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BOARD OF SCIENTIFIC COUNSELORS (BSC)

SEVENTY-FIFTH MEETING

August 4, 2020

**The verbatim transcript of the
Meeting of the Board of Scientific Counselors Meeting held on
August 4, 2020, 01.00 p.m.**

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PARTICIPANTS

(alphabetically)

- LAUREN BARTON, MD - MEMBER
- PAULINE BENJAMIN
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- LOUIS COX, PhD - MEMBER
- CRISTINA DEMIAN, MD - MEMBER
- MARY DOYLE - MEMBER
- KENNY FENT, PhD
- MICHAEL FOLEY - MEMBER
- JESSICA GRAHAM, PhD - MEMBER
- MARGARET KITT, MD
- GRACE LEMASTERS, PhD - COCHAIR
- STEVEN LERMAN, MD - MEMBER
- PATRICK MORRISON - COCHAIR
- EMILY NOVICKI - DFO
- JILL RAUDABAUGH
- TIINA REPONEN, PhD – MEMBER
- ROBERT ROY - MEMBER
- MARC SCHENKER, MD - MEMBER
- MIRIAM SIEGEL, DrPH
- JUDITH SU, PhD - MEMBER
- WILLIAM WEPSALA
- ANDREA WILKINSON

INTRODUCTION, AGENDA, AND MEETING LOGISTICS

MS. NOVICKI: So it's 1:01, I think we have a full house so let's go ahead and get started. So, welcome, everyone, to this meeting of the NIOSH Board of Scientific Counselors, and I want to extend a warm welcome to all of you and to any members of the public who have joined us.

So I am Emily Novicki, I am the newly minted Designated Federal Official for the BSC—I just finished training last week—and this is my first meeting as the DFO, so I want to take a moment to introduce myself. I am a health scientist and I have been at NIOSH since 2014. I work in the NIOSH Office of Policy, Planning and Evaluation, which is situated in Atlanta. I have two master's degrees, one in public health and one in applied anthropology, both from the University of South Florida, and I like to think of myself as a utility player at NIOSH and so I do all kinds of things including coordinating the 37 research programs in our portfolio as well as 17 NORA councils. I also do strategic planning, performance monitoring and evaluation too, and I just finished the last five months working in the CDC Emergency Operations Center on COVID-19. So I am happy to be here with you all today as the new DFO, and thank you for having me.

So, there are also a number of administrative issues to deal with on the front end for our meeting today. First of all, I hope that wherever you are, you're staying safe, and I'll ask you to make sure you know how to exit safely from wherever you are in case of an emergency.

And as a Federal Advisory Committee, the BSC is subject to the many rules and regulations of the Federal Advisory Committee Act or FACA. So we'll be following all of those for this meeting. And so, part of those procedures are developing minutes of our meetings, and so for this meeting, we want to make sure everyone is aware that the meeting is being recorded and that a verbatim transcript will be developed and put on the BSC's website.

And the Program, the National Firefighter Registry Program, is very interested in hearing comments from the public about their proposed protocol —and so the FACA rules are pretty formal in how comments can be received for the public. So, members of the public cannot be invited to provide comments during the time the BSC is deliberating, so that time is just for the members alone.

But there are two ways for the public to provide comments. So, one way is for members of the public to snail mail their comments into the NIOSH docket, and the address for that is in the Federal Register Notice for this meeting and it's also on the BSC website. The other way is to sign up to present during the meeting, during the set time, and so we are going to have public comments at 2:00 p.m. this afternoon Eastern Time. No one has signed up to provide public comments, but I want to give members of the public here to have an opportunity to provide

comments if they would like. So if you are a member of the public and you're here, and—we want you to go ahead and type in the chat box or speak up now if you would like to sign up for one of those five-minute slots when we get to the public comment time. So I'm just going to pause for a second and see if anyone would like to sign up for public comments.

Okay, so hearing—hearing nothing and seeing nothing typed on the screen, I'm going to move on, but we'll still, you know, pause at that 2:00 p.m. timeslot and make sure. And if no one requests to provide a comment, we'll just keep moving right ahead.

So, at this point, I'd like to move to the roll call, so one of the FACA rules is that we have to do a roll call at the beginning of the meeting, and we'll repeat it after our break later on this afternoon to ensure we have a quorum. So when I call out your name, please indicate your presence for the record. And for this roll call, I also need you to state whether there's been any changes that would change your conflict of interest status since you filled out the OGE-450 form a couple of months ago. So that might include things like a change in your employer, or being awarded a grant relevant to the Firefighter Registry. Members, also, if you need to leave at any point, please make sure to let me know when you go and then when you return, because we need to make sure that we stay at quorum, which is nine for the BSC.

So, let's do the roll call. So I'm going to start with our chair, Terry Bunn.

