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### The likelihood of participation in clinical trials can be measured: The Clinical Research Involvement Scales (CRIS)

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#### Abstract

**Objective**—We developed the Clinical Research Involvement Scales (CRIS) to assess clinical trial willingness-to-participate.

**Study Design and Setting**—Diverse populations (N=919) aged  $\geq$  18 years from Atlanta, Georgia were included in comprehensive testing of the 41-item CRIS instrument. The formative phase focused on item content for the new measures (n=54). Questionnaires from potential vaccine trial participants (n=865) collected at multiple timepoints resulted in evaluation of scale reliability and validity (i.e., attitudes, behavioral and normative beliefs, perceived social support for clinical research participation, social norm compliance, perceptions of the clinical research organization, and perceived relevance of the research endeavor).

**Results**—Qualitative testing revealed adequate comprehension and content validity of the initial item set. The subjective norms domain (n=3) initially exhibited poor internal consistency in pilot testing (Cronbach's  $\alpha = 0.525$ ), yet rewording of the items resulted in consistently stable measurement improvement (Cronbach's  $\alpha = 0.850$ ). Each of the CRIS subscales demonstrated extremely high reliability, ranging from 0.734 – 0.918. Confirmatory factor analysis verified itemfactor relationships and determined construct and convergent validity (RMSEA=.068; CFI=0.835).

**Conclusions**—CRIS is a reliable instrument for measuring community attitudes toward participation in biomedical research studies. Results of this study support the use of these scales to recruit diverse populations to clinical trials.

#### Keywords

HIV Psychometrics; HIV Vaccines; Patient Selection; African Americans; Women

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#### Introduction

The achievement of diverse participation in clinical trials is critical to the attainment of new therapies and prevention products [1,2]. Although evidence exists on underrepresentation of specific groups in clinical studies [3,4], there is a dearth of information on how communities become engaged in clinical research and on the development of tools to systematically measure public opinion [5–8]. Moreover, little attention has been given to theoretically-driven measurement of social and network-level factors that may influence study recruitment [2,9].

Important policies have been implemented to address inclusion of underrepresented groups in research [10]. For example, studies funded by the United States National Institutes of Health (NIH) are subject to the 1994 mandate specifying inclusion of women and minorities in sponsored research [11–15]. Despite support for the community engagement in clinical studies, the development of psychometric measures to assess acceptability of clinical research has not been the focus of empirical investigations. We were able to locate two studies that conducted psychometric analyses to assess willingness-to-participate among minorities [16,17]. Yet, we were unable to locate any valid and reliable instruments that measure predisposing attitudes, perceptions, and beliefs toward clinical research participation that can be administered in a variety of field settings, and that are appropriate for diverse populations.

Our previous findings indicated that constructs from established behavioral theory including the Theory of Reasoned Action (TRA) may be useful in predicting clinical trial involvement among African Americans [18]. Among racial and ethnic minorities, willingness-to-participate extends beyond reasoned appraisal of the research endeavor (i.e., perceived benefit of a new product to self and community) to affective considerations (i.e., trust in researchers) [19–21]. Previous studies of minorities' clinical trials participation and other forms of elective health behaviors (i.e., bone marrow donation) suggest that decisional pathways are complex and have strong emotional components [7,22,23]. Although participation of women and minorities in research may be hindered by many issues, there are factors that may facilitate greater involvement of those who may not have considered participating in clinical trials [19,21,24,25]. Favorable appraisal of the clinical research organization and its community interactions, demonstrated respect for study participants, and other organizational attributes may serve as motivators for minorities to participate in studies [26–29].

We developed and evaluated our measures to specifically understand the factors driving community participation in HIV vaccine research, as it is generally more difficult to accrue study volunteers in this field compared to other types of clinical research [30,31]. Under these rigorous conditions, our study sought to identify the predictive validity of the CRIS instrument to gauge participatory intentions of those whose involvement is needed.

#### Methods

#### Study design and sample

There were five waves of recruitment for this study spanning from March 2007 to January 2008 resulting in a sample of 919 participants. A convenience sample of 54 individuals from a community-based HIV educational event, the "African American Outreach Initiative," participated in the formative phase of this study (phase one). This two-day annual forum focuses on HIVAIDS education tailored to the needs of African Americans. This event provided an opportunity to test the preliminary instrument for length acceptability and to

In subsequent phases, a venue-based sampling strategy was utilized for recruitment to occur during randomly selected blocks of time. This method has proven successful in obtaining representative populations in cross-sectional survey samples [32]. Our target populations included those whose participation is sought in HIV vaccine research including men-who-have-sex-with-men, transgender persons, and minority women. Venues were selected by study staff and partner agencies that hosted HIV vaccine-related functions in these settings. The study staff determined venue suitability based upon discussions with agency staff, target population observation at the locations, and other considerations (e.g., safety). Project assistants performed recruitment and data collection based on a master schedule of monthly activities. The sampling frame included 28 locations including churches, bookstores, educational forums, health fairs, community meetings, and special events such as Pride festivals that demonstrated the potential to recruit an adequate number of participants within identified timeframes.

