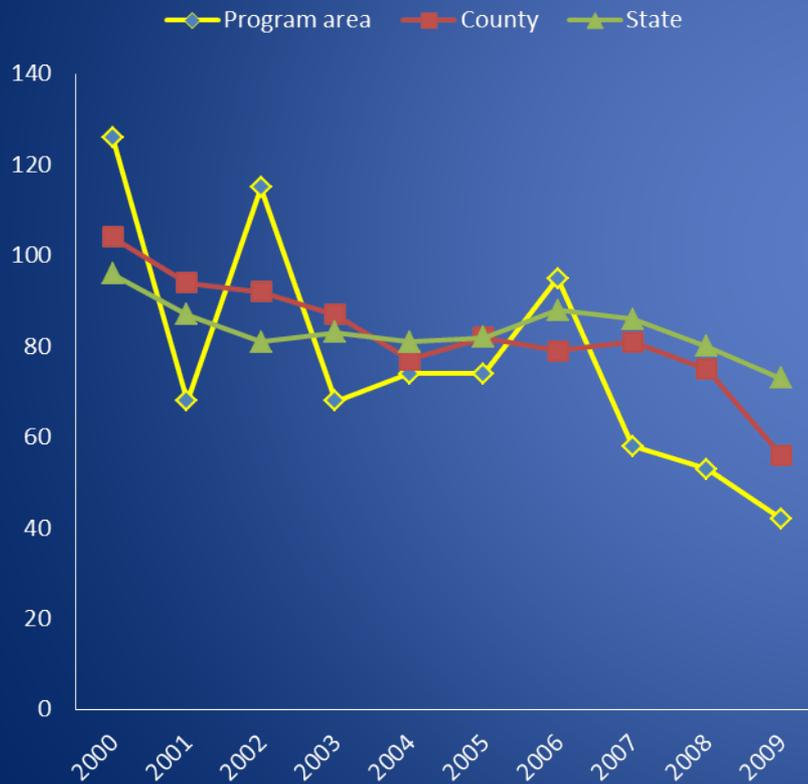
Key JD, Hoffman CM+, Neal D, Hulsey TC. Teen Pregnancy in South Carolina: A Local Needs Assessment of Charleston County. *The Journal of the South Carolina Medical Association* 99:360-364, 2003.

- New Morning Foundation, 2004-2012
- Developed following needs assessment with community and school input
- School-based, community multicomponent teen pregnancy prevention program
- Located in rural school constituent district (high school, middle school and 3 elementary schools – all Title 1)
- Primarily a service project with program improvement data including clinic utilization, attendance in educational programs, birth certificate DHEC data, etc.
- Outside evaluation
- Internal evaluation of subgroups including focus groups and surveys
- Full IRB approval with off campus forms for focus groups but not program improvement information
- No school IRB

Sea Islands Teen Opportunity for Prevention Programs



Sea Islands Teen Opportunity for Prevention Programs



- Ongoing close collaboration with school to the point that program is “embedded” in school
- Facilitation of recent survey conducted by outside evaluator for survey of middle and high school students
- **Lesson Learned: Programs that work require constant modification based on outcomes**
- **Lesson Learned: Outside evaluation cannot be completed without program support**

The Lean Team: The Boeing Center for Children's Wellness



- Many funders since 2007: Duke Endowment, SC DHHS, Food Lion, Coastal Community Foundation, Junior League, ESMM SC, Boeing

- Developed following 15 years of collaboration with school district through CCMS School Health Committee

- Constantly evolving “portfolio” of programs and approaches
- Overall program goal of obesity prevention, wellness promotion



www.musc.edu/leanteam

The Lean Team: The Boeing Center for Children's Wellness



- 2008 prospective study using identified repeated measurement (height, weight) and survey of nutrition and physical activity
- Approval by school IRB with consent from each participating school
- Expedited MUSC IRB approval with waiver for Protected Health Information
- Witnessed signed parental consent and participant assent
- Consent printed on letterhead for each school
- Students enrolled & baseline measurements obtained at school events with parents present (n=601)

