

## Center Liaison Transmittal Form

Please indicate the submission type:

New Submission

**RIHSC Protocol Number (to be filled if new submission):**

**I concur that:**

**A. For protocols applying for RIHSC review:**

1. The protocol as submitted, has undergone scientific review for technical merit and programmatic relevance by the Center or Office and has been approved by the Center Director or Office Director or designee.

2. The principal investigators are qualified to do the research.

3. The study site has been documented to be adequate.

4. The FDA sponsor and investigators have completed the required training in human subject's protection and the sponsor understands his/her obligations under the regulations and is qualified to provide adequate oversight of this protocol.

5. The potential risks to the subjects are appropriate for the potential benefits.

6. The informed consent document conveys the risks and benefits in a clear, scientifically accurate and balanced manner.

7. The completed submission form (Form RIHSC-PROT) and, if appropriate, the request for expedited review form (Form RIHSC-EXPD) are accurate and the supporting information have been attached.

8. IDE/IND required?

An IDE/IND is not required.

**B. For protocols requesting exemption from RIHSC review and for Continuing Review Submissions:**

1. The protocol has undergone scientific review for technical merit and programmatic relevance by my Center/Office and has been approved by the Center Director/Office Director or designee

2. The completed exemption form (Form RIHSC-EXT) is accurate and supporting information have been attached.

**C. For amendments to an existing study:**

**D. For continuing review submissions or continuing review form (Form RIHSC-CR)**

**Upload center specific review materials.**

**Please Upload IRB Authorization Agreement**

By checking this box I attest that I have conducted a review all of the information above.

<b>Active Protocol</b> FDA CTP E-Blast Survey Audience Analysis Study	<b>IRB</b>	<b>Case Number</b> 17-052CTP	
<b>Sponsor</b> Navarro, Mario	<b>Organization</b> CTP-White Oak	<b>Email</b> mario.navarro@fda.hhs.gov	<b>Phone</b>
<b>Approved</b>		<b>Date Submitted</b> 8/23/2017	<b>Expiration Date</b>

Doc Ver: 281-311

**Laboratory Not in List**

Laboratory: NA

**Recommendations**

8-25-17 IRB Admin: Your research study, RIHSC# 17-052CTP, does not require Research Involving Human Subjects Committee (RIHSC) review and approval because it is exempt from the requirements of 45 CFR §46.101b(2).

In the future if you propose changes that you think have the potential to alter the exemption status of this study, discuss the changes with your liaison and decide together if you need to file an amendment. When you file an amendment, please include a narrative describing any changes made since the last submission.

Although this research activity is exempt from RIHSC oversight, the Sponsor and the Principal Investigator (PI) are not relieved of the responsibility to ensure that the research activity involving human subjects is conducted in an ethical manner. It is the Sponsor and PI's responsibility to safeguard the rights and welfare of each human subject participating in the research activity. You are reminded of your obligations under applicable federal, international, state, local laws regulations, and policies that provide additional protection for human subjects participating research.

Additional relevant documents and information, such as the Belmont Report and links to the Code of Federal Regulations citations and OHRP's policy and guidance, as well as a copy of the RIHSC Standard Operating Policies and Procedures, may be found on the RIHSC webpage at <http://inside.fda.gov:9003/OC/OfficeofScientificMedicalPrograms/OfficeofScientificIntegrity/ucm336966.htm>

For your reference, the regulation containing the Department of Health and Human Services general requirements for informed consent (45 CFR 46.116) can be found at <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46>.

Liaison: short evaluation survey for adults - exempt

**Point of Contact**

None

**Inventory Requests**

None

**Associated Researchers**

None

**Associated Registrations**

None

**Registration Document Approved by Admin**

**Registration Document Approved by Chair, IRB**

**Registration Document Approved**

8/25/2017

**Project Information [45 CFR 46 101  
(b)(2)]**

**Name of Principal Investigator**

Mario Antonio Navarro

**My project involves only ADULTS (18 years and older or as defined by state requirements for age of majority).**

Yes

**AND this Project uses only:**

Survey procedures

**Please check the items that also apply to this project:**

Information is recorded in such a manner that subjects cannot be identified, directly or through identifiers.

**Project Documents [45 CFR 46 101  
(b)(2)]**

**Please attach the study protocol, including either focus group or survey questions.**

App\_B\_CTP\_EBLAST\_SURVEY\_INSTRUMENT.docx

App\_D\_CTP\_EBLAST\_SURVEY\_INFORMED\_CONSENT.docx

CTP\_EBLAST\_SURVEY\_RIHSC\_PROTOCOL.docx

**Please attach information on who will be conducting the interviews/focus group testing including documentation that the person(s) has been trained.**

Dineva\_A\_CITI\_2017.pdf

Dineva\_A\_CV.pdf

Macario\_E\_CITI\_2017.pdf

Macario\_E\_Resume\_June\_2017.pdf

Navarro\_M\_CITI\_2016.pdf

Navarro\_M\_CV.doc

Siddiqui\_J\_CITI\_Program\_Certificate.pdf

Siddiqui\_J\_CITI\_Program\_Certificate\_2.pdf

Siddiqui\_J\_CV.docx

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If applicable, please attach the following below:

**Recruitment and/or Advertisement Information**

App\_A\_CTP\_EBLAST\_SURVEY\_INVITATION\_RECRUITMENTEMAIL.docx

**Please indicate if you will be including any of these documents and attach any relevant documents accordingly.**

Participants will be asked to agree to terms and conditions (consent) before completing web based survey.

**Upload center specific review materials.**

**Study Data [45 CFR 46 101 (b)(2)]**

**Please indicate any sources of data**

Web based Surveys

**Confidentiality of Data (Please check all that apply and attach applicable documentation)**

No personally identifiable information will be sent to FDA (please attach documentation).

**Storage of Data (please check all that apply)**

All electronic data will be maintained in a secure manner with limited authorized access

**Please check and answer all that apply:**

Written documentation will be transferred to a locked storage facility and will be destroyed (please indicate after how many years)

Comment: *Three years*

**Sponsor Attestation**

**Carefully read the following statement and indicate by checking the box that you agree. This protocol cannot be submitted without affirming the statement.**

I understand that if any changes are proposed for the study, I will need to resubmit the materials to the RIHSC to make sure none of the proposed changes alter the basis for the above exemption.

**Please have your FDA Sponsor (or if you are the Sponsor) sign-off this submission by clicking the red "Sponsor E-Signature" button located at the bottom right of the screen. Please note your protocol must be complete.**

This protocol has been fully reviewed.



Food and Drug Administration  
Center for Tobacco Products  
10903 New Hampshire Ave.  
Silver Springs MD 20993-1058

**FDA CTP E-Blast Survey Audience Analysis Study**

**Principal Investigator:**

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**FDA Sponsor:**

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<b>Federalwide Assurance:</b>	#00006196
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## **Abstract**

The FDA Center for Tobacco Products (CTP) email communications are sent to approximately 40,000 subscribers. Currently, there is little that is known about the subscribers and their opinions and beliefs about CTP email communications. The goal of this study is to learn more about the CTP email subscriber base. Investigators will administer a short, one-time, anonymous and voluntary online survey with a sample of approximately 400 to 1,200 CTP email subscribers, depending on the response rate. These CTP email subscribers are comprised of the general public. This survey includes self-reported items assessing demographic information, opinions about CTP email communications and what aspects of CTP communications can be improved. Study aims are: (1) to obtain demographic information about the email subscriber base; (2) to determine the current information gaps that exist for subscribers; (3) to assess the opportunities that exist to engage subscribers in CTP activities; and (4) to identify the reach and impact of CTP email communications. The findings from this study will help guide CTP in developing content, engaging stakeholders, and tailoring effective public affairs activities.

## **I. SUMMARY OF PROJECT**

The goal of the research study, FDA Center for Tobacco Products (CTP) E-blast Survey Audience Analysis Study, presented in this protocol is to learn more about the CTP email subscriber base across its three email communications (i.e., CTP Connect, CTP News, and Spotlight on Science). The results from the CTP E-blast Survey Audience Analysis Study will help guide the Center in three areas:

- Content development. What are the current information gaps, and what content does CTP need to develop to address those gaps?
- Stakeholder engagement. What opportunities exist to leverage stakeholders' communication channels and to engage stakeholders in the Center's activities?
- Public affairs activities. What is the reach and impact of CTP messaging, news, and research?

The CTP research team will send an email, with a specific website URL, to its approximately 40,000 E-blast subscriber base inviting subscribers to complete the FDA CTP E-blast Survey. The FDA CTP E-blast Survey will be in the field for three weeks. IQ Solutions will send two reminders to complete the survey during this three-week period. These reminders will be sent to all email subscribers, regardless if they have already completed the survey or not. Respondents may complete the survey on a desktop computer, tablet, or mobile phone. To reduce the potential for any one individual completing the survey more than once, IQ Solutions will program the survey to limit one survey per device.

The survey consists of 14 questions, including 3 multi-part questions, and takes 10 minutes to complete. While IQ Solutions hopes for a large number of invitation recipients to complete the survey, given our experience with similar surveys, IQ Solutions anticipates that between one percent and three percent of the 40,000-subscriber base will complete the survey (for a sample size of 400 to 1,200 completed surveys).

This study will provide CTP with an audience analysis that will deepen the Center's understanding of the information needs and preferences of its current and intended target audiences. With this understanding, CTP will develop resources of greatest value to its target audience and as such, increase engagement with CTP among target audience members.

## **II. INTRODUCTION / BACKGROUND**

FDA's Center for Tobacco Products oversees the implementation of the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act, signed into law on June 22, 2009. Also, section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) provides that FDA may take appropriate action to protect the public's health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to the FDA for the enforcement of the FD&C Act. Further, the FD&C Act also authorizes the FDA to conduct educational and public information programs (21 U.S.C. Section 393(d)(2)(D)). In addition to regulating the manufacture, distribution, and promotion of tobacco products, CTP conducts studies to inform regulatory actions and communications.

FDA sends email communications to subscribers in order to have the highest potential to be received, understood, and accepted by those for whom they are intended. FDA offices plan to conduct research and studies of those communications. This proposed study is the initiation of studies to conduct research of these communications. This proposed study will improve the following CTP email communications:



1. CTP Connect
  - This newsletter serves as a digest on the latest announcements and stories out of CTP as they happen, including information about regulations, guidance, enforcement actions, and other compliance-related announcements.
2. CTP News
  - This newsletter offers messages from CTP leadership, a regulatory news roundup, feature articles on current tobacco issues, and educational resources.
3. Spotlight on Science
  - This newsletter offers updates on CTP's tobacco regulatory science and research efforts, tobacco scientific publications and study findings, and CTP grants.

### III. STUDY GOAL AND OBJECTIVES

An analysis of CTP's audiences will deepen the Center's understanding of the information needs and preferences of its current and intended target audiences. The analysis also will inform the development of key performance indicators. The results of this study will allow CTP to more effectively reach a broader audience of stakeholders who need to be aware of the changing regulatory environment and other breaking news and updates related to tobacco products.

The objectives of the FDA CTP E-blast Survey Audience Analysis Study is to determine the following:

- Who are CTP's subscribers (private citizens, governmental, industry)?
  - Who is currently engaging with CTP?
  - What are the demographic characteristics and job descriptions of CTP subscribers?
- How well are CTP's intended audiences being reached?
- How satisfied are CTP's intended audiences with CTP's emails?
- How can CTP improve what it does to better serve subscribers?

Armed with a clearer image of its current subscribers, CTP will have the needed insights to:

- Develop and disseminate relevant and valuable content, in preferred formats via high value communication channels.
- Establish an audience baseline for measuring progress and optimizing tactics.

### IV. METHODS AND STUDY POPULATION

CTP is requesting approval of this study protocol for collecting information through the use of a brief, one-time, self-administered online survey.

CTP maintains an email subscriber list of approximately 40,000 members. These members have opted in, voluntarily, to be included in the database by registering through either the CTP website page, "Sign Up for Email Updates from CTP"

(<http://www.fda.gov/TobaccoProducts/AboutCTP/ucm176164.htm>), or the GovDelivery network.

