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Ethics of Online Assent: Comparing Strategies to Ensure Informed Assent among Youth

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Keywords

Adolescents; Teenagers; Youth; Informed Consent By Minors; Research Ethics; Online; Informed Consent

Online studies have successfully impacted, for example, weight, anxiety, depression, and management of diseases among youth (An, Hayman, Park, Dusaj, & Ayres, 2009; Caelear & Christensen, 2010; Hamel, Robbins, & Wilbur, 2011; Stinson, Wilson, Gill, Yamada, & Holt, 2009). The Internet presents advantages over face-to-face research, such as increased access to hard-to-reach populations, reduced time and cost, and greater ease in studying stigmatized phenomena (Bull, Levine, Black, Schmiede, & Santelli, 2012; Levine, McCright, Dobkin, Woodruff, & Klausner, 2008; Mechael, 2009; Swendeman & Rotheram-Borus, 2010; Young & Jaganath, 2013).

Internet research is however at an early stage and there are ethical issues that require attention (Anderson & Simpson, 2007; Whitehead, 2007). One ethical issue is related to informed consent, specifically, providing participants with information (e.g. risks and benefits, voluntariness) to help them to decide whether or not to participate (Cassileth, Zupkis, Sutton-Smith, & March, 1980). In comparison to face-to-face processes, individuals feel less pressured to participate as coercion may be minimized (Barchard & Williams, 2008; Pequegnat et al., 2007). However, studies also suggest that simply providing informed consent information online is insufficient (Pequegnat et al., 2007). Individuals may indicate their consent without reading consent documents (Rosser, et al., 2009). Studies have assessed strategies to engage participants in the online consent process, such as follow-up emailed consent documents and requiring individuals to respond to refresher questions (Barchard & Williams, 2008; Kim, Young, Neimeyer, Baker, & Barfield, 2008; Mathy, Kerr, & Haydin, 2003).

The process is more complex with youth. Institution Review Boards often require researchers to obtain youth assent along with parental consent. Further, parental consent is at times waived when obtaining parental consent will put youth at risk. However, youth may not read assent information (Fisher et al., 2002). Obtaining the assent of youth such that minors understand study risks and can voluntarily decide whether or not to participate is obviously important. However, few studies have focused on improving the process of informed assent with youth online. Therefore, we assessed the impact of including questions as part of the assent process on adolescents' willingness to complete the assent process and understanding of assent information by comparing these groups: 1) asking youth only to read study information and then indicate their willingness to participate, 2) requiring youth to correctly answer 2 questions about the study's risks and voluntary nature as part of the assent process, and 3) requiring youth to correctly answer 7 questions about the study (Table 1 for description). Our analysis was performed as part of a study of gay youth that collected data to inform the development of online outreach strategies for this population (i.e., the types of websites they visit most and youth they communicate with online). The larger survey contained 12 questions.

Method

Design, Recruitment and Procedures

This study used a three-arm randomized design (Figure 1). Participants were male, age 14 to 17 years old, US residents, and 4) gay or bisexual. Approximately half were recruited from Facebook and half from gay youth websites. Individuals clicked on advertisements our team developed and paid to be placed on these websites. Individuals were then automatically directed to the eligibility page. Individuals deemed eligible were randomized into one of three groups using software developed by our computer scientist (Figure 1). Assent was processed electronically. The 2 questions about study risks and voluntary nature of participation included in the 2-question and 7-question assent processes were repeated at the end of survey for all three groups to compare understanding and retention of information (Table 1).

Individuals who agreed to participate were taken to the main survey that inquired about online behaviors. Using a combination of age, birth dates, zip codes and IP addresses, we prevented individuals from completing the survey more than once. Participants received \$10 of Amazon credit upon completing the survey. A waiver of parental consent and all procedures were approved by the University of XXXX IRB.

Statistical Analysis

Analyses were conducted using IBM SPSS Statistics. Bonferroni correction ($\alpha = 0.05/n$) was applied to group comparisons, and comparisons were based on $\alpha = 0.017$ ($n=3$). Chi-square analysis was used for all comparisons. Logistic regression was used to assess associations between group assignment, assent completion and understanding of assent information. All logistic models were adjusted for demographics.

Results

Basic Demographics

Most participants self-identified as gay in the study; specifically, 91.4%, 90.4%, and 88.7% of the no question, 2-question, and 7-question groups. There were no demographic differences across groups (Table 2).

Assent completion

Of 623 eligible youth, 55 were excluded after being identified as attempting to complete the survey more than once. 568 youth were therefore randomized: 186 in the no-question, 187 in the 2-question, and 195 in the 7-question group. Of these, 25 (13.4%) in the no-question group, 61 (32.6%) in the two-question group, and 79 (40.5%) in the 7-question group dropped out prior to completing the assent process. Dropout rates between groups were significantly different ($p < 0.001$). In pair-wise comparisons, differences between the 2-question and no-question groups ($p < 0.001$) and between the 7-question and no-question groups ($p < 0.001$) were significant. The difference between 2- and 7-question groups was not ($p = 0.110$) (Table 2). In multivariable models, the odds of completing the assent were 0.32 ($p < 0.01$) times lower for the 2-question group and 0.24 ($p < 0.01$) times lower for the 7-question group than the no-question group (Table 3).