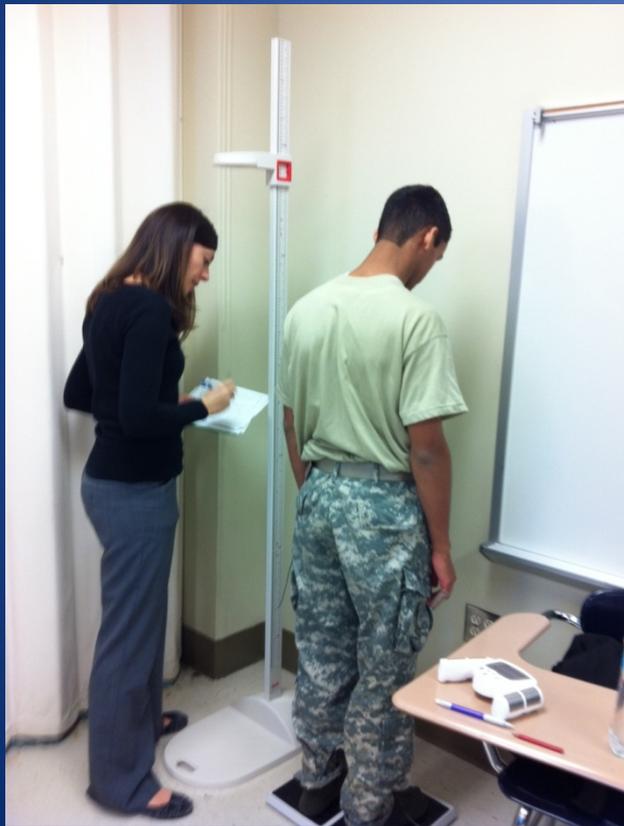
•Key JD, Oexmann MJ, and Russell AM. Community and school-based interventions to prevent obesity in children and adolescents. *Journal of the South Carolina Medical Association* 105:59-63, 2009.

The Lean Team: The Boeing Center for Children's Wellness



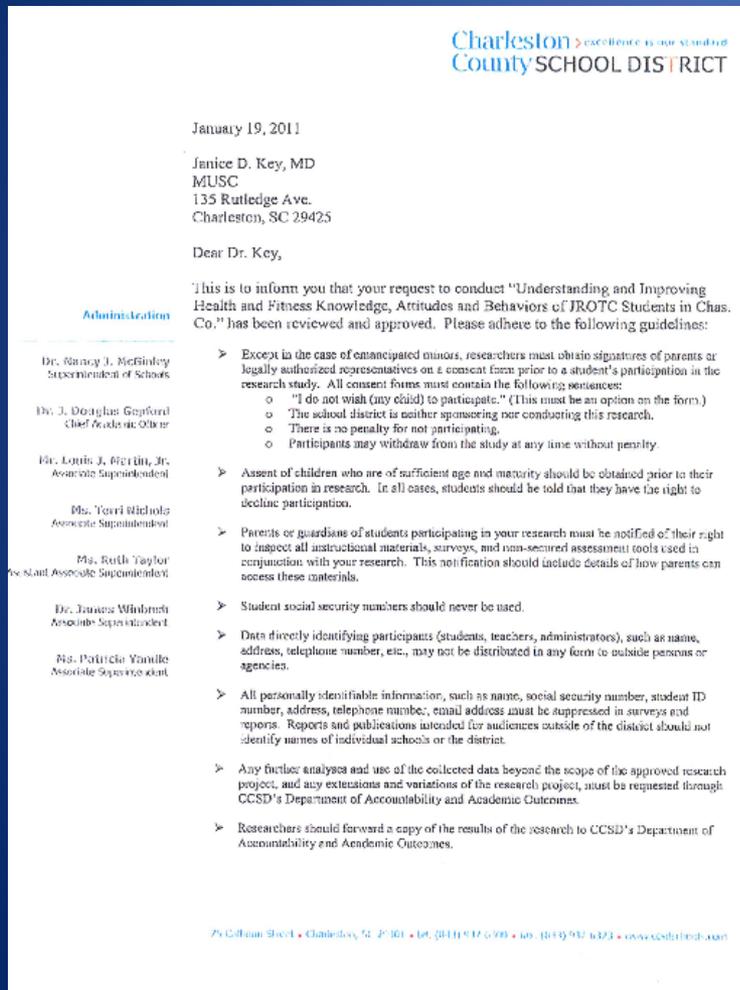
- 2011 Docs Adopt
- Goal to support school wellness efforts by recruiting & training physicians for each school's committee
- Data included survey (paper/web-based and telephone) of participating physicians
- Exempted MUSC IRB approval
- No school approval required

