Memorandum

To: Brenda Aguilar, Office of Management and Budget

Through: Sherette Funn-Coleman, ONC Information Clearance Officer

From: Rachel Seeger, OCR, and Peter Garrett, ONC

Date: February 25, 2013

Re: Under Approved Generic OMB Control No: 0955-0005;

ICR Reference No: 201106-0990-003

Request Approval to Conduct Focus Groups to Test Messages and Materials

The Office for Civil Rights and the Office of the National Coordinator for Health Information Technology (ONC) are requesting approval for communications testing under Approved Generic OMB Control No. 0955-0005.

The following content and information is provided for your review:

1. Title of Project: Communications Testing for Comprehensive Communication Campaign for HITECH Act

The research includes in-person focus groups among consumers to test messages and materials related to the privacy and security of personal and protected health information.

- 2. Control Number: 0955-0005, expiration date 07/31/2014.
- 3. Public affected by this Project:

Consumers: Because Education on Health Information Privacy is mandated in the HITECH Act, Sec. 13403, we are proposing to test messages and materials among adult consumers, with specific segments and locations described as follows:

We are proposing to test messages and ads in support of public communication to increase awareness of HIPAA regulations and rights among Black men who have sex with men (BMSM) and who have been diagnosed as HIV Positive within five years to date.

A total of three focus groups will be conducted in March 2013, in three markets: Washington, D.C.; New York, NY; and San Francisco, CA. We will recruit **9** participants for each consumer focus group, for a total of **27** participants.

4. Time needed per Response:

Focus Groups: Based on the assumption that the average length of screening for the focus

group sessions will be 10 minutes per participant, the burden hours associated with 270 screening participants is 45 hours (10 minutes \times 270 = 2,700 minutes = 45 hours).

Based on the assumption that the average length of the focus group discussions will be 120 minutes per participant, the burden hours associated with 27 focus group participants is 54 hours (120 minutes \times 27 = 3,240 minutes = 54 hours).

Total burden hours associated with the data collection is 99 hours.

Estimated Annual Reporting Burden, by Anticipated Data Collection Methods				
	Number of	Frequency of	Hours Per	
	<u>Respondents</u>	<u>Response</u>	<u>Response</u>	<u>Total Hours</u>
Consumer Focus Group Interviews	27	1	2	54
Screening for Consumer Focus Group Interviews	270	1	10/60	45
Total	297			99

5. Background

The Office of the National Coordinator for Health Information Technology (ONC) serves as the Health and Human Services (HHS) Secretary's principal advisor on the development, application, and use of health information technology (health IT). ONC was originally created under Executive Order (EO) 13335, but has since been codified in law by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009. The HITECH Act builds on EO13335 and establishes additional purposes for the ONC and duties for the National Coordinator. Chief among these new HITECH Act responsibilities are to: promote the development of a nationwide health IT infrastructure that allows for electronic use and exchange of information; coordinate health IT policy; and update the Federal Health IT Strategic Plan to meet the objectives specified in the HITECH Act. Meeting certain objectives such as "methods to foster the public understanding of health information technology" will require additional information from the public at large to determine what education is needed and what types of communication techniques will be most effective.

Education on Health Information Privacy is mandated in the HITECH Act, Sec. 13403, to develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. According to the HITECH act, the education effort must present information in a clear and understandable manner. Therefore, testing of messages and materials is essential to the effort, to ensure consumers understand topics related to protected health information.

ONC is collaborating with the HHS Office for Civil Rights (OCR) to oversee the education and

communication activities regarding health information privacy.

6. Methodology for Focus Groups

Focus Group Objectives:

- Test print ads composites designed to raise awareness of rights under the HIPAA Privacy Rule, in particular, access to PHI;
- Better understand characteristics of the target audiences, including attitudes, beliefs, and behaviors as related to messages included in print ad composites;
- Use these insights in the continual development of effective communications;
- Help determine promotion and distribution channels to reach the target audience with appropriate messages; and
- Expend limited program resource dollars wisely and effectively.

Methodology, Design and Data Analysis:

Recruitment and Screening: OCR, through its vendor, Better World Advertising (BWA), will conduct focus groups among 27 adult participants in three locations. BWA will work with three focus group facilities during recruitment. Facilities will screen and recruit participants with direction by BWA, and BWA will supply screening materials designed to vet qualifying participants. Screening materials will serve to identify HIV+ BMSMs between the ages of 18 and 39 with behavioral and attitudinal traits that are congruous with the campaign's target audience.

Participants will be recruited from facilities' opt-in recruiting databases, which offers the most expedient and efficient means of recruiting. If necessary, recruitment may be expanded through referrals from database participants, who provide to the recruiter the name of a candidate for contact. The recruiting process begins with phone calls or direct emailing of announcement with information about the date, time, incentive and subject matter of the focus group. Interested participants will be screened by professional recruiters to assure that they meet the specific target audience requirements required by the research.

Moderation: Focus groups will be moderated by BWA and observed by staff from BWA and the Health and Human Services Office for Civil Rights. Advertising mock-ups will be presented to groups comprised of HIV + BMSM. The purpose of the groups will be to test each ad for effectiveness, clarity and message resonance.

Focus groups will last two hours per session. The moderator will explain focus group procedure, hand out confidentiality documentation, present print ad mock-ups, allow for notation and then engage participants in discussion.

Participants will be asked to describe their understanding of each ad. Moderator will attempt to elicit information about their attitudes, beliefs and perceptions as related to each ad's message. Participants will be asked to expand on their insights and experiences for the purpose of identifying cultural and group norms, addressing barriers and determining how to minimize challenges.

Participants will rate each concept on a scale of 1 to 10, with 10 serving as the highest possible score. They will also be asked to rank their top three favorite ads, with 1 being the most favored. This will be repeated for each mock-up.

BWA will interpret and report quantitative and qualitative findings. After testing has been completed, BWA will deliver a testing report summarizing participant reactions and rating/rankings. The report will include a recommendation for communication efforts.

All focus group sessions will be audio recorded.

Incentives for participants: Focus group participants are typically provided with an incentive – usually a cash or check payment at the close of their research session. We anticipate the total incentive/travel reimbursement offered to each consumer participant to be \$75.

Confidentiality: Participants are assured by the research facility, and always by the moderator at the beginning of each group, that their names and responses are kept confidential, and will not be disclosed to anyone but the individuals conducting research in this investigation, except as otherwise required by law. They are also assured that no one will try to sell them anything following this research.

Outcome:

The final report of the focus groups will be both descriptive and quantitative in nature, but is not intended to be generalizable to populations beyond participants. Findings will be used to modify messages and materials if necessary to respond to the communication needs of the OCR constituencies. Findings will be considered descriptive and directional but not definitive.

- 6. Federal Costs: \$50,000 for the focus groups, including government oversight
- 7. Requested Approval Date: March 11, 2013
- 8. Formative Research Instruments:
 - a. Screening questionnaire for focus groups (Attachment A)
 - b. Moderator guide for focus groups (Attachment B)
- 9. Stimuli (Materials for Tested) included in PDF file as supplemental document

OCR and BWA anticipate testing 6-8 print ad composites. Each concept will be mounted and displayed on 12"X8" boards.