Any individual can register if they so desire. Once registered, members receive complimentary copies of CTP newsletters and announcements via email. The approximately 40,000 subscribers are registered to at least one of the CTP newsletters or announcements, including:

- CTP Connect
- CTP News
- Spotlight on Science

To meet the goal of the CTP E-blast Survey Audience Analysis Study, the CTP research team will send an email, with a specific URL, to all email subscribers inviting them to complete an online survey (see **Appendix A, Survey Invitation Email Announcement [Includes Reminders]**). The web URL is not directly connected to the survey so participants' email addresses will not be collected. Subscribers have the ability to read and write in English. Although subscribers may not all be from the United States, they will all have the opportunity to participate in the survey.

During Week 1, the CTP research team will send an email blast (E-blast) to the entire database of approximately 40,000 CTP email subscribers, inviting them to participate in the online survey (See **Appendix B, Online Survey Instrument.**).

For a previous Substance Abuse and Mental Health Services Administration (SAMHSA) survey, sent to GovDelivery subscribers, whose focus was to understand the information seeking behaviors of the current SAMHSA audience base (inclusive of collecting demographic information), IQ Solutions received a 1.5 percent response rate. Moreover, the successful average delivery rate of the CTP E-blast is 97 percent, the average CTP E-blast open rate is 13.9 percent, and the average CTP E-blast click-through rate is 2.9 percent. IQ Solutions thus expects to receive between 400 and 1,200 completed surveys—that is, between one percent and three percent of the approximately 40,000 current CTP email subscribers.

To avoid the potential of one individual completing the survey more than one time, IQ Solutions will program the survey to limit one survey per device. This is possible using an IP address detector from Qualtrics. Even though the Qualtrics software will detect IP addresses, there is an option that will be used by the researchers which does not give the researchers access to the IP addresses of participants. This option will be chosen.

IQ Solutions will maintain the survey link live for three weeks. IQ Solutions will send two reminders during this period—the first reminder during Week 1 and the second reminder during Week 3 (see **Appendix A, Survey Invitation Email Announcement [Includes Reminders]**).

**(See Appendix C for the CTP E-blast Survey Audience Analysis Study Timeline.)**

Mario Navarro, Ph.D. (Center for Tobacco Products) is the Principal Investigator and FDA Sponsor for the research. An additional FDA CTP research staff member, in Atanaska (Nasi) Dineva, M.S, will be involved with the study. They will be involved both with survey design and analysis. CVs and certificates of completion of Human Subjects Protection training are included with this application.

The research team consists of the following IQ Solutions staff:

- Everly Macario, Sc.D., M.S., Ed.M. – Research Analyst
- Juaned Siddiqui, M.S. – Research Analyst

The IQ Solutions staff will be working with the Qualtrics software and will have a supportive role in developing the survey design and analysis. CVs and certificates of completion of Human Subjects Protection training are included with this application.

## **V. STUDY RECRUITMENT AND PARTICIPANT SCREENING**

To be eligible to participate in the online survey for the CTP E-blast Survey Audience Analysis Study, each respondent must:

- Subscribe to at least one of the following: CTP Connect, CTP News, Spotlight on Science (IQ Solutions will be using the database of subscribers to these resources to send an email inviting each subscriber to take the e-blast survey.)

- Be 18 years of age or older (as determined by a screener question on the survey)
- Have access to the Internet

*Note:* The online survey will be mobile-friendly.

The survey includes 14 –questions, including 3 multi-part questions and will take 5 minutes to complete. These questions were inspired by other satisfaction surveys (Cullen, 2001; Nelson & Niederberger, 1990). It uses a combination of Likert scale items (Albaum, 1997; Allen & Seaman, 2007) and Semantic Differential items (Kanungo, 1982; Tam, 2004) to better assess satisfaction from participants on various dimensions. This was determined by internal review of the survey in its online format. The survey begins with initial information that provides potential respondents with the informed consent information, including the purpose of the study, the benefits and risks of the study, and informs participants about the anonymous nature of the study. The survey is classified as anonymous as no personally identifiable information is asked of participants. This includes a detachment of email address from survey. This is possible as an independent survey link will be given to participants through the survey and the link will not be connected to their email address. Although Qualtrics will limit the survey to one time per device, the researchers will not be able to obtain IP information as it will be masked. This is possible as an option through Qualtrics. The item immediately following this background information invites the potential respondent to click either “Start survey now” or “Exit survey” to assure that those respondents who complete the survey are doing so voluntarily.

Once the survey is initiated, the survey will detect what type of device respondents are on (i.e., personal computer, phone, or tablet). In line with the anonymous nature of this survey, no IP addresses or other forms of PII will be recorded. Although the survey does prevent participants from taking the survey more than once based on participant’s IP address and internet cookies, Qualtrics’ propriety methods mask the IP address and cookies to the researcher and thus they are never recorded in the data set. The survey first asks respondents three demographic questions (age cohort, country of residence, the state of employment (if in the United States), and education level).

The survey questions that follow ask respondents about:

- Their country and/or state of origin.
- Their level of education.
- To which email option they are subscribed (CTP Connect, CTP News, and/or Spotlight on Science).
- Their professional backgrounds (i.e., professional role).
- Whether or not they are a government employee and if so, at what level of government do they work.
- A ranking of CTP topics from least to most interested.
- On which topics they wish to see information presented in more plain language.
- How valuable they rate certain CTP communication characteristics.
- Level of satisfaction with CTP email communications.
- How helpful they rate certain CTP email communications at keeping them informed about the work of the Center.
- To what degree they find CTP’s email content fresh and relevant.
- A ranking of sources of information from least to most used.
- An item assessing if they were paying attention to the survey.
- An item asking participants to make additional suggestions for how email communications can be improved.

Only individuals 18 years of age or older will be eligible for this study. If the respondent indicates that they are 17 years of age or younger, the program will terminate this respondent's participation at the screener.

## VI. PROCEDURE

Potential survey respondents will receive an invitation to complete the survey via a CTP E-blast emailed to the current E-blast subscriber base. If a recipient of the invitation is interested in taking the survey, they will click on a link URL provided to them in the electronic invitation.

The first page of the online survey will include informed consent information as well as the contact information of the study's Principal Investigator should a respondent wish to contact a study team member for any reason (see **Appendix D for the Informed Consent Information**).

## VII. JUSTIFICATION FOR SENSITIVE QUESTIONS

Although this survey is about tobacco related communications, there are no questions about tobacco use behaviors, attitudes, or feelings. This study does ask respondents about the country in which they live, the state in which they work, their age cohort, and their education level thus making this survey anonymous. The purpose of these questions is to describe the survey respondent sample, make comparisons across selected demographic groups, and tailor services and resources to CTP audience segments. These potentially sensitive questions are asked at the end of the survey, by which point respondents are more comfortable with the survey instrument, process, and sponsor. Some of the survey's questions may induce negative thoughts, and respondents may feel uncomfortable sharing reservations or criticisms they might have with CTP email communications. Again, respondents will be assured that the information is voluntary and will be treated as private and anonymous, and they do not have to respond to any question that makes them uncomfortable. If participants desire to not answer a question, there is a "prefer not to answer" option. For questions that do not have this response option, participants may skip the item.

Raw data from this data collection effort will not be retained once the data have been extracted and aggregated. The information will never become part of a system of records containing permanent identifiers that can be used for retrieval. As there are no personal identifiers, only the raw data will be ever contained. The survey data on Qualtrics will be deleted within 3 years from collection. As previously mentioned, email addresses will not be linked to their responses as the web link is independent from a participant's email.

## VIII. PROCEDURES FOR OBTAINING INFORMED CONSENT

Prior to the informed consent page, participants will be given a short description of the survey with the two screener questions assessing eligibility in the study. These two questions are directly regarding the informed consent and are used slightly before the informed consent so participants will not fabricate answers to ensure eligibility in the study. The online survey for the CTP E-blast Survey Audience Analysis Study will include the informed consent information and a statement, prior to beginning the survey, inviting prospective respondents to actively choose to participate in the survey voluntarily and noting there will be no negative repercussions for participating or choosing not to participate. The item after the informed consent information invites the potential respondent to click "Start survey now" or "Exit survey" to assure that those respondents who complete the survey are doing so voluntarily. The survey statement that will provide respondents' informed consent is worded as follows:

**If you click on "Start survey now," you are voluntarily agreeing to take part in this survey. Click one of the options below.**

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

**Start survey now** / I voluntarily agree to participate in this study.

[\[Go to Age Screener\]](#)

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

**Exit survey** / I do not want to participate in this study.

[\[TERMINATE SURVEY; GO TO TERMINATION TEXT 1\]](#)

[\[TERMINATION TEXT 1:\]](#) You have indicated that you do not want to participate in the CTP E-Blast Survey and will now exit the survey. If you decide later that you would like to participate, you can use the same email invitation to access the survey. Thank you for your time!

## **IX. ASSURANCE OF PRIVACY PROVIDED TO PARTICIPANTS**

### **A. Potential Risks and Benefits**

The methodology for the CTP E-blast Survey Audience Analysis Study involves a one-time online survey. The risk level for survey respondents is less than minimal risk (i.e., the probability of harm or discomfort anticipated in the research is not greater in and of itself than what would ordinarily be encountered in daily life or during the performance of routine physical or psychological examinations or tests). Moreover, identification of the survey respondents or their responses reasonably would not place them at risk of criminal or civil liability; would not be damaging to their financial standing, employability, insurability, and reputation; and would not be stigmatizing. The project team is committed to abiding with strict anonymity best practices in research investigations.

Respondents will have the option of not answering any questions they do not want to answer.

Respondents will receive no direct benefit from the study but their information will provide for better tailored, targeted, and effective CTP communications.

### **B. Privacy, Data Handling, and Recordkeeping**

All data collection activities will be conducted in full compliance with FDA regulations to maintain the privacy of data obtained from respondents and to protect the rights and welfare of human research subjects as contained in their regulations. Qualtrics will be the software used for data collection and storage. Qualtrics is a trusted survey tool used by both researchers and marketing companies alike. To be more specific, Qualtrics software is provided via an Application Service Provider, accessed using a modern internet browser where data is stored in a single secure data center. The data are encrypted at rest, and in transit, under password protection. Data will be stored via the Qualtrics data center under secure monitoring by Qualtrics staff. As the privacy of their customers is of utmost importance to Qualtrics only the researchers will have access to the data.

For raw data collected during this research, all servers are hosted using industry standard firewalls. Industry standard firewalls include the ability to allow or block traffic based on multiple forms of connection (e.g., state, port, and protocol), rather than only one connection, meaning that access is limited to those who are allowed entry. In addition, IQ Solutions will follow the Standard of Good Practice (SoGP, <https://www.securityforum.org/research/thestandardofgoodpractice2016/>) security practices which emphasize security management, safe business application protocol, safe computer installations, network fidelity, awareness of systems development requirements, and

safety of the end-user environment. Following these guidelines, the monitoring of data and sensitive information will take place following the SoGP security practices such as limiting access to information and data encryption. Members of the CTP research team will access the information through a secure log-in using a password on an HTTPS site, which ensures that data will be in an encrypted format when it is transmitted. This data transfer will occur via an encrypted and secure broadband connection.

The CTP research team will keep all anonymous electronic data downloaded from Qualtrics for the CTP E-blast Survey Audience Analysis Study in a password-protected computer. The data and actual surveys will only be available through the password protected Qualtrics website. Only IQ Solutions team members who are directly involved with the research study will have access to the surveys. All team members will have access to the aggregated data. IQ Solutions will send the data to the CTP research, thus no member of the CTP research team will have access to the surveys. The Principal Investigator will be responsible for overseeing that these data protection measures are put in place and sustained responsibly over time.

IQ Solutions will combine all survey responses in the aggregate when IQ Solutions and the CTP research team report results in a summary report.

The CTP research team will not collect any personally identifiable information from survey respondents (such as respondent name, mailing address, phone number, or social security number), and thus all respondent records will remain anonymous.

IQ Solutions will assign a unique number for each online survey respondent record. These record numbers will be used only for the CTP E-blast Survey Audience Analysis Study.