Study settings were located throughout metropolitan Atlanta, Georgia. Persons were eligible for this study if they were ≥18 years of age and could read and speak English. Approximately 1,100 people were invited to participate and 919 provided written informed consent (response rate =84%). A health promotion incentive was offered for participation. The Emory University Institutional Review Board approved the study protocol prior to study implementation.

#### Procedures

The scale items were developed based on previous quantitative and qualitative research findings, literature review, and HIV clinical and community experience [27,33–38]. Qualitative research focusing on HIV trial issues among women and minorities was content analyzed to form the basis of questions regarding beliefs and attitudes [33,39,40].

New items were developed for most of the domains based on recommendations by TRA theory progenitors [41,42]. Variables included willingness to participate in clinical research, subjective norms, attitudes, motivations, and beliefs about engaging in clinical research. A team of clinicians, psychometricians, and behavioral researchers reviewed the instrument for adequacy of the measures.

#### **Scale Measures**

The following briefly describes each CRIS domain. The CRIS inventories used the summative response format, a 5-point Likert scale (1-strongly agree to 5-strongly disagree), to assign meaningful values to an underlying continuum of ratings [43].

**Attitudes**—Much of the literature has focused on the importance of the attitudinal domain for study recruitment, looking at factors like negative attitudes toward health research, its role in the community, and the benefits arising from clinical study participation [5,29,40,44].

**Subjective Norms**—Participants were asked if they thought people, including family and friends, would support their participation. Favorable social opinion of research involvement is theorized to increase participatory intention.

**Behavioral Beliefs**—Beliefs about medical research favoring participatory behavior should increase intentions to become a study volunteer.

**Outcome Evaluations**—Issues related to HIV vaccine trial participation such as concerns related to time and trouble related to study participation, fear of needles, risk aversion, and potential problems arising from vaccine-induced seropositivity were measured by this domain.

**Normative Beliefs**—Participant beliefs about the effects of research on a community should influence subjective norms and participatory intentions.

**Motivation to Comply**—The theorized influence of family, friends, and others on behavioral performance will exert social pressure to act or engage in avoidance of performing the behavior (i.e., rejecting opportunity to become a study volunteer). Greater self-agency should lead to greater participatory intention.

**Organizational Involvement**—These items measure perception of the clinical research site and the extent to which persons identify with its research agenda. We adapted the items from marketing literature measuring "brand involvement" (i.e., engagement with entities producing consumer products) [45–48] and theorized their independent prediction or mediation on subjective norms and intentions [41,42].

**Personal Relevance of Volunteerism**—The marketing "involvement" construct is closely linked to values and interests, along with inherent needs [49]. We renamed consumer "involvement" as "personal relevance" which may exert influence on behavioral intention.

#### **Statistical Analysis**

In the first phase, an exploratory factor analysis with varimax rotation was conducted with 51 items resulting in a 13-factor solution that explained 85.4% of overall variance. Factor loadings identified cognitive domains, low item communalities, and facets that could be enhanced in future iterations.

The second phase included a principal components factor analysis with varimax rotation resulting in an eight-factor solution. Reliability estimates were obtained for all CRIS factors. We determined that a Cronbach alpha reliability estimate of  $\geq 0.70$  would support reliability of each CRIS subscale [50–53].

Lastly, we included a check for multicollinearity followed by confirmatory factor analysis. Bivariate correlations were computed for all indicators as a first step in factor structure validity. This study included a confirmatory factor analysis of measurement fit to establish the components of the factors by estimating the strength of the relationships between indicators and constructs with 486 complete cases that did not contain any missing outcome data (i.e., intention to become an HIV vaccine study volunteer) [54]. One indicator per construct was fixed to define the scales of the indicators. An *a priori* alpha level was set at p < .05 for all factor patterns.

This study generated fit indices for the measures. A chi-square statistic was produced along with the Standardized Root Mean Square Error of Approximation (RMSEA). Values less than 0.08 are acceptable [43].We also used the comparative fit index (CFI) as an ideal measure in structural equation modeling research [43]. CFI good fit guidelines suggest that a good fit is > 0.90, an adequate/marginal fit is 0.80 to 0.90 [43,55].

#### Results

#### Subjects

Table 1 details population characteristics by testing phases. The population characteristics were similar for phases two and three with the exception of gender (t=2.3, p=.022) and age (t=5.77, p<.001). The first AAOI sample was demographically different than the other venue-recruited samples except for age (t=1.28, p=.205). The similarities between the other two samples ensured stability of scale estimates which were remarkably consistent across all phases.

