Institutional Review Board
Registration Number 00000900

8 May 2015

James Bethea, Principal Investigator
Danya International, Inc.
#9 Corporate Blvd., Suite 1100,
Atlanta, GA 30329

RE: ***"Review of Existing CDC Materials" – Study #1***
Contract No. 200-2009-TO-31372-TO-0058
Division of Community STD Prevention (DCSTDP),
Centers for Disease Control & Prevention (CDC)

Dear Mr. Bethea:

This will confirm that the Danya International, Inc. Institutional Review Board (IRB) met in expedited session (Chairman plus one other reviewer) on 13 March 2015 to review the above-captioned research project's Initial Review Memo, Proposal Statement of Work, research protocol, draft survey instruments, focus group questions, consent forms, facilitator guides, and other data collection instruments. (In all, there were 16 attachments (forms, etc.) submitted to the IRB; each was viewed separately.) This was an Expedited Review and an Initial Review for this project. The project was conditionally approved, with numerous changes required. What follows summarizes your project's approach and then details the IRB's conclusions.

Overview of the Research Project

Danya has received funding from CDC's Division of STD Prevention (DSTDP) to address the immediate need for useful communication resources to reach target populations, and to optimize the use of available technology to deliver timely, accurate STD-related information to target audiences, including staff in STD programs; clinicians; and affected populations, such as adolescents and men who have sex with men (MSM), and the general public. Danya will be conducting message testing of existing CDC informational materials to gauge the overall message effectiveness and usability of those materials. To this end, among other activities under the grant, Danya plans to conduct the following study:

- ***Study 1--Online Surveys***: Danya will conduct anonymous online surveys with groups of adolescents (ages 15 - 24) (n = 75) and men who have sex with men (MSM) (n = 75). Respondents will answer survey questions about how much they like images and messages found on existing fact sheets as well as a brief demographics section.

This study will be conducted online using Think Tank for the online focus groups. Project staff are located in the Atlanta and Silver Spring offices of Danya. In Study #2, Danya researchers hope to recruit a total of 20 clinicians, 20 adolescents, and 20 MSMs for focus groups.

The researchers will use the feedback garnered from focus groups to modify and update CDC fact sheets and informational materials to make them more relevant and appropriate for intended target audiences. Pending completion of the studies with key stakeholders, feedback will be generalized and prioritized in our report to the client; feedback will be used in developing

recommendations for revisions to materials and suggested next steps. All materials will be revised, as appropriate, and re-posted on the CDC-INFO website for download.

Online surveys will be completely anonymous, thus there will be no confidentiality issues. All identifying information for focus group participants will be collected during recruitment. All focus group participants will be asked to use only their first names when logging into the focus group and will be encouraged to not share personal or identifying information during the focus group. An experienced moderator will ensure that personal responses are addressed.

- Study 1 – Potential respondents will be e-blasted a link to their respective survey. Respondents interested in completing the online surveys will follow the link to the survey. Each survey should take respondents approximately 7-10 minutes to complete. Survey responses will be anonymous.

- For the MSM target group, Danya will utilize the National Prevention Information Network (NPIN), partners from Community Based Organization (CBO), and any recommended DSTDP partners. Danya staff will provide key contacts with links to both the online survey and the focus group screener, with brief descriptions of each study, to be e-blasted to potential participants. Danya staff will also post the links and brief study descriptions on its social media channels.

- For the adolescent target group, Danya will be working with Advocates for Youth, which champions youth involvement in sexual and reproductive health advocacy. Similar to recruitment for the MSM group, Danya will provide our contact at Advocates for Youth with links to the survey and focus group screener to be e-blasted to their listserv. Danya staff will also post the links and brief descriptions on its social media channels.

- All focus group participants will receive a check for their participation: clinicians will receive $100, and MSMs and adolescents will receive $50. Because the researchers are relying on recruitment partners to e-blast the survey links to potential youthful respondents, they will have very limited control over the diversity of our survey participants. That said, it is anticipated that the pool of potential focus group participants will be limited based on the recruitment partners' reach, as well as by the modest incentives being provided focus group participants. In contrast, the clinician group's recruitment will come heavily from DSTDP's health department contacts, NPIN, Prevention Training Centers (PTCs), and potentially health care provider professional organizations such as the American College Health Association or the National Medical Association. Similar to the other groups, links to the survey and focus group screener, as well as brief descriptions of the studies, will be e-blasted to listservs and posted on Danya's social media channels.

- Focus group participants will be encouraged to not share any personal or identifiable information. All questions are designed to garner feedback regarding the likability of informational materials and perceived usefulness or effectiveness of the materials and should not garner any sensitive information from participants.