#### **D. DATA PRIVACY AND SECURITY**

Information provided by respondents will be kept private and anonymous to the extent allowable by law. This will be communicated to respondents in the informed consent information placed first in the survey instrument (i.e., the informed consent information is what a prospective respondent will see first after clicking the survey URL).

Respondents also will be advised of the following: the nature of the data collection activity; the purpose and use of the data collected; the FDA sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions. There is also a prefer not to answer response option to allow participants to opt out of a question.

All CTP research team staff will adhere to measures to ensure the privacy and anonymity of data. All electronic and hard copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers and hard copy data will be maintained in secure building facilities in locked filing cabinets. As a further guarantee of privacy and anonymity, all presentation of data in reports will be presented at the aggregate level, with no links to individuals preserved. Reports will be used only for research purposes and for the development of resources. The only identifier that exists in the data will be a random identification number given by the Qualtrics platform.

Dr. Mario Navarro and Atanaska (Nasi) Dineva of CTP, along with Dr. Everly Macario and Junaed Suddiqui of IQ Solutions, Inc., will have access to the raw data. They have completed their CITI Human Subjects certificates. **(Please see Appendix E for CITI Certificates and CVs.)**

IQ Solutions will store all data records safely for a minimum of 3 years after completion of this study, as is standard practice, and IQ Solutions will destroy the study data after this storage period.

## **X. INCENTIVES**

Since engagement in the study is minimal, no respondents will be paid an incentive to participate in the online survey. All participation in this study is voluntary.

## **XI. DATA ANALYSIS PLAN**

The IQ Solutions team will program the online survey of the CTP E-blast Survey Audience Analysis Study using Qualtrics software. The survey includes 14 questions, including 3 multi-part questions. Except for one open-ended question, the survey questions include closed-ended response categories where the respondent must select one of various options. For the multi-part questions, respondents who answer a specific way on one question will receive other specific questions afterwards.

To analyze the quantitative data collected from the online survey's closed-ended questions, the CTP research team, from the aggregated data, will summarize the descriptive statistics, such as means, standard deviations, and percentages, generated by the Qualtrics software as well as create cross-tabs to assess how demographic and other variables and survey items may be associated.

## **XII. ASSESSMENT AND REPORTING OF PROTOCOL DEVIATIONS AND ADVERSE EVENTS**

The Principal Investigator (PI) will ensure that there are appropriate oversight systems in place to monitor all research activities and identify any adverse events or deviations from the study protocol. Upon discovery of an adverse event, the Principal Investigator is responsible for reporting protocol deviations to the IRB using the standard reporting form.

Furthermore, the FDA CTP Sponsor will be actively involved in monitoring the study by conducting weekly oversight calls with the PI. All protocol deviations will be reviewed by the PI to assess whether participant safety or study integrity has been affected by the deviation and to what extent the deviation has affected the project. If the deviation is a protocol violation, appropriate measures will be taken to address the occurrence, which may include the development of a corrective action plan. All protocol deviations, violations, and corrective action plans will be reported to IRB. Corrective actions that lead to a change in the protocol shall be submitted to the FDA Sponsor and forwarded to and approved by FDA RIHSC as an amendment to the protocol prior to implementation.

Subject privacy and data confidentiality breaches are serious risks and will be reported within one hour of discovery to the FDA Sponsor who will immediately notify CTP and FDA RIHSC ([RIHSC@fda.hhs.gov](mailto:RIHSC@fda.hhs.gov)).

The following will be communicated as at least an initial notification to the FDA Sponsor and FDA RIHSC ([RIHSC@fda.hhs.gov](mailto:RIHSC@fda.hhs.gov)) as soon as possible (generally within 24 hours) with a full report submitted within 10 days. In the case of any adverse events, IQ Solutions will remove the respondent's survey from the analysis and provide support to the respondent as needed.

- **Serious Adverse Event:** An adverse health event that is life-threatening or results in death, initial or prolonged hospitalization, disability or permanent damage, congenital anomaly or birth defect, or requires medical or surgical intervention to prevent one of the other outcomes.

- Unexpected Adverse Event: Adverse health events that were not identified in nature, severity, or frequency in the research protocol / informed consent documents.
- Unanticipated Problem: Any incident, experience, or outcome that meets all of the following criteria:
  - 1) Unexpected (in terms of nature, severity, or frequency) given a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and b) the characteristics of the subject population being studied;
  - 2) Related or possibly related to the subject's participation in the research; and
  - 3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.
- Protocol Violation: Any change, divergence, or departure from the study design or procedures of a research protocol that affects the subject's rights, safety, or well-being and/or the completeness, accuracy and reliability of the study data.

The following will be communicated on a routine non-urgent basis but no less than annually:

- Expected adverse events: Those health effects and other risks that are listed in the protocol and informed consent forms as being likely to occur or as a result of participation in the study.
- Protocol deviation: Any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB.
- Minor Protocol Deviation: Any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

**Contractor Information:**

Everly Macario, Sc.D., M.S., Ed.M.  
 Senior Research and Evaluation Director  
 IQ Solutions, Inc.  
 11300 Rockville Pike, Suite 901  
 Rockville, MD 20854  
 773.752.7732 direct  
 224.244.3965 cell  
[EMacario@iqsolutions.com](mailto:EMacario@iqsolutions.com)

**Study Materials:**

- Appendix A. CTP E-Blast Survey Invitation Email Announcement [Includes Reminders]
- Appendix B. CTP E-Blast Online Survey Instrument
- Appendix C. CTP E-Blast Survey Audience Analysis Study Timeline
- Appendix D. CTP E-Blast Informed Consent Information
- Appendix E. CITI Certificates and CVs





## References

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## Appendix D. CTP E-Blast Informed Consent Information

Welcome to the FDA Center for Tobacco Products' (CTP) E-BLAST SURVEY!

You must be 18 years of age or older to be eligible to complete this survey.

The purpose of this research study, E-BLAST SURVEY, is to see how satisfied recipients are with CTP's email communications (i.e., CTP Connect, CTP News, and Spotlight on Science), and for us to learn a little bit about you.

This 5-minute, anonymous, survey is completely voluntary and you may quit, without penalty, at any time. As such, no personal identifying information is requested. Responses will be kept anonymous. In addition, there are no foreseeable risks or discomforts by participating in this survey. There are no additional costs that may result from participating in this study. Your data will be reported at the aggregate level. If you feel uncomfortable about answering any question(s) you may choose the "prefer not to answer" response. There are no direct benefits to your participation.

If you have questions or concerns about the study, please contact Dr. Everly Macario at IQ Solutions, Inc., at 224-244-3965 or EMacario@IQSolutions.com.

If you have questions about your rights as a research participant, please contact the Food and Drug Administration's Research Involving Human Subjects Committee at RIHSC@fda.hhs.gov or 301-796-9605. This committee is a group of people who review research studies to protect the rights and safety of research participants. If you would like a copy of this form, please print a copy of this page.

If you click on "Start survey now," you are voluntarily agreeing to take part in this survey. Click one of the options below.

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

**Start survey now** / I voluntarily agree to participate in this study.

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

**Exit survey** / I do not want to participate in this study. [\[TERMINATE SURVEY; GO TO TERMINATION TEXT 2\]](#)

[\[TERMINATION TEXT 2:\]](#) You have indicated that you do not want to participate in the CTP E-Blast Survey and will now exit the survey. If you decide later that you would like to participate, you can use the same email invitation to access the survey. Thank you for your time!

## Appendix B. CTP E-blast Online Survey Instrument

Note: The survey respondent will not see any text in blue.

### [Screening Questions]

The purpose of this E-BLAST SURVEY is to see how satisfied you are with the Food and Drug Administration's Center for Tobacco Products' (CTP) email communications in general (i.e., CTP Connect, CTP News, and Spotlight on Science) and for us to learn about the email communications' user base. Would you like to participate in this study?

- a. Yes
- b. No [TERMINATE SURVEY; GO TO TERMINATION TEXT 1]
- c. Prefer not to answer [TERMINATE SURVEY; GO TO TERMINATION TEXT 1]

What year were you born?

[Drop-down menu]

[TERMINATE SURVEY AND GO TO TERMINATION TEXT 1 IF RESPONDENT WAS BORN IN 1998 OR LATER]

[TERMINATION TEXT 1:] Based on your answer, you do not qualify for this survey. Thank you very much for your time.

[Landing Page/Introduction]

[INSERT APPENDIX D, INFORMED CONSENT FORM HERE]

The first few questions ask a little bit about you.

1. In what country do you live? [Drop down menu of countries]

- Prefer not to answer

1a. [For those who responded “United States”] What state do you work in? [Drop down menu of states]

- Prefer not to answer

2. Which of the following categories best describes your level of education? [This will be just a single response item]

- Some high school
- High school diploma or GED
- Trade or technical school
- Some college
- Associate’s degree
- Bachelor’s degree
- Graduate or professional degree (e.g., M.A., Ph.D., Psy.D., J.D., M.D.)
- Prefer not to answer

3. To which of our three email options are you subscribed?

[SELECT ALL THAT APPLY.]

- CTP Connect (This newsletter serves as a digest on the latest announcements and stories out of CTP as they happen, including information about regulations, guidance, enforcement actions, and other compliance-related announcements.)
- CTP News (This newsletter offers messages from CTP leadership, a regulatory news roundup, feature articles on current tobacco issues, and educational resources.)
- Spotlight on Science (This newsletter offers updates on CTP’s tobacco regulatory science and research efforts, tobacco scientific publications and study findings, and CTP grants.)
- I Don’t Know

4. Which of the following best describes you?

a Public health professional

Please check the role that best describes you: [These options will only appear if the respondent checks “Public health professional”]

- i Researcher/scientist
- ii Advocate
- iii Educator/Trainer
- iv Communicator
- v Other: Please specify: \_\_\_\_\_ [Open-ended text box]

b Healthcare professional

Please check the role that best describes you: [These options will only appear if the respondent checks “Healthcare professional”]

- i Physician
- ii Nurse
- iii Administrator
- iv Other: Please specify: \_\_\_\_\_ [Open-ended text box]

- c Tobacco industry representative
  - Please check the role that best describes you: [These options will only appear if the respondent checks "Tobacco industry representative"]
  - i Retailer
  - ii Manufacturer
  - iii Wholesaler or Distributor
  - iv Importer
  - v Grower
  - vi Trade Association Representative
  - vii Other: Please specify: \_\_\_\_\_ [Open-ended text box]
- d Media professional
  - Please check the role that best describes you: [These options will only appear if the respondent checks "Media professional"]
  - i Member of the press/reporter
  - ii Other communications professional
  - iii Other: Please specify: \_\_\_\_\_ [Open-ended text box]
- e General public
  - Please check the role that best describes you: [These options will only appear if the respondent checks "General public"]
  - i A tobacco product consumer
  - ii Family/friend of product consumer
  - iii Other: Please specify: \_\_\_\_\_ [Open-ended text box]
- f Other: Please specify: \_\_\_\_\_ [Open-ended text box]
- g Prefer not to answer

**5. Are you a government employee?**

- a Yes
  - Please check the level of government that you work in: [These options will only appear if the respondent checks "Yes"]
  - i Federal
    - Please check the role that best describes you: [These options will only appear if the respondent checks "Federal"]
    - i Food and Drug Administration
    - ii Other: Please specify: \_\_\_\_\_ [open-ended text box]
  - ii State
  - iii Local
- b No
- c Prefer not to answer

The next several questions ask about your opinions on and needs related to CTP communications.

6. Please rate the following 5 topics in order of interest level, 1 being of most interest and 5 being of least interest: (Please drag each response to your preferred ranking position)

- \_\_\_\_\_ Youth education campaigns
- \_\_\_\_\_ Adult consumer information
- \_\_\_\_\_ Compliance and enforcement actions
- \_\_\_\_\_ Policy, rulemaking, and guidance information
- \_\_\_\_\_ The latest science and research

6a. Are there any additional topics not listed above that are of interest to you?