#### Phase One: Formative Phase

The first instrument was tested with participants of the "African American Outreach Initiative" in March 2007 to assess item phrasing and respondent understanding. Study staff was available to answer any potential inquiries and were instructed to catalogue participant comments for instrument evaluation. The questionnaire Flesch Reading Ease (62.7) and Flesch-Kincaid (6.8) scores were acceptable, corresponding with a  $6 - 8^{th}$  grade reading level fluency [56].

In this first phase, participants (n=54) completed a questionnaire that included 75 questions inclusive of CRIS scale items. The formative results indicated difficulty with questionnaire completion given participant fatigue and time constraints; therefore, the resulting questionnaire reduced scale items to 41 from the original 51 items.

#### Phase Two: Pilot Phase

The second phase of data collection occurred from May 2007 to July 2007. Two study team members evaluated the merit of each item and made changes to the instrument. We were able to reduce the reading level (6.7) and reading ease (61.8) scores. The completion time was also reduced from 25 minutes to  $\leq 20$  minutes.

The results indicated that, with the exception of "subjective norms" (Cronbach's  $\alpha = 0.525$ ), the reliabilities of the initial subscales had moderate to high internal consistency (Cronbach's  $\alpha = 0.714-0.925$ ) (Table 3). Assessment of the "personal relevance" (n = 7 items) resulted in the highest level of internal consistency among scales (Cronbach's  $\alpha = 0.925$ ). Item total correlations ranged from 0.708 to 0.811. Construct validity was assessed for the "personal relevance" scale and the subsequent factor analysis confirmed the unidimensional nature of the measure, with a distinct factor of 7 items that explained 70% of the variance in the data.

#### Phase Three: Instrument Validation

**Reliability Analysis**—Phase three data (n=653) was analyzed with three groups, to examine if reliability measures for the 41 items held constant among similar samples and over different time periods. In this phase we were able to gather a more representative ageeligible population of potential study participants for HIV vaccine studies (mean age = 35.9 years) as the studies typically enroll those ages 18 to 50 years. This population more reasonably approximated a pool of study-eligible volunteers. Each of the 8 scales demonstrated strong reliabilities, with standardized Cronbach's alpha statistics that ranged from 0.734 to 0.918. After rewriting the subjective norms items, reliability increased from 0.525 to 0.851. Personal relevance exhibited the strongest reliability over time with consistent alpha values of 0.912 to 0.927. When the total sample was analyzed, the standardized Cronbach's alpha reliabilities ranged from 0.734 to 0.918. Examination of the subsets of women and minorities resulted in similar alphas for these groups (0.754 to 0.920).

**Measurement Model Testing**—Bivariate correlations were computed for factor structure validity. A subsequent check of factor correlations validated the unidimensionality of each domain. Correlations of the eight factors' composite scores indicated that multicollinearity was not a concern for individual items or the factor structure with the intercorrelation threshold set at  $\geq 0.85$  [57]. The subset included in the model testing (N=486) was remarkably similar to the larger sample (N=657) on all demographic characteristics (e.g., gender:  $\chi^2$  (3)=3.94, p=.268; race:  $\chi^2$  (1)=.993, p=.334).

Factor analysis results support the validity of the constructs. Loadings were consistent with most items in the range of  $\geq$  .448 to  $\leq$  .867. The only low factor loading ( $\leq$ .50) was the attitude measure of HIV being a serious community concern (Table 3). The confirmatory factor analysis results showed an acceptable model fit to the data (RMSEA = .068; CFI = 0.835) demonstrating construct validity.

#### Discussion

This study applied six concepts of the Theory of Reasoned Action in addition to two adapted scales to assess individual readiness for clinical research. Specifically, we uncovered important pathway effects that favor diverse community participation in HIV vaccine research. Although we assessed broader clinical trial concerns such as health issue relevance and concerns about peer perceptions in this study, it is important to note that we also assessed aspects that are relevant to healthy, uninfected persons' decision-making on participation in HIV vaccine trials (e.g., vaccine-induced seropositivity). Understanding the critical factors that promote women and minorities' engagement in this type of clinical research is an important step in the formulation of community engagement efforts. Measuring community sentiment over time will enable study teams to develop tailored programs that hone in on contextual issues to facilitate timely recruitment.

Phase one demonstrated the steps in an effective instrument development process. The second phase was useful in developing the factor structure and gauging preliminary reliability estimates. The final Clinical Research Involvement Scales (CRIS) consist of 41 items that exhibit good internal consistency ( $\alpha$  range = 0.730–0.917). This instrument provides a tool to further explore the personal and socio-community factors that promote community engagement in clinical research with healthy persons.