IRB Actions

The IRB has determined that this project is minimal risk and without any direct benefits to study participants. It received a "conditional" approval in March 2015, based on changes required in ten (10) major areas, as follows:

1. ***Attachment 1/Planned Enrollment Tables for Study 1a (MSM Online Surveys)*** - Incorrect totals are included under "Racial Category". The totals for "Males" and "Total" = 70 not 75.
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2. ***Attachment 4/DSTDP Survey for MSM - Define STD in introduction.*** Define CDC at first use. Each image should include a reference number so that questions pertaining to that image are more obvious. It is difficult to follow which image some of the questions are referring to (see pages 3, 4, 5 and 6).

3. ***Attachment 5/Adolescent Online Survey*** - Each image should include a reference number so that questions pertaining to that image are more obvious. It is difficult to follow which image some of the questions are referring to (see pages 3, 4, 5 and 7). A high proportion of adolescents may not understand the words "stereotypical" or "stigmatizing."
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4. ***Attachment 6/Clinician Screener***. No message to eligible, ineligible respondents.

5. ***Attachment 7 /Clinician Focus Group Participant Consent procedures***.
6.
    - At page 1, "Procedures" - Please include the total number of study participants (20) in addition to the number of participants to be included in a given focus group (6-8). PLEASE NOTE THAT THIS COMMENT APPLIES TO EACH CONSENT.
    - Please briefly descibe how a transcript of the focus group will be "generated automatically". PLEASE NOTE THAT THIS COMMENT APPLIES TO EACH CONSENT.
    - "Privacy", 2nd paragraph - Please expound on where information will be kept secure. Specifically, expound on "locked place" . PLEASE NOTE THAT THIS COMMENT APPLIES TO EACH CONSENT. Please indicate whether email addresses will be kept and for how long (this is relevant to each consent form).

7. ***Attachment 8/Clinician Focus Group Moderator's Guide*** – At page 8, iii, #6: Does Question #6 ("…does it address questions or needs you'd have when taking a patient's sexual history?") apply to the Pocket Guide in question (STD Treatment Guidelines) or does it apply to "Guide to Taking a Sexual History"?

8. ***Attachment 11/ MSM Focus Group Moderator's Guide:***
    - At page 1, Item B.e. - Revise "…, please also think about consider how…" to read, "…, please also think about how…".
    - At page 1, Item D.c. - Revise "Why do you and go to these sources?" to read "…Why do you go to these sources?".
    - At pages 7-8, questions 2 (Line A), 3 (Line B) and 4 (Line C) - Item "i" for Lines A, B and C should be revised from "…would not be helpful for gay or bisexual men.." to read "…would not be helpful to gay, bisexual or other MSMs…".
    - At page 10, Item "f" - Revise "…appropriate and relevant for gay or bisexual men.." to read "…appropriate and relevant for gay, bisexual or other MSMs…".

- At page 10, Item "g" - Revise "…important to a gay man…" to read "…important to MSMs…"

9. ***Attachment 12/Adolescent Focus Group Screener*** - Please specify when and how the parent/guardian will be contacted for permission. Revise term "adolescents, ages 15-24," to adolescents and young adults, ages 15-24."

10. ***Attachments13, 14 and 15***. Revise "youth, ages 15-24," to "youth and young adults, ages 15-24."

11. ***Attachment 16/ Adolescent Focus Group Moderator's Guide:***

    - At page 3, Item "d. iii." - This item is blank, please delete.
    - At page 4, Item "f. iii." - Revise "Is there or images…" to read "Are there other images…".
    - At page 12, Item "D. 1" - Revise "…not for gay or bisexual men or other MSMs, etc." to read "…not for youth, etc."
    - At page 12, Item "D. 2" - Revise "Is this designed for gay or bisexual men or other MSMs?" to read "Is this designed for young people?"
    - At page 12, Item "D. 3" - Revise "…for gay or bisexual men or other MSMs?" to read "…for young people?".

Conclusion and Approval to Begin Data Collection

The answers to the above questions and all the required changes related to these questions were reviewed and approved by the IRB Chairman and the IRB Coordinator on 2 April 2015 and approved. Data collection efforts may now commence. It is your responsibility to notify your government project officer, your government contract officer that your project has been reviewed and approved.

Please note that you are required to notify the Danya IRB immediately if you make changes to the data collection protocol that affect the participants. This initial approval is effective for 12 months from the date the IRB met and approved the project, after which time your project must again be presented to the IRB for an annual review.

If questions, please feel free to contact me.

Sincerely yours,

John P. Bellassai

John P. Bellassai, JD
Authorized Institutional Official
Danya International, Inc.

/jpb