Understanding of Assent Information

159 participants in the no-question group, 126 in the two-question group, and 114 in the 7-question group completed the assent, agreed to participate and started the survey (Figure 1). Of these, 131 and 131 in the no-question group completed the “study risks” and “voluntary nature of the study” questions respectively that were presented at the end of the survey, 114 and 113 completed these questions respectively in the 2-question group, and 107 and 106 completed these questions respectively in the 7-question group. The difference in the number of participants starting the survey and completing these two questions were a result of participant drop-out while taking the survey or answering one but not both of the two questions.

Of those who answered the “study risks” question at the end of the survey, 77.9% of the no-question group, 95.6% of the 2-question group, and 93.5% of the 7-question group answered this question correctly. Of those who answered the “voluntary nature of the study” question at the end of the survey, 48.1% of the no-question group, 89.4% of the 2-question group, and 92.5% of the 7-question group answered this question correctly. The proportions were significantly different for both questions ($p < 0.001$). For both questions, pair-wise comparisons between both the 2- and 7-question groups with the no-question group were found to be significant ($p < 0.001$); however, proportions between the 2- and 7-question groups were not significantly different (Table 2). After controlling for demographics, having 2 or 7 questions in the assent is associated with a 620% and 330% increase in the odds of answering the “voluntary nature of the study” question correctly. Moreover, being in 2- and 7-question groups increased the odds of responding to the “study risks” question correctly by 10.4 ($p < 0.001$) and 16 times ($p < 0.001$), respectively (Table 3).

Discussion

This study found that participants in the “assent as usual” (no questions following presentation of student information as part of the assent process) group were significantly less likely to understand key study information. This is consistent with prior data suggesting that individuals often do not read consent information online (Stanley & Guido, 1996). It is important to note that similar proportions of youth in the 2-question and 7-question groups correctly answered the questions about study risks and voluntary nature of the study that were asked again at the end of the survey. However, while participants in the 2-question and 7-question groups were more likely to understand key study information, a price was paid to achieve this outcome. Specifically, participants in the 2-question and 7-question groups were less likely to complete the assent process in comparison to participants in the no question group, respectively.

This study has a few limitations. In accordance with the approved IRB protocol, the study did not collect any information on participants who dropped out during or refused to give informed consent. For example, in the MINTS-II study, one of the largest online HIV/STI studies with men who have sex with men, it was found that length of the survey and concerns about confidentiality were the two most common reasons given by those who did not consent to the study (Rosser et al., 2009). In addition, because the study’s participants were young gay males, it is impossible to determine the degree to which the findings are generalizable to other groups of youth. This study is a first step in terms of advancing understanding in this area. More work with other populations of youth is needed.

Best Practices

As the “digital divide” continues to diminish, the Internet has emerged as a promising platform to reach a large number of at-risk individuals. For example, an increasing proportion of HIV research is now implemented over the Internet (Rosser et al., 2010; Young & Jaganath, 2013). However, as described above, there are many relevant ethical issues associated with these studies (Pequegnat et al., 2007; Young, 2012). The implications of these findings with respect to protecting the welfare of participants are apparent given the need to ensure that potential study participants understand the nature of the studies they are being asked to participate in. It is imperative for researchers to understand that online informed consent is not as simple as posting informed consent/assent materials online.

Research Agenda

This study suggests that researchers should consider using a simple automated process that can dramatically increase the likelihood that individuals will understand important study characteristics before agreeing to participate. Future studies are also needed to further determine how research can best engage participants while not causing participants to drop out prematurely.

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Biographies

Mark Friedman is an Assistant Professor in the Department of Behavioral and Community Health Sciences, Graduate School of Public Health, University of Pittsburgh. His research interests include the victimization of and promotion of health among sexual minority youth, school-based violence prevention, the adaptation of evidence-based public health interventions, and online interventions including ethical considerations. He helped to conceptualize the study, participated in data analysis, and wrote the majority of the manuscript.

ChingChe J. Chiu is a social epidemiologist and hospital administrator. He has been involved with developing and evaluating innovative social media-based HIV prevention with individuals at-risk of HIV, such as the HOPE study at UCLA. He managed the implementation of the study and the analysis of data, and edited and approved the final article.

Colby Croft is a psychiatry resident at the University of California, San Francisco. His research interests include medical education regarding sexual minority health, and health promotion of sexual minority youth. He assisted with the background literature review, wrote the introduction to the paper, and edited and approved the final article.

Thomas E. Guadamuz is Assistant Professor of Medical and Health Social Sciences at Mahidol University in Thailand. He is trained as an infectious disease epidemiologist and health social scientist who has worked in Thailand for over a decade in HIV prevention research, programming and advocacy for sexual minority populations. His research interests are in the social determinants of health, HIV research ethics, including consent challenges of young sexual minority populations. He helped to conceptualize the design of the experiment and participated in data analysis and edited and approved the final article.