- No
- Yes; What additional topics are of interest to you? Please enter topics here:  
 \_\_\_\_\_ [\[open-ended text box\]](#)

7. Would you like more plain language (easy-to-understand) information and resources for the following topics? [\[Participants are only able to choose one option per item\]](#)

		1 Yes	2 No	6 Don't know/Not Applicable	9 Prefer not to answer
7_1	General compliance information	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _6	<input type="checkbox"/> _9
7_2	Tobacco product application pathways	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _6	<input type="checkbox"/> _9
7_3	Harmful and potentially harmful constituents	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _6	<input type="checkbox"/> _9
7_4	The compliance check inspection process	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _6	<input type="checkbox"/> _9
7_5	Tobacco product research	<input type="checkbox"/> _1	<input type="checkbox"/> _2	<input type="checkbox"/> _6	<input type="checkbox"/> _9

7a. Are there any additional topics not listed above that are of interest to you?

- No
- Yes; Please specify: \_\_\_\_\_ [\[open-ended text box\]](#)

The next few questions ask about your satisfaction with CTP communications.

8. The following question is different from the ones asked previously. Please look at each item carefully as the response options have changed. Please rate the value of each of the following characteristics of our emails. [Participants are only able to choose one option per item]

							Don't know/NA	Prefer not to answer
<b>Length of Articles</b>								
<b>8_1 Too short</b>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<b>Too long</b>	<input type="checkbox"/> 6	<input type="checkbox"/> 9
<b>Depth of Coverage</b>								
<b>8_2 Too little</b>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<b>Too much</b>	<input type="checkbox"/> 6	<input type="checkbox"/> 9
<b>Amount of Graphics</b>								
<b>8_3 Too few</b>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<b>Too many</b>	<input type="checkbox"/> 6	<input type="checkbox"/> 9
<b>Amount of Content That Can Be Shared Through Twitter</b>								
<b>8_4 Too little</b>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<b>Too much</b>	<input type="checkbox"/> 6	<input type="checkbox"/> 9
<b>Frequency of Communications</b>								
<b>8_5 Too infrequently</b>	<input type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5	<b>Too often</b>	<input type="checkbox"/> 6	<input type="checkbox"/> 9

9. Overall, how satisfied or dissatisfied are you with the email communications you receive from CTP?

- Very satisfied
- Somewhat satisfied
- Neutral (neither satisfied or dissatisfied)
- Somewhat dissatisfied
- Very dissatisfied
- Prefer not to answer

10. How helpful are the email communications you receive from CTP in keeping you informed about the work of the Center?

- Very helpful
- Somewhat helpful
- Neutral (neither helpful or unhelpful)
- Somewhat unhelpful
- Very unhelpful
- Prefer not to answer

11. Do you find CTP's email content fresh and relevant?

- Yes, always
- Yes, usually
- No, not usually



- No, never
- Don't know/Not sure
- Prefer not to answer

**This question asks about information sources.**

**12. Please rate the following sources of information where you receive information from CTP from 1 to 4, 1 being your primary source and 4 being the source you use least:  
(Please drag each response to your preferred ranking position)**

- \_\_\_\_\_ Emails from CTP
- \_\_\_\_\_ Non-CTP emails
- \_\_\_\_\_ CTP Twitter
- \_\_\_\_\_ CTP Facebook
- \_\_\_\_\_ Non-FDA/CTP social media channels
- \_\_\_\_\_ Television
- \_\_\_\_\_ Radio
- \_\_\_\_\_ Print (e.g., newspapers, magazines)
- \_\_\_\_\_ Government websites
- \_\_\_\_\_ Non-government websites
- \_\_\_\_\_ Prefer not to answer

**13. Most of the people who take our surveys read the questions carefully, but a few do not. To let us know that you have carefully read the questions in this survey, please select the color yellow from the response options below.**

- Red
- Blue
- Yellow
- Purple
- Prefer not to answer

**14. Please feel free to make suggestions here for how we can improve our email communications:**

[\[Open-ended text box\]](#)

**Thank you very much for taking the time to complete our E-Blast Survey!**

**The FDA CTP Team**

[\[End of survey\]](#)

## Appendix A. CTP E-blast Survey Invitation Email Announcement [Includes Reminders]

Note: The survey respondent will not see any text in blue.

**Email subject heading:** Voice Your Opinion on CTP's Email Communication Services and Resources

**Body of email:**

The FDA Center for Tobacco Products (CTP) wants to hear your thoughts about the information you receive from us via email from (i.e., **CTP Connect**, **CTP News**, and **Spotlight on Science**).

Please take our survey so that we can learn about you, as well as how we are doing, to provide you with high-quality email services and resources. If you have already completed the survey, thank you for your time. If you have not yet completed the survey, please take the time to complete the survey.

The survey is anonymous and takes 5 minutes to complete. Please complete the survey **by Month X, 2017**. [The date will be set at 3 weeks after the survey is launched]

**TAKE THE SURVEY**

**URL Link**

[A visual meant to grab potential respondents' attention will be inserted for better recruitment]

-----  
For the first reminder, we will include the following message in the email subject heading and send the same announcement as above in the body of the email:

**Reminder #1: Don't forget to complete the CTP's E-BLAST SURVEY!**

For the second reminder, we will include the following message in the email subject heading and send the same announcement as above in the body of the email:

**Reminder #2: This is the last day to complete the CTP's E-BLAST SURVEY!**

# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Atanaska (Nasi) Dineva (ID: 3535691)
- **Institution Affiliation:** FDA (ID: 2617)
- **Institution Email:** atanaska.dineva@fda.hhs.gov
- **Institution Unit:** CTP/OHCE
  
- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.
  
- **Record ID:** 22805622
- **Completion Date:** 04-Apr-2017
- **Expiration Date:** 03-Apr-2020
- **Minimum Passing:** 80
- **Reported Score\*:** 95

### REQUIRED AND ELECTIVE MODULES ONLY

	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	04-Apr-2017	3/3 (100%)
History and Ethical Principles - SBE (ID: 490)	04-Apr-2017	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	04-Apr-2017	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	04-Apr-2017	5/5 (100%)
Assessing Risk - SBE (ID: 503)	04-Apr-2017	5/5 (100%)
Informed Consent - SBE (ID: 504)	04-Apr-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	04-Apr-2017	3/5 (60%)
Internet-Based Research - SBE (ID: 510)	04-Apr-2017	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	04-Apr-2017	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?k1bf1926e-cf53-4fda-8c3a-6d7ecd20da4e-22805622](http://www.citiprogram.org/verify/?k1bf1926e-cf53-4fda-8c3a-6d7ecd20da4e-22805622)

### Collaborative Institutional Training Initiative (CITI Program)

Email: [support@citiprogram.org](mailto:support@citiprogram.org)

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT\*\*

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Atanaska (Nasi) Dineva (ID: 3535691)
- **Institution Affiliation:** FDA (ID: 2617)
- **Institution Email:** atanaska.dineva@fda.hhs.gov
- **Institution Unit:** CTP/OHCE
  
- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.
  
- **Record ID:** 22805622
- **Report Date:** 05-Apr-2017
- **Current Score\*\*:** 95

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethical Principles - SBE (ID: 490)	04-Apr-2017	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	04-Apr-2017	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	04-Apr-2017	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	04-Apr-2017	5/5 (100%)
Assessing Risk - SBE (ID: 503)	04-Apr-2017	5/5 (100%)
Informed Consent - SBE (ID: 504)	04-Apr-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	04-Apr-2017	3/5 (60%)
Internet-Based Research - SBE (ID: 510)	04-Apr-2017	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	04-Apr-2017	5/5 (100%)

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

Verify at: [www.citiprogram.org/verify/?k1bf1926e-cf53-4fda-8c3a-6d7ecd20da4e-22805622](http://www.citiprogram.org/verify/?k1bf1926e-cf53-4fda-8c3a-6d7ecd20da4e-22805622)

### Collaborative Institutional Training Initiative (CITI Program)

Email: [support@citiprogram.org](mailto:support@citiprogram.org)

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

# ATANASKA (NASI) DINEVA

10603 Whiterock Court  
Laurel, MD 20723  
(443) 850 - 0023  
nasi.dineva@gmail.com

## SUMMARY OF QUALIFICATIONS

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9+ years' experience developing, implementing, and evaluating science-based communication and marketing strategies in the public health arena. Substantive knowledge of global and domestic tobacco control issues, including tobacco product regulation. Proven track record of developing high-quality communication materials and devising effective strategies to reach a variety of audiences. Strong analytical and problem-solving skills. Demonstrated resourcefulness in the completion of projects. Highly trustworthy, reliable, and self-motivated.

## EDUCATION

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<b>MS in Marketing</b> Johns Hopkins University, Carey Business School	2009 - 2012 Baltimore, MD
<b>BA in Communications and Mass Media</b> Goucher College	1998 - 2002 Towson, MD

## EXPERIENCE

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<b>Health Communication Specialist</b> FDA Center for Tobacco Products (CTP) Office of Health Communication and Education (OHCE)	03/2013 – Present
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Support the work of OHCE's Research and Evaluation team with developing, testing, and timely dissemination of science- and audience-based products, tools, and messages to different audiences in a variety of formats. Participate in formative research, testing concepts and messages, and evaluation of campaigns and programs. Also worked with OHCE's Strategic Partnership Alliances team to develop and launch the TRACE Cooperative Agreement Program. Gained the foundational knowledge needed to award and monitor grants and cooperative agreements effectively from pre-award through closeout.

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**FDA Tobacco Regulatory Science Fellow**  
FDA Center for Tobacco Products (CTP)  
Office of Health Communication and Education (OHCE)

09/2012 – 03/2013

Participate in the development of science-based public health strategies. Serve as the lead on a project that aims to increase stakeholder and partner engagement with the goal of broadening the dissemination and uptake of CTP messages in the public health community. Contribute to OHCE's day-to-day activities, as needed. Meet with policy makers. Develop new competencies to further define and develop the field of regulatory science as it relates to the regulation of tobacco products and FDA's new authorities under the Family Smoking Prevention and Tobacco Control Act.

---

**Communications Associate**  
Institute for Global Tobacco Control  
Johns Hopkins Bloomberg School of Public Health

2007 – 2012

Served as a communication and marketing expert for the Institute for Global Tobacco Control (IGTC). Managed all of IGTC's communication, public relations, and marketing activities. Planned, implemented and evaluated science-based communication and marketing strategies to achieve optimal program results. More specifically:

- Developed and oversaw the execution of an annual marketing and communications plan that effectively implemented IGTC's strategic plan through internal and external communications, publications, media relations, and electronic presence.
- Responsible for public outreach, including the development of press materials, email marketing, and use of new media to communicate the depth, breadth, and quality of the Institute's initiatives to a variety of audiences. Served as initial point-of-contact for media inquiries. Planned and managed IGTC's presence at conferences and special events to enhance visibility, increase brand awareness, and strengthen stakeholder outreach.
- Planned and oversaw the development of all print and electronic communications materials for the IGTC, ensuring content accuracy, quality, and appropriateness for the target audience. Managed project execution through all stages of production.
- Provided technical assistance to IGTC's research team in the areas of communications and social media on projects aimed at promoting positive health outcomes by changing knowledge, attitudes, and behavior related to tobacco use.
- Led planning, development, and evaluation of websites and online resources, including an Intranet site for the Bloomberg Initiative to Reduce Tobacco Use ([www.GlobalTobaccoControlPartners.org](http://www.GlobalTobaccoControlPartners.org)) and an interactive, e-learning Web site for tobacco control ([www.GlobalTobaccoControl.org](http://www.GlobalTobaccoControl.org)), among others.

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**Web Communications Specialist**

2005 - 2007

Institute for Global Tobacco Control  
Johns Hopkins Bloomberg School of Public Health

Responsible for content creation and maintenance of IGTC's websites and the development of print communication materials, including reports, factsheets, and brochures. Redesigned IGTC's website and expanded its content to include information on projects in 40+ countries. Organized website content around core activities of the Institute and provided the organizational structure for all subsequent marketing materials. Also planned and oversaw the development of websites for the FAMRI Center of Excellence ([www.hopkins-famri.org](http://www.hopkins-famri.org)) and the Global Tobacco Research Network ([www.tobaccoresearch.net](http://www.tobaccoresearch.net)).