Southeastern Virtual Institute for Health Equity and Wellness: JROTC Study



- 2010 Department of Defense
- Prospective study of JROTC students in 11 high schools, assessing obesity and fitness
- Data includes identified weight, height, % body fat, and survey about daily nutrition, physical activity
- MUSC full IRB approval with off campus form for each high school
- School IRB approval
- New school “boilerplate” approval letter
- DOD IRB approval
- Signed (not witnessed) parental consent, participant assent

Southeastern Virtual Institute for Health Equity and Wellness: JROTC Study



- Approval obtained from school → MUSC → DOD (but DOD recommended → their initial approval)
- DOD required statement from an outside expert stating research had been reviewed and found scientifically valid
- DOD required more stringent adherence to school IRB approval than did the school district itself
- Required several presentations to parents (with very low attendance) to discuss study
- **Lesson Learned: Ask for specific assistance with regulatory bodies**

South Carolina Clinical & Translational Research Center for Community Health Partnerships (SCTR/CCHP)



Learn. Link. Leverage. Lead.

SCTR/CCHP's Vision, Mission & Goal

Vision:

To transform health care and eliminate health disparities by engaging community-academic partnerships in South Carolina and beyond.

Mission:

To engage community members and academic partners in research and initiatives that promote health, reduce the risk of illness and disease, and build community resilience to help transform health care and eliminate health disparities.

Goal:

To promote the translation, implementation, diffusion, and adoption of evidence-based interventions and treatments in clinical and community settings, designed to improve the health of diverse populations.

Community Based Research & IRB Guidance

MEDICAL UNIVERSITY OF SOUTH CAROLINA COMMUNITY ENGAGEMENT IN RESEARCH



MUSC Researchers may contact the IRB or Success Center early in the planning phase of the study and prior to submitting an application to discuss:

- Application process
- Types of Assurances that may be needed
- Scope of research activities and engagement of community partners in those activities
- Human subjects education training (CITI) that may be needed and options for community partners
- Responsibility of the MUSC Researcher and Community Partner

eIRB application is submitted

IRB evaluates and reviews

Study approval is granted when:

- All engaged community partners have completed required human subjects training.
- The Community Partner has provided a Letter of Support to the IRB. (if required)
- All FWA and IAA's are signed by the community partner Institutional official and the MUSC University Institutional Official if the site is engaged in research and provided to the IRB.
- All contingencies regarding the study have been resolved.
- BAA or Data Usage Agreement Signed and provided to IRB.
- Notification of study approval will be sent to the MUSC Researcher via eIRB. The MUSC Researcher is responsible for communicating with the community partner.
- MUSC will provide oversight for community engaged research studies done in collaboration with MUSC investigators if granted this authority thru the FWA/IAA process.

Engagement of the CP for regulatory purposes

Not Engaged

-No further action is needed regarding assurances or human subjects training for community partners. This may still be listed as a non-engaged research site on IRB submissions using the Off Campus Site Form.
- Letter of Support may be required

Not Engaged But Collecting Identifiers

-PI's should speak with ORSP about Data Usage Agreement and/or Business Associates Agreement
-Letter of Support may be required from CP
-Complete Off Campus Site Form

CP Engaged

FWA may be needed
-Complete Off Campus Site Form
-Letter of Support may be required

CP Applies for FWA

FWA covers both CP and employees of CP

Human subjects' training is required. (CITI MIAMI)

Based on chart from wustl.edu (with permission)

Thank you



*Please join the Lean Team and walk the Ravenel Bridge
Saturdays, 9am (8am starting in April)
www.musc.edu/leanteam*