#### **Study Limitations and Strengths**

This theory-based instrument provides multidimensional measures of factors that affect willingness-to-participate in health studies. Construct validity was established for the domains associated with trial participation. The information obtained from the CRIS can help community educators, outreach staff, and study investigators establish evidence-based priorities for community engagement activities and therefore design more effective and efficient programs in a variety of field settings.

We acknowledge the limitations in this study. The instrument would benefit from further reliability testing. The design of this study did not allow for test-retest reliability. Further replications with different populations other than lower-income Southern populations should be conducted. CRIS should be adapted for use outside of the realm of HIV biomedical prevention field in order to confirm the factor structure found in our analysis. Predictive or criterion validity was also not tested given the lack of instrumentation available in this arena.

#### Conclusions

The CRIS is a reliable and valid questionnaire for measuring multiple psychosocial determinants of study participation unique to clinical research. Development of this instrument will encourage and enable further evaluation efforts of community efforts to promote biomedical research, in addition to providing a model for other community engagement measures.

#### What is New?

#### **Key Finding**

The "Clinical Research Involvement Scales" (CRIS) instrument is a reliable and valid questionnaire for measuring multiple determinants of study participation for clinical research. This study builds upon what is known about clinical trial recruitment challenges and the factors contributing to underrepresentation of specific groups in clinical studies by offering a measurement tool to systematically assess willingness-to-participate in clinical research.

#### What is the Implication

The CRIS questionnaire enables researchers to measure the likelihood that individuals will participate in clinical research studies.

#### What Should Change Now

Use of this questionnaire will help community educators, outreach staff, and investigators establish evidence-based priorities for community engagement activities and therefore design more effective and efficient recruitment programs.

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#### References

- 1. Nash D. Issuing an EDICT. Pharmacy and Therapeutics 2007:32.
- Carter RE, Sonne SC, Brady KT. Practical considerations for estimating clinical trial accrual periods: application to a multi-center effectiveness study. BMC Medical Research Methodology 2005;5:1–5. [PubMed: 15636638]
- 3. Simon V. Wanted: women in clinical trials. Science 2005;308
- 4. Seto B. History of medical ethics and perspectives on disparities in minority recruitment and involvement in health research. Am J Med Sci 2001;322:246–250.
- Comis RL, Miller JD, Aldige CR, Krebs L, Stoval E. Public attitudes toward participation in cancer clinical trials. Journal of Clinical Oncology 2003;21:830–835. [PubMed: 12610181]
- Murthy V, Krumholz H, Gross C. Participation in cancer clinical trials: race-, sex-, and age-based disparities. JAMA 2004;291:2720–2726. [PubMed: 15187053]
- Curbow B, Fogarty LA, McDonnell KA, Chill J, Scott LB. The role of physician characteristics in clinical trial acceptance: Testing pathways of influence. Journal of Health Communication 2006;11:199–218. [PubMed: 16537288]