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**Program Coordinator**

2003 - 2005

Institute for Global Tobacco Control  
Johns Hopkins Bloomberg School of Public Health

Provided program support with emphasis on development of presentations, brochures, flyers, and preparation of grant and manuscript submissions.

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**Media Coverage Analyst/Writer**

2002

Accuracy In Media

Monitored news coverage in the media and wrote briefs for one of the leading Washington, D.C., think-tanks. Topics included taxation, the death penalty, OPEC, and immigration, among others.

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**VOLUNTEER WORK****Chair, Communications Workgroup**

2012

Global Smokefree Partnership

Led and coordinated the communication activities of the Global Smokefree Partnership aimed at disseminating evidence-based findings to support the implementation and enforcement of smoke-free policies around the world.

---

**PRESENTATIONS**

*Providing Global Online Training for Tobacco Control in Six Languages: Lessons Learned*, 15<sup>th</sup> World Conference on Tobacco OR Health (WCTOH), Singapore, March 2012.

*Assessing the Needs of the Global Tobacco Control Community* (Panel), 14<sup>th</sup> World Conference on Tobacco OR Health (WCTOH), Mumbai, India, March 2009.

## HONORS AND AWARDS

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All Star Award	Constant Contact, 2011
Dean's Alumni Board Award	Johns Hopkins Carey Business School, 2010
Maureen and Kenneth Rowan Award	Goucher College, 2002
Brownlee Corrin Award	Goucher College, 2000

## SPECIALIZED TRAINING

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RIHSC Training	U.S. Food and Drug Administration, 2013
Contracting Officer Representative Course	Management Concepts, 2013
Monitoring Grants and Cooperative Agreements	Management Concepts, 2013
Uniform Administrative Requirements for Grants	Management Concepts, 2013
Cost Principles	Management Concepts, 2013
Food Drug and Law Course	Center for Tobacco Products, 2013
Tobacco Regulatory Science Course	Georgetown University, 2012
Health Policy Orientation	Academy Health, 2012
Media Training	CommCore Consulting Group, 2012
Social Marketing and New Media	Mid-Atlantic Public Health Training Center, 2010
Public Health Communication Campaigns	Mid-Atlantic Public Health Training Center, 2009
Writing for the Web	Johns Hopkins Bloomberg School of Public Health, 2005
Reference Manager	Welch Medical Library, 2004

## TECHNOLOGY SKILLS

---

<b>Microsoft Office</b>	PowerPoint, Excel, Word, Outlook, Publisher
<b>Social Media</b>	Facebook, Twitter, YouTube
<b>Email Marketing</b>	Contacts management, list segmentation, analytics
<b>Web</b>	HTML, CSS, Adobe Dreamweaver
<b>Web Analytics</b>	Google Analytics, Search Engine Optimization
<b>Design</b>	Adobe Photoshop, InDesign
<b>Reference Tools</b>	PubMed, Reference Manager, EndNote

## LANGUAGES

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Fluent in **English**, **Russian**, and **Bulgarian**. Reading skills in **German**.



## REFERENCES

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**Jonathan Samet, MD, MS**

Director, Institute for Global Health  
Professor and Flora L. Thornton Chair, Department of Preventive Medicine  
Keck School of Medicine  
University of Southern California  
Telephone: 323-865-0803  
Email: jsamet@usc.edu

**Joanna Cohen, PhD, MHSc**

Director, Institute for Global Tobacco Control  
Bloomberg Associate Professor of Disease Prevention  
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**Blair Johnson, MS**

Lecturer and Faculty Director of Capstone Projects, Johns Hopkins Carey Business School  
Joint Appointment, Johns Hopkins School of Nursing, Dept. of Health Systems and Outcomes  
National Faculty, Robert Wood Johnson Foundation Executive Nurse Fellows Program  
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**Benjamin Apelberg, PhD, MHS**

Epidemiologist, Center for Tobacco Products  
U.S. Food and Drug Administration  
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# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 1 OF 2

### COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Everly Macario (ID: 6381766)
- **Institution Affiliation:** Independent Learner (ID: 569)
- **Phone:** 2242443965
  
- **Curriculum Group:** Human Subjects Research - BASIC
- **Course Learner Group:** Human Subjects Research – Social-Behavioral-Educational Basic
- **Stage:** Stage 1 - Independent Learner
  
- **Record ID:** 23414524
- **Completion Date:** 07-Jun-2017
- **Expiration Date:** 07-Jun-2018
- **Minimum Passing:** 80
- **Reported Score\*:** 100

#### REQUIRED AND ELECTIVE MODULES ONLY

	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	05-Jun-2017	3/3 (100%)
History and Ethical Principles - SBE (ID: 490)	05-Jun-2017	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	05-Jun-2017	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	05-Jun-2017	5/5 (100%)
Assessing Risk - SBE (ID: 503)	06-Jun-2017	5/5 (100%)
Informed Consent - SBE (ID: 504)	06-Jun-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	06-Jun-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	06-Jun-2017	5/5 (100%)
Research with Prisoners - SBE (ID: 506)	06-Jun-2017	5/5 (100%)
Research with Children - SBE (ID: 507)	06-Jun-2017	5/5 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	06-Jun-2017	5/5 (100%)
International Research - SBE (ID: 509)	07-Jun-2017	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	07-Jun-2017	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	07-Jun-2017	5/5 (100%)
Cultural Competence in Research (ID: 15166)	07-Jun-2017	5/5 (100%)

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

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#### Collaborative Institutional Training Initiative (CITI Program)

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# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 2 OF 2

### COURSEWORK TRANSCRIPT\*\*

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Everly Macario (ID: 6381766)
- **Institution Affiliation:** Independent Learner (ID: 569)
- **Phone:** 2242443965
  
- **Curriculum Group:** Human Subjects Research - BASIC
- **Course Learner Group:** Human Subjects Research – Social-Behavioral-Educational Basic
- **Stage:** Stage 1 - Independent Learner
  
- **Record ID:** 23414524
- **Report Date:** 07-Jun-2017
- **Current Score\*\*:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethical Principles - SBE (ID: 490)	05-Jun-2017	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	05-Jun-2017	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	05-Jun-2017	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	05-Jun-2017	5/5 (100%)
Assessing Risk - SBE (ID: 503)	06-Jun-2017	5/5 (100%)
Informed Consent - SBE (ID: 504)	06-Jun-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	06-Jun-2017	5/5 (100%)
Research with Prisoners - SBE (ID: 506)	06-Jun-2017	5/5 (100%)
Research with Children - SBE (ID: 507)	06-Jun-2017	5/5 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	06-Jun-2017	5/5 (100%)
International Research - SBE (ID: 509)	07-Jun-2017	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	07-Jun-2017	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	07-Jun-2017	5/5 (100%)
Cultural Competence in Research (ID: 15166)	07-Jun-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	06-Jun-2017	5/5 (100%)

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## Core Competencies

- Qualitative & quantitative research design, implementation, evaluation, & report writing
- Research protocol development
- Focus group moderation
- In-depth interviewing
- Surveys
- Formative research
- Audience analyses
- Literature reviews; environmental scans; gap analyses
- Campaign design (branding)
- Campaign evaluation
- Social marketing
- Behavior change communication
- Health/medical writing
- Scientific journal article writing
- Health literacy
- Grant/proposal writing
- IRB & OMB submissions
- Strategic planning
- Partnership development
- Message development & testing
- Health education products development
- Hispanic/Latino multicultural outreach/“transcreations” (fluent in Spanish)
- Media/public relations (press releases)
- Project leadership & management (budgets, timelines)
- Presentations

## Education

**HARVARD UNIVERSITY**,  
Cambridge, MA

- **Doctor of Science (Sc.D.)**, Health & Social Behavior, 1997
- **Master of Education (Ed.M.)**, 1993
- **Master of Science (M.S.)**, Health Policy & Management, 1992

**UNIVERSITY OF PENNSYLVANIA**,  
Philadelphia, PA

- **Bachelor of Arts (B.A.)**, History & Sociology of Science, 1988

## Independent Consultant, Public Health Research and Communications 1999-present

As a bicultural/bilingual (English/Spanish) behavioral scientist with expertise in health communications and social marketing, I have spent 30 years designing and directing qualitative and quantitative research on public health topics, creating research-informed health education campaigns, messages, and products, and assessing the impact of those campaigns, messages, and products for Federal government agencies, health departments, universities, foundations, research organizations, and pharmaceutical companies. I have provided my services to 50+ clients on 50+ health topics in 35+ U.S. locations over 15 years. See below for highlights.

## Professional Experience

### **IQ Solutions, Inc. – Rockville, MD** **Senior Research Director (part-time)**

**2001-present**

Design rigorous research methodologies appropriate to research questions for:

- Food and Drug Administration (FDA), Center for Tobacco Products (CTP)
- National Heart, Lung and Blood Institute (NHLBI)
- National Institute on Deafness and other Communication Disorders (NIDCD)
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Multicultural Outreach Initiative
- *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), *Back to Sleep* Campaign, *Media-Smart Youth—Eat, Think, and Be Active!* Program
- National Institute of Dental and Craniofacial Research (NIDCR), Spanish-language website
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA), Office of Science Policy and Communications, *Drugs + HIV: Learn the Link* Campaign, *NIDA Goes Back to School* Campaign
- National Eye Institute (NEI), National Eye Health Education Program, outreach to American Indians and Alaska Natives
- Office of Disease Prevention and Health Promotion (ODPHP)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
- WomenHeart: The National Coalition for Women with Heart Disease

#### *Selected Accomplishments*

- Part of the team that received the 2014 National Health Information Award (Gold) for the NIAMS A Year of Health / *Un año de salud* Health Planner.
- Part of the team that received the 2010 NIH Gold Plain Language Award for the Spanish-language NIDCR website.
- Part of the team that created the bilingual “After the Party” (“*Después de la fiesta*”) Public Service Announcement (NIDA, 2008) nominated for an Emmy Award.

### **The Hannon Group, Inc. – Fort Washington, MD**

**2009-present**

#### **Director of Research (part-time)**

Engage in strategic planning, social marketing, market research, multicultural outreach and promotion, materials development, communications, and media relations services (clients: Centers for Disease Control and Prevention, Institute for Public Health Innovation, National Institute for Occupational Safety and Health, Department of Energy, American Society of Civil Engineers, Office of the National Coordinator for Health IT).

*Selected Accomplishment:* Part of the team that received the 2012 Public Relations Society of America Thoth Award in the “Research/Evaluation” category for the *Safety Pays, Falls Cost* campaign.

### **University of Chicago Medical Center – Chicago, IL**

**2008-2013**

#### **Research Administrator**

Co-founded the MRSA Research Center to prevent, control, and treat MRSA (methicillin-resistant *Staphylococcus aureus*) through basic scientific and clinical research.

*Selected Accomplishment:* Developed the Center’s website and promotion materials, engaged in fundraising, contributed to research design proposals, and submitted IRB packages.

**Publications**

I have published 30+ peer-reviewed articles in the following scientific journals, many for which I am first author.

- *American Journal of Health Promotion*
- *American Journal of Industrial Medicine*
- *Californian Journal of Health Promotion*
- *Cases in Public Health Communication & Marketing*
- *CANCER*
- *Communication in Healthcare: Strategies, Media, and Engagement in Global Health*
- *Ethnicity & Disease*
- *Health Education & Behavior*
- *Health Promotion Practice*
- *Journal of the American Dietetic Association*
- *Journal of Communication in Healthcare*
- *Journal of Health Disparities Research and Practice*
- *Journal of Infection Prevention*
- *Journal of the National Cancer Institute*
- *Journal of Nutrition Education*
- *Journal of the Pediatric Infectious Diseases Society*
- *Journal of School Violence*
- *Journal of Social Marketing*
- *Public Health Nursing*
- *Women & Health*
- *Women and Smoking: A Report of the Surgeon General*
- *Women's Health Issues*

**Presentations**

- American Public Health Association
- CDC National Conference on Health Communication, Marketing and Media
- Interscience Conference on Antimicrobial Agents and Chemotherapy
- National Hispanic Medical Association
- National Immunization Conference
- Public Relations Society of America, Health Academy
- Social Marketing in Public Health
- WomenHeart: The National Coalition for Women with Heart Disease

**Spokesperson**

*Supermoms Against Superbugs*,  
Pew Charitable Trusts

Researcher for *Health4Chicago—Helping Students Grow Strong*, a south side Chicago school-based immunization and medical home initiative.