Ron Stall is a professor in the Department of Behavioral and Community Health Sciences, Graduate School of Public Health, University of Pittsburgh. The primary focus of his research has been in HIV prevention and behavioral epidemiology, both in the United States and abroad. He has conducted numerous research projects in the areas of substance abuse epidemiology, smoking, aging, mental health, and housing as health care. He helped conceptualize the study and edited and approved the final article.

Michael P. Marshal is an Associate Professor of Psychiatry and Pediatrics at the University of Pittsburgh. Dr. Marshal has been studying psychosocial risk and protective factors for adolescent substance use for over 15 years. He is the recipient of multiple career development and research awards through NIAAA, NIDA, NIMH, NICHD, and the

Pittsburgh Foundation. He has a strong history of quantitative training. Over the past five years, he has developed a program of research to describe and understand mental health disparities among sexual minority youth. He helped conceptualize the study, oversaw data analysis, and edited and approved the final article.

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Figure 1.**Study Flow Chart**

Time cases: Those who completed the survey under 2 minutes and did not respond to any questions were not included.

Table 1

Description of randomized groups

Groups	Procedures	Questions and Response Items
Assent As Usual	Participants were asked to read the study information as part of the assent process and then indicate their willingness to participate.	N/A
2-Question	Participants were asked to read study information about potential risks of the study and were required to correctly answer 2 questions before being permitted to enter the study.	<p>What are the possible risks, side effects, and discomforts of this research study? ***</p> <ul style="list-style-type: none"> • There is a chance that you could become quite satisfied by being in this study or that someone else would want to be in this study as well. • There is a very small chance that you could get others to be in this study and have others be quite satisfied with you being in the study. • There is a very small chance that you could become upset by being in the study or that someone else could find out that you are in it and react negatively. • There is a great chance that you could become upset by being in the study and discourage someone else from being in this study. • There is a great chance that you could get nobody to be in this study or have others be quite dissatisfied with you being in this study. <p>Is my being in this study voluntary?</p> <ul style="list-style-type: none"> • My being in this study is not voluntary and I am expected to complete this study. • My being in this study is voluntary and it is perfectly okay to not agree to participate or to quit in the middle of it. • My being in this study depends on my level of interest in the subject. • My being in this study is voluntary, however, it's not okay to quite in the middle of it once started. • My being in this study is not voluntary and the decision of not being in it would affect my relationship with the website or organization.
7-Question	Participants were asked to read study information and were required to correctly respond to 7 questions before being permitted to enter the study.	The same 2 questions about risks associated with and voluntary nature of the study plus 5 additional multiple-choice questions about the study's purpose, participants, procedures, potential benefits, and confidentiality.

Individuals were given two chances to answer each question correctly. This prevented youth from randomly choosing response items in an attempt to answer the question correctly.

Table 2

Descriptive Data

Assent	N = 568	No Question Group		2 Question Group		7 Question Group	
		N	%	N	%	N	%
		186		187		195	
Sexual Orientation	Gay	170	91.4	169	90.4	173	88.7
	Bisexual	16	8.6	18	9.6	22	11.3
Age	14	23	12.4	24	12.8	28	14.4
	15	37	19.9	35	18.7	41	21.0
	16	54	29.0	58	31.0	54	27.7
	17	72	38.7	70	37.4	72	36.9
Referral Source	Gay Web Sites	90	48.4	90	48.1	99	50.8
	Facebook	96	51.6	97	51.9	96	49.2
Assent Process **	Completed Assent	161 ^a	86.6	126 ^a	67.4	116 ^a	59.5
	Did not Complete	25	13.4	61	32.6	79	40.5
Risks Associated with Study ^b	Correct	102	77.9	109	95.6	100	93.5
(N = 352)	Incorrect	29	22.1	5	4.4	7	6.5
Voluntary Nature of Study ^b	Correct	63	48.1	101	89.4	98	92.5
(N = 350)	Incorrect	68	51.9	12	10.6	8	7.5

1. Chi-square comparison * < 0.05, ** < 0.01, *** < 0.001

^a Of the individuals who completed the assent process, 2 individuals in the no question group, zero individuals in the 2-question group and 2 individuals in the 7-question group chose not to participate in the study.

^b Questions about "Risk Associated with Study," "Voluntary Nature of Study" were presented at the end of the survey.

Table 3

Multivariable models and adjusted odds ratios (AORs)

Outcomes	Predictors	AORs	95% Confidence Interval	P-value
Assent Completion	2-Question **	0.32	(0.19, 0.53)	<0.01
	7-Question **	0.22	(0.13, 0.38)	<0.01
Possible Risks	2-Question ***	10.4	(5, 21.5)	<0.001
	7-Question ***	15.9	(6.8, 37.1)	<0.001
Voluntary Nature	2-Question **	7.2	(2.3, 22.4)	<0.01
	7-Question **	4.3	(1.7, 11)	<0.01

All analysis used no question group as the control.

*
p < 0.05,

**
p < 0.01,

p < 0.001