- Wendler D, Kington R, Madans J, Wye GV, Christ-Schmidt H, Pratt LA, et al. Are racial and ethnic minorities less willing to participate in health research? PLoS Medicine 2006;3:e19. [PubMed: 16318411]
- Lovato LC, Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for controlled clinical trials: literature summary and annotated bibliography. Controlled Clinical Trials 1997;18:328–352. [PubMed: 9257072]
- 10. Wood, A.; Grady, C.; Emanuel, EJ. The crisis in human participants research: identifying the problems and proposing solutions. Available at http://www.bioethics.gov/emanuelpaper.html
- 11. New schemes aim to boost minority participation in research. Nature Medicine 2007;13:764-765.
- 12. United States Government. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. National Institutes of Health. 1994
- Wermeling D, Selwitz A. Current issues surrounding women and minorities in drug trials. Ann Pharmacother 1993;27:904–911. [PubMed: 8364277]
- Baird K. The new NIH and FDA medical research policies: Targeting gender, promoting justice. J Health Politics Policy Law 1999;24:531.
- 15. Haynes, M.; Smedley, B., editors. The Unequal Burden of Cancer: An Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved. Washington, D.C.: National Academy Press; 1999.
- Katz RV, Kegeles SS, Kressin NR, Green BL, Wang MQ, James SA, et al. The Tuskegee legacy project: Willingness of minorities to participate in biomedical research. Journal of Health Care for the Poor and Underserved 2006;17:698–715. [PubMed: 17242525]
- 17. Sengupta S, Strauss RP, DeVellis R, Quinn SC, DeVellis B, Ware WB. Factors affecting African-American participation in AIDS research. J Acquir Immune Defic Syndrome 2000;24:275–284.
- Frew PM, Archibald M, Martinez N, del Rio C, Mulligan M. Promoting HIV Vaccine Research in the African American Community: Does the Theory of Reasoned Action Explain Potential Outcomes of Involvement? Challenge. The Journal of the Morehouse Research Institute 2008;13:61–97.
- Smith YR, Johnson AM, Newman LA, Greene A, Johnson TRB, Rogers JL. Perceptions of clinical research participation among African American women. Journal of Women's Health 2007;16:423– 505.
- 20. Gamble V. Under the shadow of Tuskegee: African Americans and health care. American Journal of Public Health 1997;87:1773–1778. [PubMed: 9366634]
- Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. Journal of General Internal Medicine 1999;14:537–546. [PubMed: 10491242]
- 22. Bagozzi RP, Lee K, Van Loo MF. Decisions to donate bone marrow: The role of attitudes and subjective norms across cultures. Psychology & Health 2001;16:29–56.
- 23. Davis C, Randhawa G. The influence of religion on organ donation and transplantation among the Black Caribbean and Black African population--a pilot study in the United Kingdom. Ethnicity & Disease 2006;16:281–285. [PubMed: 16599384]
- Shavers-Hornaday VL, Lynch CF, Burmeister LF, Torner JC. Why are African Americans underrepresented in medical research studies? Impediments to participation. Ethnicity and Health 1997;2:31–45. [PubMed: 9395587]
- 25. Khaliq W, Gross M, Thyagarajan B, Jones-Webb R. What motivates minorities to participate in research? Minnesota Medicine 2003;86:39–42. [PubMed: 14621943]
- Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. J Natl Cancer Inst 1995;87:1747–1759. [PubMed: 7473831]
- Frew PM, del Rio C, Clifton S, Archibald M, Hormes J, Mulligan MJ. Factors influencing HIV vaccine community engagement in the urban South. Journal of Community Health 2008;33:259– 269. [PubMed: 18389351]
- 28. Gorelick PB, Richardson D, Hudson E, Perry C, Robinson D, Brown N, et al. Establishing a community network for recruitment of African Americans into a clinical trial. The African-American antiplatelet stroke prevention study (AAASPS) experience. Journal of the National Medical Association 1996;88:701–704. [PubMed: 8961687]

- BeLue R, Taylor-Richardson KD, Lin J, Rivera AT, Grandison D. African Americans and participation in clinical trials: Differences in beliefs and attitudes by gender. Contemporary Clinical Trials 2006;27:498–505. [PubMed: 16962382]
- Frew PM, del Rio C, Lu L, Clifton S, Mulligan M. Understanding differences in enrollment in a Phase IIb HIV vaccine trial among high-risk populations. Journal of Acquired Immune Deficiency Syndrome 2009;50:314–319.
- 31. Djomand G, Katzman J, di Tommaso D, Hudgens MG, Counts GW, Koblin BA, et al. Enrollment of racial/ethnic minorities in NIAID-funded networks of HIV vaccine trials in the United States, 1988 to 2002. Public Health Reports 2005;120:543–548. [PubMed: 16224987]
- Muhib F, Lin L, Stueve A, Miller R, Ford W, Johnson W, et al. A venue-based method for sampling hard-to-reach populations. Public Health Reports 2001;116:216–222. [PubMed: 11889287]
- Frew PM, Crosby RA, Salazar LF, Gallinot L, Bryant LO, Holtgrave DR. Acceptance of an HIV/ AIDS vaccine among minority women. Journal of the National Medical Association 2008;100:802–813. [PubMed: 18672557]
- Fuchs J, Durham M, McLellan-Lemal E, Vittinghoff E, Colfax G, Gurwith M, et al. Negative social impacts among volunteers in an HIV vaccine efficacy trial. Journal of Acquired Immune Deficiency Syndromes 2007;47:1–7.
- 35. Buchbinder SP, Metch B, Holte SE, Scheer S, Coletti A, Vittinghoff E. Determinants of Enrollment in a Preventive HIV Vaccine Trial: Hypothetical Versus Actual Willingness and Barriers to Participation. J Acquir Immune Def Syndr 2004;36:604–612.
- 36. Koblin BA, Holte S, Lenderking B, Heagerty P. Readiness for HIV vaccine trials: changes in willingness and knowledge among high-risk populations in the HIV network for prevention trials. J Acquir Immune Defic Syndr 2000;24:451–457. [PubMed: 11035616]
- Priddy FH, Cheng AC, Salazar LF, Frew PM. Racial and ethnic differences in knowledge and willingness to participate in HIV vaccine trials in an urban population in the Southeastern US. International Journal of STDs & AIDS 2006;17:99–102.
- 38. Crosby RA, Holtgrave DR, Bryant L, Frew PM. Factors associated with the acceptance of an AIDS vaccine: an exploratory study. Preventive Medicine 2004;39:804–808. [PubMed: 15351549]
- Salazar LF, Holtgrave DR, Crosby RA, Peterson J, Frew PM. Issues related to gay and bisexual men's acceptance of a future AIDS vaccine. International Journal of STDs & AIDS 2005;16:546– 548.
- 40. Mills E, Wilson K, Rachlis B, Griffith L, Wu P, Guyatt G, et al. Barriers to participation in HIV drug trials: A systematic review. Lancet 2006;6:32–38.
- 41. Ajzen, I.; Fishbein, M. Understanding attitudes and predicting behavior. Englewood Cliffs, NJ: Prentice-Hall; 1980.
- 42. Fishbein, M.; Ajzen, I. Belief, attitude, intention, and behavior. Menlo Park, CA: Addison-Wesley; 1975.
- 43. Meyers, LS.; Gamst, G.; Guarino, AJ. Applied Multivariate Research: Design and Interpretation. Thousand Oaks: Sage Publications; 2006.
- 44. Allen M, Liang T, Salvia T, Tjugum B, Gulakowski R, Murguia M. Assessing the attitudes, knowledge, and awareness of HIV vaccine research among adults in the United States. Journal of Acquired Immune Deficiency Syndrome 2005;40:617–624.
- 45. Gregory JR, McNaughton L. Brand logic: A business case for communications. J Adv Research 2004:232–236.
- Miller S, Berry L. Brand salience versus brand image: Two theories of advertising effectiveness. J Adv Research 1998:77–82.
- 47. Mangini MK. Branding 101: It's time for healthcare to embrace this marketing mainstay. Marketing Health Services 2002:20–23. [PubMed: 12233233]
- 48. Moran WT. Brand presence and the perceptual frame. J Adv Research 1990:9–15.
- 49. Zaichkowsky JL. Measuring the involvement construct. Journal of Consumer Research 1985;12:341–352.