*Selected Accomplishment*: Second author in *Journal of the Pediatric Infectious Diseases Society* article on *Health4Chicago*.

The Chicago Center for HIV Elimination – Grant writer

**Centers for Disease Control and Prevention – Atlanta, GA  
Consultant****2003-as needed**

Moderated hundreds of focus groups and crafted next step recommendations related to:

- Maternal vaccinations (Tdap, influenza, Group B Streptococcus, Respiratory Syncytial Virus)
- Legionnaires' disease
- Vaccine-hesitant parents
- Infant, childhood, preteen, adolescent, and adult immunizations
- Seasonal influenza/vaccine; HPV (human papillomavirus) vaccine; 2009 H1N1 influenza/vaccine
- Traumatic brain injuries
- Secondhand smoke

**California Department of Public Health – Richmond, CA  
Consultant****2003-2010**

Engaged in strategic thinking, product development, and target audience research for:

- *Más vale prevenir que lamentar. Vacune a sus hijos contra el virus del papiloma humano* (“An Ounce of Prevention: Vaccinate your children against the human papillomavirus (HPV)”) Spanish/English fotonovela.
- *Vaccines: Wading Through the Confusion*, a virtual public health town hall discussion (launched February 2009).
- *brochure 2 BLOG: Public Health Communication for a New Age*, May 2008 documentary and hands-on scavenger hunt activity.
- *Immunizations Are Your Best Shot! California's Preteen Vaccine Week*, annual social marketing campaign targeting tweens.
- *Pandemic Influenza Preparedness for Schools 2007*, schools-based training program consisting of a video, tabletop exercise, and online toolkit.
- *Pandemic Influenza and Public Health Law 2006*, satellite broadcast and tabletop exercise training on the legal implications of pandemic influenza.
- *Public Health Preparedness: Pandemic Influenza California Update 2005*, emergency preparedness response training program consisting of a satellite broadcast and small problem-solving tabletop exercise.

*Selected Accomplishments*

- Part of the team that received the Silver award, New Media Category, National Public Health Information Coalition, for the *brochure 2 BLOG* documentary.
- Part of the team that received (a) 2nd place National Health Literacy Innovators Award, 2011 and (b) Bronze Award (brochures category), The National Public Health Information Coalition Annual Award for Excellence, 2011, for the Spanish/English fotonovela on the HPV vaccine (*Más vale prevenir*).

**Porter Novelli – Washington, DC****1997-1999****Account Supervisor, National Cancer Institute (NCI) account**

Oversaw the day-to-day planning and implementation of activities related to 5 A Day, breast and cervical cancer, clinical trials, patient education, health promotion, science awareness, cancer risk communications, and Cancer Information Service (CIS) programs.

**Dana-Farber Cancer Institute – Boston, MA****1994-1997****Project and Data Management Coordinator**

Oversaw daily operations and budget of the “Nutrition Intervention to Reduce Cancer Risk Among Adults with Limited Literacy” study; collected and analyzed survey data for “5 A Day Worksite Nutrition Intervention” study for my dissertation.

# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Mario Navarro (ID: 5964115)
- **Email:** mario.navarro@fda@hhs.gov
- **Institution Affiliation:** FDA (ID: 2617)
- **Institution Unit:** Center for Tobacco Products
- **Phone:** 281-799-6883

- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 21453145
- **Completion Date:** 15-Nov-2016
- **Expiration Date:** 15-Nov-2019
- **Minimum Passing:** 80
- **Reported Score\*:** 98

### REQUIRED AND ELECTIVE MODULES ONLY

	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	14-Nov-2016	3/3 (100%)
History and Ethical Principles - SBE (ID: 490)	14-Nov-2016	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	14-Nov-2016	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	14-Nov-2016	5/5 (100%)
Assessing Risk - SBE (ID: 503)	14-Nov-2016	5/5 (100%)
Informed Consent - SBE (ID: 504)	14-Nov-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	14-Nov-2016	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	14-Nov-2016	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	15-Nov-2016	4/5 (80%)

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# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT\*\*

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Mario Navarro (ID: 5964115)
- **Email:** mario.navarro@fda.hhs.gov
- **Institution Affiliation:** FDA (ID: 2617)
- **Institution Unit:** Center for Tobacco Products
- **Phone:** 281-799-6883

- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

- **Report ID:** 21453145
- **Report Date:** 15-Nov-2016
- **Current Score\*\*:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethical Principles - SBE (ID: 490)	14-Nov-2016	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	14-Nov-2016	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	14-Nov-2016	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	14-Nov-2016	5/5 (100%)
Assessing Risk - SBE (ID: 503)	14-Nov-2016	5/5 (100%)
Informed Consent - SBE (ID: 504)	14-Nov-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	14-Nov-2016	5/5 (100%)
Research with Prisoners - SBE (ID: 506)	15-Nov-2016	5/5 (100%)
Research with Children - SBE (ID: 507)	15-Nov-2016	5/5 (100%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	15-Nov-2016	5/5 (100%)
International Research - SBE (ID: 509)	15-Nov-2016	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	14-Nov-2016	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	15-Nov-2016	5/5 (100%)
Cultural Competence in Research (ID: 15166)	15-Nov-2016	5/5 (100%)

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# Mario Navarro

4615 Arkansas Avenue NW, Washington, DC, 20011

Phone: (281) 799-6883 • Email: [mario.navarro@fda.hhs.gov](mailto:mario.navarro@fda.hhs.gov)/[navarm@gmail.com](mailto:navarm@gmail.com)

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## Summary

### *Research Scientist*

Proven success and technical competence designing and conducting research experiments, quasi-experiments, surveys, mixed-method studies and qualitative studies through field studies, Internet studies, and classroom studies. Achievements include:

- Completed 7 manuscripts with 6 published as peer reviewed academic publications and 1 in the revision process in applied domains such as organ donation.
- Assisted faculty and graduate students by reviewing research protocols and analyses to determine if they are appropriate for their intended purposes. Determined if the results support the researcher's academic conclusions. Reviewed over dozens of methodological protocols for both faculty and students.
- Spent 6 years conducting extensive literature reviews of literatures spanning different academic disciplines, in time sensitive situations, to use for social psychological and health psychological research.
- Lead assistant in writing and implementing a 1.3 million dollar grant project to develop an intervention to increase organ donation. Have assisted in writing 2 other grant applications to both the Human Resources and Services Administration (HRSA) and the National Institutes for Health (NIDA).
- Presented 9 presentations at 5 different conferences and helped develop a presentation once for the Center of Disease Control (CDC).
- Develop and maintain contacts within professional and scientific organizations such as the Association for Psychological Science and the Society for Personality and Social Psychology.

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## Skills

### **Applied Research and Evaluation (5 years of experience)**

- Over five years of experience designing surveys, quasi-experiments, and experiments utilizing social psychological principles to increase healthy behavior.
- Developed measures of emotion constructs for a grant-funded project as well as developed dozens of scales for publications with several of those undergoing tests of validation.
- Conducted and reported 1 qualitative analysis and over a dozen quantitative analyses for both academic publications and grant reports.
- Managed a team of 2 community outreach groups and participated in several teams of 3 or more academics.
- Led a team of researchers (1 student with 5 professors) to conduct and report a focus group study.

### **Survey Development and Methodology (5 years of experience)**

- Designed dozens of complex surveys, including creating items, using advanced survey logic, using skip patterns and display patterns, and using embedded data. Minimized response effects and increase response rates, in addition to obtaining accurate responses, using proper survey methods and question design.
- Prepared and conducted dozens of online survey studies using Qualtrics and Survey Gizmo.
- Led 2 workshops (1 formal and 1 informal) teaching individuals how to use Qualtrics and Survey Gizmo.

### **Scale & Construct Development (5 years of experience)**

- Capacity to design surveys and analyze data to assess the validity and reliability of a scale. Created many scales that measure abstract psychological constructs such as attitudes, emotions, and beliefs.
- Have conducted several factor analyses and parallel analyses.

### **Quantitative and Qualitative Data Analysis (6 years of experience)**

- Ability to conduct an interpret ANOVA, regression, bootstrapped indirect effects (mediation analysis), moderation/simple slope analysis, factor analysis, multivariate statistics and Structural Equation Modeling using SPSS, AMOS, & MPLUS statistical programs. Have conducted many of these analyses many times (40-70).
- Have written up results for dozens of studies for publications.
- Have designed and conducted a focus group study that utilized a content analysis. Identified themes and coded data for presence of these themes.

### **Social Sciences (6 years of experience)**

- A comprehensive understanding of the literature regarding persuasion, motivation, and emotion applied to the health domain.



# Mario Navarro

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Phone: (281) 799-6883 • Email: [mario.navarro@fda.hhs.gov](mailto:mario.navarro@fda.hhs.gov)/[navarm@gmail.com](mailto:navarm@gmail.com)

## Oral Communication

- Presented research to both academic and non-academic audiences.
- Translated research skills to others through teaching and workshops several times, once to a lay audience.
- Have taught statistics twice along and social psychology once to undergraduate students.

## Written Communication

- Have written 2 technical reports for organizations and 8 academic reports for academic journals that are in preparation or have been published.

## Spanish

- An advanced ability to speak and write in Spanish. Experience in translating surveys into Spanish.

## Teamwork

- Have worked on dozens of group projects, 7 culminating into publishable manuscripts and 6 being published.
- Have presented in 9 group presentations at 5 different conferences.
- Led a team of researchers to conduct a qualitative focus group study that culminated into a publishable manuscript.

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## Professional Experience

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### Food and Drug Administration (FDA)

#### Center for Tobacco Products, Office of Health Communication & Education

*Social Scientist*

*October 2016- Present*

- Helps to design surveys and protocols for creative concept focus groups and copy testing studies for a youth targeted and lesbian, gay, bisexual, and transgender (LGBT) campaign, a multicultural youth behavior change campaign, and an American Indian and Alaska Native (AI/AN) campaign.
- Works on IRB and OMB protocol and development.
- Supports ongoing campaign development and implementation.

### HRSA Grant: *Maximizing donor registrations among Hispanics: A positive psychology approach* (approximately \$1,300,000)

*Research Assistant*

*August 2014-October 2016*

- *Description of Grant Project:* This research project seeks to determine through a survey experiment whether positive emotions (e.g., elevation, gratitude) are better motivators of organ donor registration behavior than negative emotions (e.g., guilt, empathy toward someone in a dire situation).
- Helped design a mixed-methods focus group discussion guide and the accompanying survey.
- Created a coding scheme to analyze themes in the focus group data.
- Assisted in the design and development of research protocols using behavioral and social science perspectives to increase organ donation.
- Analyzed, transcribed, and translated focus group data using a content analysis to explore positive emotions in the sub-population of Spanish-dominant Hispanics.
- Evaluated impact of focus groups through surveys and focus group discussions.
- Prepare a focus group publication (see Selected Publications).
- Prepared reports and made presentations on the research results to grant funders, peers, and professional conferences.
- Helped create videos to induce positive emotions in Hispanics to increase organ donation.
- Designed a series of complex surveys to be conducted in the consulates using Qualtrics.
- Helped to lead an organized training seminar of survey administrators and stake holders from the Donor Network of Arizona.
- Routinely manage data, communication with community groups, and communication with funders.

## Mario Navarro

4615 Arkansas Avenue NW, Washington, DC, 20011

Phone: (281) 799-6883 • Email: [mario.navarro@fda.hhs.gov](mailto:mario.navarro@fda.hhs.gov)/[navarm@gmail.com](mailto:navarm@gmail.com)

### Health Psychology and Prevention Science Institute, Claremont, CA

*Methodology, Survey, and Statistics Consultant*

*September 2012-October 2016*

- Help professors and students resolve methodological, survey, and statistical problems including scale validations, structural equation modeling, and complex online survey design using integrative logic and survey flow.
- Participate in the initial formulation and review of studies prior to their initiation. This includes several studies that other students and professors have submitted for publication.
- Fix methodological concerns after the launch of a study or help design studies that compensate for the problems of the previous study.
- Lead, prepare, and conducted workshops and presentations that provide unique and uncommon methods for survey design and data collection. These workshops have included content knowledge such as unique recruitment methods including Amazon's MTurk and simple programming code.