- 50. Shinn E, Basen-Engquist K, Le T, Hansis-Diarte A, Bostic D, Martinez-Cross J, et al. Distress after an abnormal Pap smear result: Scale development and psychometric validation. Preventitive Medicine 2004;39:404–412.
- 51. Alexander M, Berger W, Buchholz P, Walt J, Burk C, Lee J, et al. The reliability, validity, and preliminary responsiveness of the Eye Allergy Patient Impact Questionnaire (EAPIQ). Health and Quality of Life Outcomes 2005;3:1–11. [PubMed: 15634354]
- 52. Chang M-W, Brown R, Nizke S. Scale development: Factors affecting diet, exercise, and stress management (FADESM). BMC Public Health 2008;8:1–7. [PubMed: 18173844]
- Hou S-I, Luh WM. The structure of a web-based HIV testing belief inventory (wHITBI) for college students: the evidence of construct validation. Med Inform Internet Med 2007;32:83–92. [PubMed: 17541858]
- 54. Brown, TA. Confirmatory Factor Analysis for Applied Research. 1st ed. New York: Guilford Press; 2006.
- 55. Knight GP, Virdin LM, Ocampo KA, Roosa M. An examination of the cross-ethnic equivalence of measures of negative life events and the mental health among Hispanic and Anglo American children. Am J Community Psychology 1994;22:767–783.
- 56. National Cancer Institute. Clear & Simple: Developing Effective Print Materials for Low-Literate Readers. 2003 [cited January 21, 2009]. Available from http://www.nci.nih.gov/cancerinformation/clearandsimple
- 57. Kline, RB. Principles and Practice of Structural Equation Modeling. 2nd ed. New York: Guilford Press; 2005.

#### Table 1

Multiphased Development of the Clinical Research Involvement Scales, Atlanta, Georgia, 2007–2008 - Participant Demographics (N=919)

	Phase I (n=54) (Total %)	Phase II (n=212) (Total %)	Phase III (n = 653) (Total %)
Age (mean age)	43.9 years	41.7 years	35.9 years
18–29	6 (12.2)	42 (19.8)	228 (36.0)
30–39	7 (14.3)	51 (24.1)	159 (25.1)
40–49	22 (44.9)	45 (21.2)	157 (24.8)
50–59	12 (24.5)	52 (24.5)	71 (11.2)
60 and over	2 (4.1)	12 (5.6)	18 (2.8)
Gender			
Male	30 (58.8)	63 (30.6)	267 (41.5)
Female	21 (41.2)	142 (68.9)	366 (56.8)
Transgendered: $M \rightarrow F$	0 (0.0)	1 (0.5)	7 (1.1)
Transgendered: $F \rightarrow M$	0 (0.0)	0 (0.0)	4 (0.6)
Race			
White	5 (9.8)	66 (32.2)	177 (28.0)
Non-white	46 (90.2)	139 (67.8)	486 (72.0)
Ethnicity			
Asian/Asian-American/Pacific Islander	1 (2.0)	5 (2.5)	31 (4.9)
Hispanic/Latino/Chicano	3 (5.9)	6 (2.9)	19 (3.0)
African-American/Black	42 (82.4)	120 (58.8)	362 (56.7)
Caucasian/White	3 (5.9)	56 (27.5)	170 (26.6
Native American/American Indian/Alaskan Native	1 (2.0)	2 (1.0)	4 (0.6)
Multiracial/Multicultural	1 (2.0)	15 (7.4)	52 (8.2)
Sexual Orientation			
Straight (heterosexual)	25 (49.0)	128 (61.5)	406 (62.8
Lesbian, Gay, Bisexual, Queer, Questioning (LGBTQQ)	26 (51.0)	80 (38.5)	240 (37.2)
Educational Attainment			
K-12 grade	23 (46.0)	53 (25.8)	201 (31.3)
Technical/Vocational/ Associates	13 (26.0)	42 (20.5)	154 (24.0)
Bachelor	4 (8.0)	60 (29.3)	172 (26.7
Master's	10 (20.0)	39 (19.0)	79 (12.3)
Doctorate	0 (0.0)	11 (5.4)	37 (5.8)
Household Income			
Less than \$40,000	35 (77.8)	99 (49.0)	340 (53.6)
\$40,001-\$60,000	5 (11.1)	42 (20.8)	114 (18.0)

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	Phase I (n=54) (Total %)	Phase II (n=212) (Total %)	Phase III (n = 653) (Total %)
\$60,001-\$80,000	3 (6.7)	27 (13.9)	76 (12.0)
\$80,001-\$100,000	1 (2.2)	18 (8.9)	36 (5.7)
Over \$100,000	1 (2.2)	15 (7.4)	68 (10.7)

# Table 2

Clinical Research Involvement Scales (CRIS) Reliability Measures from Final Testing Phase Groups, Atlanta, Georgia, 2007–2008 (N=653)

Frew et al.

	Attitudes	Behavioral Beliefs	Outcome Evaluation	Subjective Norms	Normative Beliefs	Motivation to Comply	Organization Involvement	Personal Relevance
Items (n)	5	L	5	3	9	5	3	7
Group $I: N = 22I$	Ič							
Cronbach's α	.675	.839	.854	.825	.785	.865	.822	.914
Standardized $\alpha$	.675	828.	.856	.827	.789	.866	.822	.915
<i>Group</i> $2$ : $N = 205$	25							
Cronbach's α	.731	.846	.787	.851	191.	.825	.767	.912
Standardized $\alpha$	.737	.849	.791	.854	.792	.825	.766	.912
<i>Group</i> $3: N = 227$	27							
Cronbach's α	.764	.867	.769	.871	.768	.753	.739	.926
Standardized $\alpha$	.768	698.	.774	.870	.775	TST.	.738	729.
Total: $N = 653$								
Cronbach's α	.730	.851	.810	.850	.782	.822	<i>L6L</i> .	716.
Standardized $\alpha$	.734	.852	.812	.851	.784	.823	<i>L6L</i> .	.918

## Table 3

Descriptive Statistics for Factor Scales, Factor Loadings, Alpha Reliability Estimates, and Subscale Items for Study Enrollment Intention, Atlanta, Georgia, 2007 (n = 486)

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r actor	Mean	SD	Min	Max	Factor Loading
<u>Behavioral Beliefs</u> ( $\alpha = 0.858$ )					
<ol> <li>My community would really benefit from (an HIV vaccine).</li> </ol>	1.505	0.775	1.00	4.00	.526
2. My actions can inspire other to act.	1.805	0.762	1.00	4.00	.666
3. My participation in a (HIV vaccine) study would be very good.*	2.079	0.884	1.00	4.00	.784
4. I benefit from health science research.	1.677	0.772	1.00	4.00	.555
5. My involvement in this cause will result in more ethical research.	2.063	0.870	1.00	4.00	.763
<ol> <li>My involvement in this cause will improve my community's trust in medical research.</li> </ol>	2.100	0.905	1.00	4.00	TTT.
7. I would participate in a (HIV vaccine) research study because it would help to prevent (AIDS).*	2.036	0.988	1.00	4.00	.707
<i>Outcome Evaluation</i> ( $\alpha = 0.820$ )					
<ol> <li>My participation in a (HIV vaccine) research study would be more trouble than it's worth.</li> </ol>	2.482	1.136	1.00	5.00	.754
2. Even if I wanted to participate in a (HIV vaccine) research study, I just don't have the time.	2.857	1.124	1.00	5.00	.692
<ol> <li>Participating in a (HIV vaccine) research study seems risky.</li> </ol>	2.893	1.216	1.00	5.00	.774
<ol> <li>I would participate in a (HIV vaccine) research study, but I don't like needles.<sup>*</sup></li> </ol>	2.810	1.270	1.00	5.00	.575
5. I am concerned that a (HIV vaccine) would cause me to test positive for (HIV).*	2.492	1.301	1.00	5.00	.680
Normative Beliefs( $\alpha = 0.795$ )					
<ol> <li>I. I think my doctor would approve of my involvement in (HIV vaccine) research.</li> </ol>	2.283	0.903	1.00	4.00	.540
2. I think my work colleagues would approve of	2.338	0.905	1.00	4.00	.602