*Research Associate and Project Lead*  
2016

*September 2012-October*

- Collaborated on three research projects funded by Federal grants from NIDA and HRSA.
- Conducted and consulted for research that applies social psychological principles to increasing organ donation.
- Experimental design, online survey design, and statistical data analysis using Qualtrics, Survey Gizmo, SPSS, AMOS, and MPLUS.
- Assist with obtaining and managing for several government funded grants.
- Published 4 papers in collaborative projects and have several more publications in preparation.

*Research Assistant*  
2012

*September 2010- September*

- Coded qualitative data for several research studies conducted by professors and students.
- Inputted data for several research studies conducted by professors and students.
- Designed several surveys using randomization and survey flow and logic using Survey Gizmo.

### Claremont Center for the Mathematical Sciences, Claremont, CA

*Statistics Consultant*

*October 2012-August 2014*

- Helped students across 7 colleges analyze data using SPSS, MPLUS, and AMOS.
- Consulted with dozens of students by troubleshooting and solving methodological and statistical problems.
- Taught dozens of students how to organize and write up data analyses.

## Education

---

### Claremont Graduate University – Claremont, CA

*Ph.D. in Psychology A.B.D.*

*December 2016*

Concentration in Applied Social Psychology

Dissertation: Unexpected Positive Events on Affect and Evaluation: The Role of Resources

*M.A. in Psychology*  
2012

*May*

Co-Concentration in Applied Social Psychology and Evaluation

Thesis: Predicting Goal Disruption: The Role of Vulnerability

### University of St. Thomas – Houston, TX

*B.A. in Psychology*

*December 2009*

## Selected Publications

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Navarro, M. A., Siegel, J. T., & Thomson, A., Alvaro, E. M., Nakamura, J., Csikszentmihalyi, M. (revise and

## Mario Navarro

4615 Arkansas Avenue NW, Washington, DC, 20011

Phone: (281) 799-6883 • Email: mario.navarro@fda.hhs.gov/navarm@gmail.com

- resubmit). A mixed mode exploration of discrete positive emotions among Spanish Language Dominant Hispanics: A lot of elevation, some gratitude, and a scintilla of serenity. *Journal of Positive Psychology*.
- Siegel, J. T., Tan, C. N., Rosenberg, B. D., **Navarro, M. A.**, Thomson, A., Lyrintzis, E. A., Alvaro, E. A., & Jones, N. D. (in press). Department of Motor Vehicles, emotions, organ donor registration and the IIFF Model: A possible problem and a potential solution. *Social Science and Medicine*.
- Siegel, J. T., Alvaro, E. A., Tan, C. N., **Navarro, M. A.**, Garner, L. & Jones, S. P. (in press). Increasing organ donor registrations: The IIFF Model and (f)utility of a lone ICRO. *Progress in Transplantation*.
- Siegel, J. T., **Navarro, M. A.**, Thomson, A. L. (2015). The impact of overtly listing eligibility requirements on MTurk: An investigation involving organ donation, recruitment scripts, and feelings of elevation. *Social Science and Medicine*, 142, 256-260.
- Siegel, J. T., Tan, C. A., **Navarro, M. A.**, Alvaro E. A., Crano, W. D. (2015). The power of the proposition: Frequency of marijuana offers, parental monitoring, and adolescent marijuana use. *Drug Use and Dependence*, 148, 34-39.
- Siegel, J. T., Thomson, A. L., & **Navarro, M. A.** (2014). Experimentally distinguishing elevation from gratitude: Oh, the morality. *Journal of Positive Psychology*, 9, 414-427. doi:10.1080/17439760.2014.910825
- Siegel, J. T., **Navarro, M. A.**, Tan, C. N., & Hyde, M. K. (2014). Attitude-behavior consistency, the principle of compatibility, and organ donation: A classic innovation. *Health Psychology*, 33, 1084-1091. doi:10.1037/hea0000062

### Selected Presentations

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- Siegel, J.T., Alvaro, E. A., & **Navarro, M. A.** (2013). Evaluating Social Media. Webinar presented for the Centers for Disease Control.
- Navarro, M. A.**, Siegel, J. T., & Thomason, A. T. (2013). Elevation, Serenity, and Gratitude: Distinct Emotions with Distinct Outcomes. International Positive Psychology Association World Congress on Positive Psychology, Los Angeles, CA.
- Siegel, J. T., Alvaro, E. M., Hohman, Z., & **Navarro, M. A.**, Crano, W. D., & Jones, S. P. (2012). Organ Donor Registration: The Interaction of Empathy and Death Myths. Western Psychological Association Convention, San Francisco, CA.
- Tan, C. N., **Navarro, M. A.**, & Siegel, J. T. (2012). Ambivalence and Attitude Behavior Consistency in Organ Donation Registration. Western Psychological Association Convention, San Francisco, CA.

### Academic Teaching Experience

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#### University of La Verne, La Verne, CA

Instructor

January 2015- December 2015

- Taught Statistics (e.g., Z-tests, t-tests, correlations, and chi-square analyses) to sociology, anthropology, and criminal justice students who typically have had no previous experience with statistics prior to the class. These students came from diverse backgrounds and many were non-traditional students.
- Created material and assignments that push students to better understand the material and grasp the statistical concepts.
- Consult with students to help them better understand the material.

#### Division of Behavioral and Organizational Sciences, Claremont, CA

Teaching Assistant  
2015

September 2011- May

- Was a teaching assistant for Research Methods (3 times), Survey Methods (3 times), and Motivation, Affect, and Cognition (1 time).
- Taught the development, implementation, and analysis of surveys in academic and organizational settings.
- Led a weekly research methods discussion section of graduate students.
- Translated and broke down social psychological theories, focused on motivation, to applicable situations and interventions.
- Helped develop curriculum, compose exams, and grade all written work for over 60 students.

## **Mario Navarro**

4615 Arkansas Avenue NW, Washington, DC, 20011

Phone: (281) 799-6883 • Email: [mario.navarro@fda.hhs.gov](mailto:mario.navarro@fda.hhs.gov)/[navarm@gmail.com](mailto:navarm@gmail.com)

- Conducted many intimate review sessions that concisely reviewed the material.

## **Mario Navarro**

4615 Arkansas Avenue NW, Washington, DC, 20011

Phone: (281) 799-6883 • Email: [mario.navarro@fda.hhs.gov](mailto:mario.navarro@fda.hhs.gov)/[navarm@gmail.com](mailto:navarm@gmail.com)

### **Argosy Inland Empire Campus, Ontario, CA**

*Instructor*

*January 2015- April 2015*

- Taught Social Psychology to Psychology majors who were non-traditional students.
- Help apply these social psychological constructs to everyday situations in the students' lives.
- Consulted with students to help them understand the material for over 60 students.

### **Kravis Leadership Institute, Claremont, CA**

*Workshop Instructor*

*March 2013*

- Led a two-hour workshop for understanding the basics of online survey design using Qualtrics.
- Topics included survey creation, survey flow, survey dissemination, embedded data, and data retrieval.

## **Affiliations/Memberships**

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*Association for Psychological Science  
2016*

*March 2014 – March*

*Society for Personality and Social Psychology*

*September 2013 – September 2014*

*Western Psychological Association*

*November 2012 – November 2014*

*Psi Chi: National Honors Society in Psychology*

*May 2008 - Present*

## **Honors**

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*Applied Social Scientist of the Year – Claremont Graduate University  
2016*

*May*

# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Junaed Siddiqui (ID: 4369123)
- **Institution Affiliation:** University of Maryland College Park (ID: 1526)
- **Institution Email:** Junaed1@umd.edu
- **Institution Unit:** Behavioral and Community Health
- **Phone:** 443-722-2507
  
- **Curriculum Group:** Social and Behavioral Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** This course is for investigators, staff and students with an interest or focus in **Social and Behavioral** research. This course contains text, embedded case studies AND quizzes.
  
- **Record ID:** 13970545
- **Completion Date:** 23-Jul-2015
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score\*:** 89

### REQUIRED AND ELECTIVE MODULES ONLY

	DATE COMPLETED	SCORE
Responsible Conduct of Research (RCR) Course Introduction (ID: 1522)	23-Jul-2015	No Quiz
Research Misconduct (RCR-Basic) (ID: 16604)	23-Jul-2015	3/5 (60%)
Data Management (RCR-Basic) (ID: 16600)	23-Jul-2015	4/5 (80%)
Authorship (RCR-Basic) (ID: 16597)	23-Jul-2015	5/5 (100%)
Peer Review (RCR-Basic) (ID: 16603)	23-Jul-2015	5/5 (100%)
Mentoring (RCR-Basic) (ID: 16602)	23-Jul-2015	4/5 (80%)
Conflicts of Interest (RCR-Basic) (ID: 16599)	23-Jul-2015	5/5 (100%)
Collaborative Research (RCR-Basic) (ID: 16598)	23-Jul-2015	5/5 (100%)
Responsible Conduct of Research (RCR) Course Conclusion (ID: 1043)	23-Jul-2015	No Quiz
University of Maryland College Park (ID: 13418)	23-Jul-2015	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?kbc5131dc-6ba4-46ac-a69e-4ebc7fc4b8fe-13970545](http://www.citiprogram.org/verify/?kbc5131dc-6ba4-46ac-a69e-4ebc7fc4b8fe-13970545)

### Collaborative Institutional Training Initiative (CITI Program)

Email: [support@citiprogram.org](mailto:support@citiprogram.org)

Phone: 888-529-5929

Web: <https://www.citiprogram.org>

# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 2 OF 2

### COURSEWORK TRANSCRIPT\*\*

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Junaed Siddiqui (ID: 4369123)
- **Institution Affiliation:** University of Maryland College Park (ID: 1526)
- **Institution Email:** Junaed1@umd.edu
- **Institution Unit:** Behavioral and Community Health
- **Phone:** 443-722-2507
  
- **Curriculum Group:** Social and Behavioral Responsible Conduct of Research
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** This course is for investigators, staff and students with an interest or focus in **Social and Behavioral** research. This course contains text, embedded case studies AND quizzes.
  
- **Record ID:** 13970545
- **Report Date:** 01-Jun-2017
- **Current Score\*\*:** 89

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Responsible Conduct of Research (RCR) Course Introduction (ID: 1522)	23-Jul-2015	No Quiz
University of Maryland College Park (ID: 13418)	23-Jul-2015	No Quiz
Authorship (RCR-Basic) (ID: 16597)	23-Jul-2015	5/5 (100%)
Collaborative Research (RCR-Basic) (ID: 16598)	23-Jul-2015	5/5 (100%)
Conflicts of Interest (RCR-Basic) (ID: 16599)	23-Jul-2015	5/5 (100%)
Data Management (RCR-Basic) (ID: 16600)	23-Jul-2015	4/5 (80%)
Mentoring (RCR-Basic) (ID: 16602)	23-Jul-2015	4/5 (80%)
Peer Review (RCR-Basic) (ID: 16603)	23-Jul-2015	5/5 (100%)
Research Misconduct (RCR-Basic) (ID: 16604)	23-Jul-2015	3/5 (60%)
Responsible Conduct of Research (RCR) Course Conclusion (ID: 1043)	23-Jul-2015	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: [www.citiprogram.org/verify/?kbc5131dc-6ba4-46ac-a69e-4ebc7fc4b8fe-13970545](http://www.citiprogram.org/verify/?kbc5131dc-6ba4-46ac-a69e-4ebc7fc4b8fe-13970545)

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# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Junaed Siddiqui (ID: 4369123)
- **Institution Affiliation:** University of Maryland College Park (ID: 1526)
- **Institution Email:** Junaed1@umd.edu
- **Institution Unit:** Behavioral and Community Health
- **Phone:** 443-722-2507
  
- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.
  
- **Record ID:** 13970544
- **Completion Date:** 23-Jul-2015
- **Expiration Date:** 22-Jul-2018
- **Minimum Passing:** 80
- **Reported Score\*:** 88

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Belmont Report and CITI Course Introduction (ID: 1127)	09-Sep-2014	3/3 (100%)
Students in Research (ID: 1321)	20-Jul-2015	7/10 (70%)
History and Ethical Principles - SBE (ID: 490)	20-Jul-2015	3/5 (60%)
Defining Research with Human Subjects - SBE (ID: 491)	20-Jul-2015	4/5 (80%)
The Federal Regulations - SBE (ID: 502)	22-Jul-2015	5/5 (100%)
Assessing Risk - SBE (ID: 503)	22-Jul-2015	4/5 (80%)
Informed Consent - SBE (ID: 504)	22-Jul-2015	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	22-Jul-2015	3/5 (60%)
Research and HIPAA Privacy Protections (ID: 14)	22-Jul-2015	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	23-Jul-2015	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	23-Jul-2015	5/5 (100%)
University of Maryland College Park (ID: 13418)	23-Jul-2015	No Quiz
International Research - SBE (ID: 509)	23-Jul-2015	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	23-Jul-2015	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	23-Jul-2015	4/4 (100%)

**For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.**

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# COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

## COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT\*\*

\*\* NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Junaed Siddiqui (ID: 4369123)
- **Institution Affiliation:** University of Maryland College Park (ID: 1526)
- **Institution Email:** Junaed1@umd.edu
- **Institution Unit:** Behavioral and Community Health
- **Phone:** 443-722-2507
  
- **Curriculum Group:** Social & Behavioral Research - Basic/Refresher
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Basic Course
- **Description:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.
  
- **Record ID:** 13970544
- **Report Date:** 01-Jun-2017
- **Current Score\*\*:** 88

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	20-Jul-2015	7/10 (70%)
University of Maryland College Park (ID: 13418)	23-Jul-2015	No Quiz
History and Ethical Principles - SBE (ID: 490)	20-Jul-2015	3/5 (60%)
Defining Research with Human Subjects - SBE (ID: 491)	20-Jul-2015	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	09-Sep-2014	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	22-Jul-2015	5/5 (100%)
Assessing Risk - SBE (ID: 503)	22-Jul-2015	4/5 (80%)
Informed Consent - SBE (ID: 504)	22-Jul-2015	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	22-Jul-2015	3/5 (60%)
Research with Prisoners - SBE (ID: 506)	23-Jul-2015	Quiz Not Taken
International Research - SBE (ID: 509)	23-Jul-2015	5/5 (100%)
Internet-Based Research - SBE (ID: 510)	23-Jul-2015	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	22-Jul-2015	5/5 (100%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	23-Jul-2015	4/4 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	23-Jul-2015	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	23-Jul-2015	5/5 (100%)

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Web: <https://www.citiprogram.org>

# CURRICULUM VITAE

**Junaed A. Siddiqui**

June 2017

## EDUCATION

---

- 2014 - Present                      University of Maryland School of Public Health, Ph.D.  
Major: Behavioral and Community Health  
Advisor: Min Qi Wang, PhD, MS
- 2012 - 2013                        Towson University, M.S.  
Major: Community Health/Health Administration  
Advisor: Susan Radius, Ph.D., MCHES
- 2005 - 2011                        University of Maryland Baltimore County, B.S.  
Major: Biological Sciences

## ACADEMIC EMPLOYMENT

---

- Fall 2015 -  
Spring 2016                        **Graduate Teaching Assistant**, University of Maryland School of  
Public Health
- May 2015 -  
August 2015                        **Recruitment Coordinator**, University of Maryland  
Tobacco Center of Regulatory Science (TCORS)
- Fall 2014 -  
Spring 2015                        **Faculty Research Assistant**, University of Maryland School of  
Public Health, Prevention Research Center
- Fall 2012 -  
Spring 2013                        **Graduate Teaching Assistant**, Towson University

## PROFESSIONAL EMPLOYMENT

---

- June 2016 - Present                      **Senior Associate- Digital Health**, IQ Solutions
- November 2015 - June 2016                      **Public Policy Fellow/ Consulting Intern**, FaegreBD Consulting
- February 2013 - November 2015                      **Community Development Analyst**, Mid-Atlantic Association of Community Health Centers
- May 2015 - August 2015                      **Consultant**, Reframe Health
- June 2007 - June 2011                      **Senior Research Analyst**, Rubin Institute of Advanced Orthopedics at Sinai Hospital

## HONORS AND AWARDS

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- 2016                      **Young Entrepreneur Alumni Award, Towson University**
- 2016                      **Runner-up, Bay Area Global Health Innovation Challenge**  
Submitted my app, e-Puffin, for consideration as a solution to address diabetes in a low resource international setting with limited infrastructure. Top 20 out of over 80 teams.
- 2016                      **Runner-up, Venture to Stop Diabetes Challenge**  
Submitted my app, e-Puffin, for consideration as an innovative app to address growing challenges with diabetes in the United States.
- 2015                      **Winner, American Public Health Association Public Health Codeathon**  
Public Health Lead on University of Maryland team that created a multi-faceted platform designed to improve life expectancy in the United States.
- 2015                      **Conference Travel Award**  
Awarded by Smith School of Business, University of Maryland.
- 2015                      **Conference Travel Award**  
Awarded by Department of Behavioral and Community Health, University of Maryland.

- 2015 **Winner, Innovate 4 Health Challenge**  
Pitched my app, ePuffin (Eliminating Prediabetes Using Fitness, Food, and Improved Nutrition) and business strategy at the Maryland Health IT Conference.
- 2015 **Finalist, Innovate 4 Health Challenge**  
Designed an app, ePuffin, designed to reduce the prevalence of prediabetes by using behavioral economics strategies, public health theory, and wearable technology.
- 2015 **Dean's Fellowship Award**  
Awarded by Department of Behavioral and Community Health at University of Maryland for academic success in the PhD program.
- 2014 **Local Public Health Policy and Practice Scholar**  
Awarded by the National Association of City and County Health Officials. Assessed the United States' emergency preparedness capabilities and response to the Ebola threat of 2014.
- 2014 **Distinguished Graduate Award**  
Awarded by Towson University Department of Health Sciences to a student who has embodied the values and ideals of a graduate student in terms of academic success, research, and professional development.
- 2013 **Neil E. Gallagher Endowed Scholarship Award**  
Awarded by Towson University based on academic merit and potential for future success as a Towson alum.

## PROFESSIONAL AFFILIATIONS AND SERVICES

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### Professional Organization Member

American Public Health Association (APHA)

American Association for the Advancement of Science (AAAS)

### Committee Member

Student Representative for Graduate Student Government (2014-2016)

Innovation & Technology Committee, School of Public Health (2015- 2016)

Academic & Career Committee, Graduate Students in Public Health (2013-2014)

## PUBLICATIONS

---

### PEER-REVIEWED JOURNAL ARTICLES AND INVITED BOOK CHAPTERS

- Mead, E., Johnson, S., **Siddiqui, J.**, Butler, J., Kirchner, T., & Feldman, R. (2017). Beyond blunts: African American young adults' reasons for dual smoking of cigarettes and cigars. *Addiction Research and Theory*. (Submitted).

- Boekeloo, B., Jones, C., Bhagat, K., **Siddiqui, J.**, & Wang, M. (2015). The role of intrinsic motivation in the pursuit of health science-related careers among youth from underrepresented low socioeconomic populations. *Journal of Urban Health* 92(5), 980-994. (In Press).
- Duany, N., Zywiell, M., McGrath, M., **Siddiqui, J.**, Bonutti, M., & Mont, M. (2010). Joint-preserving surgical treatment of spontaneous osteonecrosis of the knee. *Archives of Orthopedic and Trauma Surgery* 130(1), 11-16.
- Laporte, D., Marker, D., Ulrich, S., Johansson, H., **Siddiqui, J.**, & Mont, M. (2009). Characterization, diagnosis, and treatment of symptomatic osteonecrosis of the distal radius. *Journal of Bone and Joint Surgery, British Volume* 91(SUPP II), 326-326.
- McGrath, M., Mont, M., **Siddiqui, J.**, Baker, E., & Bhave, A. (2009). Evaluation of a custom knee device for the treatment of flexion contractures after total knee arthroplasty. *Clinical Orthopedics and Related Research* 12(1), 1485-1492.
- Duany, N., Zywiell, M., McGrath, M., **Siddiqui, J.**, Jones, L., & Mont, M. (2009). Clinical characteristics of spontaneous osteonecrosis of the knee, and results of a proposed treatment algorithm. *Journal of Bone and Joint Surgery-British Volume* 93(131), i-vii.
- Jessup, N., **Siddiqui, J.**, Monesmith, E., & Ulrich, S. (2008). Total knee arthroplasty using cementless keels and cemented tibial trays: 10-year results. *International Orthopedics* 33: 117-121.

## CONFERENCE PRESENTATIONS

---

### TALKS

- Siddiqui, J.**, Shah, K., Maniar, S., Padhye, N., Gupta, U., Gunpark, D. (2015). Text4Health-Increasing Life Expectancy by Creating Change at the Individual, Organizational, and Policy Level. Talk presented at the *American Public Health Association Annual Meeting*, Chicago, IL.
- Siddiqui, J.** (2013). The Affordable Care Act Toolkit: A Guide for Implementation in Maryland and Delaware. Presented at *Health Resources and Services Administration (HRSA) Region III Meeting*, Philadelphia, PA.
- Siddiqui, J.**, and Smith, C. (2012). Tips for Developing Competency-Based Health Programs. Webinar, presented to Society for Public Health Education (SOPHE), Washington, DC.

## ***POSTERS***

**Siddiqui, J.** (2017, November). What does a puffin have to do with health? Usability testing of a gamified physical activity app for adolescents. Poster session accepted for presentation at American Public Health Association 2017 Annual Meeting, Atlanta, GA.

**Siddiqui, J.** (2017, April). ePuffin- A mobile app seeking to eliminate prediabetes using fitness, food, and improved nutrition. Poster session presented at Public Health Research@Maryland, College Park, MD.

**Siddiqui, J.** (2016, October). ePuffin- A mobile app seeking to eliminate prediabetes using fitness, food, and improved nutrition. Poster session presented at Maryland Public Health Association Annual Conference, Towson, MD.

Mead, E., Johnson, S., **Siddiqui, J.**, Butler, J., Kirchner, T., & Feldman, R. (2016, March). Motivations for dual use of cigars and cigarettes among African American young adults. Poster session presented at Society for Research on Nicotine and Tobacco, Chicago, IL.

**Siddiqui, J.**, Hosack, D., Slaton, A., Parikh, P., Young, J., Wilson, J., Kidanu, A., Loiselle, H., & Grutzmacher, S. (2015, April). School gardens as a farm-to-table tool to address malnutrition in Ethiopia. Poster session presented at Public Health Research@Maryland, College Park, MD.

Slaton, A., Hosack, D., **Siddiqui, J.**, Young, J., Parikh, P., Wilson, J., Kidanu, A., & Grutzmacher, S. (2015, April). Public Health Without Borders in Ethiopia: A model for sustainable, community-driven global health practicum. Poster session presented at Public Health Research@Maryland, College Park, MD.

Boekeloo, B., Jones, C., Bhagat, K., **Siddiqui, J.**, and Wang, M. (2015, April). The role of intrinsic motivation in the pursuit of health careers among minority youth. Poster session presented at Public Health Research@Maryland, College Park, MD.

## **TEACHING EXPERIENCE**

---

### ***TEACHING ASSISTANTSHIPS***

Spring 2016

**Public Health Internship (HLTH491)**, University of Maryland

Fall 2015

**Public Health Internship (HLTH491)**, University of Maryland

### **TEACHING INTERESTS**

---

**Lectures:** Health Behavior Theory, Health Informatics, Health Technology, Program Planning, Introduction to Public Health, Research Methods, Program Evaluation, Epidemiology, Health Informatics, Digital Health