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Factor	Mean	SD	Min	Max	Factor Loading
my involvement in this cause.					
3. My immediate family is supportive of my involvement in (HIV vaccine) research.*	2.595	0.851	1.00	4.00	.715
<ol> <li>Most people important to me think my involvement in (HIV vaccine) research is good.</li> </ol>	2.431	0.843	1.00	4.00	.793
<ol><li>Most people important to me usually support my interests.</li></ol>	1.883	0.715	1.00	4.00	.563
<ol> <li>If my pastor supported (HIV vaccine) research, I would be inclined to get involved.<sup>*</sup></li> </ol>	2.640	0.893	1.00	4.00	.590
<i>Motivation to Comply</i> ( $\alpha = 0.840$ )					
1. I tend to be concerned about what people think of me, even if I don't know them.	2.381	1.214	1.00	5.00	677.
2. I generally do what my family expects of me.	2.787	1.249	1.00	5.00	.643
3. I would not want to do something my friends disapproved of.	2.455	1.150	1.00	5.00	.756
<ol> <li>If my superiors told me to do something I disagreed with, I would obey their wishes.</li> </ol>	2.448	1.125	1.00	5.00	.646
5. Sometimes I do what my friends say to do, even though I know they are wrong.	2.104	1.078	1.00	5.00	.760
<u>Attitudes</u> ( $\alpha = 0.736$ )					
1. I like to do good for others.	1.373	0.591	1.00	4.00	.548
2. I like getting involved with (HIV vaccine) research.	2.194	0.907	1.00	4.00	169.
3. (HIV) is a serious concern in my immediate community.*	1.673	0.877	1.00	4.00	.448
4. (HIV) testing is a benefit of a (HIV vaccine) study.*	1.661	0.762	1.00	4.00	.578
<ol> <li>I would benefit from the medical care associated with a (HIV vaccine) study.</li> </ol>	2.107	0.988	1.00	4.00	.624
<u>Subjective Norms</u> ( $\alpha = 0.842$ )					
<ol> <li>Most people who are important to me think I should participate in the (HIV vaccine) effort.*</li> </ol>	2.693	0.857	1.00	4.00	.710
2. Most people who are important to me would	2.271	0.857	1.00	4.00	.867

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Factor	Mean	SD	Min	Max	Factor Loading
approve of my involvement in this cause.					
3. Most people who are important to me would support my interest in this cause.	2.135	0.857	1.00	4.00	.833
<u>Organization Involvement(<math>\alpha = 0.812</math>)</u>					
<ol> <li>Being active with the (clinical research site) would help me to express who I am.</li> </ol>	2.589	0.807	1.00	4.00	.801
2. Hearing that somebody else is involved with the (clinical research site) tells me a lot about that person.*	2.474	0.827	1.00	4.00	.773
<ol> <li>Others would view me favorably if I volunteered for a study at the (clinical research site).*</li> </ol>	2.571	0.788	1.00	4.00	.726
<u>Personal Relevance</u> ( $\alpha = 0.921$ )					
<ol> <li>Being involved with the (clinical research) site helps me to feel empowered.<sup>*</sup></li> </ol>	2.531	0.798	1.00	4.00	.758
2. I experience a sense of community in this cause.	2.233	0.778	1.00	4.00	.845
3. I feel a sense of belonging through my participation in this effort.	2.428	0.792	1.00	4.00	.829
4. My involvement is helping to protect the rights of others.	2.218	0.794	1.00	4.00	.781
<ol><li>1 am advancing the public's health and well- being through my support of this cause.</li></ol>	2.089	0.758	1.00	4.00	.754
<ol> <li>Getting involved in the (HIV vaccine) effort is liberating.</li> </ol>	2.461	0.807	1.00	4.00	.772
7. I feel a sense of purpose in this cause.	2.131	0.766	1.00	4.00	.801
* study topic, health issue, clinical research site names may be substituted on these items	s may be	substitut	ed on th	lese item	S