DR. BUNN: Terry Bunn, and no conflict of interest.

MS. NOVICKI: Thank you. Kyle Arnone. Okay, it doesn't look like he's here. Okay, Lauren Barton?

DR. BARTON: Lauren Barton is here, and no change in conflicts of interest.

MS. NOVICKI: Perfect, thanks. Louis Cox. Okay, Cristina Demian.

DR. DEMIAN: Yes, and no conflict of interest. Cristina Demian. I have no conflicts of interest.

MS. NOVICKI: Perfect, thank you. Okay, Mary Doyle.

MS. DOYLE: Mary Doyle, no conflict of interest.

MS. NOVICKI: Thank you. Michael Foley.

MR. FOLEY: Michael Foley, no change in conflict of interest.

MS. NOVICKI: Okay, thanks. Jessica Graham.

DR. GRAHAM: Hi, Jessica Graham. No change in conflict of interest.

MS. NOVICKI: Thank you. Steve Lerman.

DR. LERMAN: Steve Lerman. No conflict of interest.

MS. NOVICKI: Thank you. Grace Lemasters.

DR. LEMASTERS: Grace LeMasters. Hello, everybody. No change in conflict of interest.

MS. NOVICKI: Okay. Patrick Morrison.

MR. MORRISON: Patrick Morrison, no change in conflict of interest.

MS. NOVICKI: Thank you. Tiina Reponen.

DR. REPONEN: Tiina Reponen is here. No change in conflict of interest.

MS. NOVICKI: Thank you. We're getting some background noise. If you can go on mute if you're not talking please. Robert Roy

MR. ROY: Robert Roy, no change in conflict of interest.

MS. NOVICKI: Thank you. Marc Schenker. Okay, no Marc. Judith Su.

DR. SU: Present. No change in conflict of interest.

MS. NOVICKI: Great, all right, so we have, it looks like, thirteen—twelve. So we definitely have quorum. So, perfect. We can keep going. So, I also want to point out that we have members from the NIOSH National Firefighter Registry team here today, and so they can answer questions about the protocol if you need them to. And so, at this point, I'm going to turn it over to Dr. Margaret Kitt for some welcoming remarks.

DR. KITT: Hi, thanks, Emily, and good afternoon, everyone. Dr. Howard regrets that he cannot join us today but wanted me to thank the Subcommittee for taking on this very important review and producing this valuable report. Also, thanks to the entire BSC for holding this meeting today and to discuss—discuss the protocol report and recommendations. We very much appreciate your continued support through some of these very challenging times, but we're looking forward to the discussion. And with that, I'll turn it back to you, Emily.

MS. NOVICKI: Great, thank you so much. So now I'd like to turn it over to our Chair, Dr. Terry Bunn, for some opening remarks and then I'll cover our agenda really quickly.

DR. BUNN: Good afternoon, everyone. Just wanted to welcome you, I guess, to the seventy-fifth, I think I read on the screen meeting of the NIOSH Board of Scientific Counselors, and with our specific charge today to discuss the National Firefighter Registry Subcommittee report and recommendations, and at the end of this meeting, to vote on either the recommendations as a whole, or we can choose to vote on each recommendation, to accept it as is or recommend changes.

As you can see from our agenda, it's pretty packed today. We'll start with an overview of the protocol itself, and then Dr. LeMasters will provide a presentation on the Subcommittee meeting and the recommendations that were based on the Subcommittee meeting, as well as input provided by the industry stakeholders and the general public. We'll then move on to public comments. As of right now, as Emily said, there are none. So if there are none, then we will move right on to the discussion of the report and recommendations.

What I do want to emphasize, and I think Emily talked about this in the email, is that our charge today is not just simply just to rubberstamp the report. We really want a great discussion initiated around each of the recommendations, and pertaining to the protocol itself. So with that said, are there any questions before we start?

DR. LEMASTERS: This is Grace, and I just want—a correction that both Pat and I will be discussing the report.

DR. BUNN: Oh, I'm sorry, yes. Sorry, Pat, did not—forgot to mention you. Both co-chairs of the NFRS. Thank you, Grace. All right, so we will move on to an overview of the

protocol by Dr. Siegel.

OVERVIEW OF NATIONAL FIREFIGHTER REGISTRY PROTOCOL

DR. SIEGEL: Great, thank you, Dr. Bunn. Emily, it looks like I have control; is that right?

MS. NOVICKI: Yes, you do.

DR. SIEGEL: Okay, great. I'll go ahead and get started then. So, by now, you're all aware that the National Firefighter Registry is a result of the Firefighter Cancer Registry Act of 2018. Although previous studies indicate that firefighting may be associated with cancer, the NFR will help answer remaining questions about cancer burden and risk factors in a diverse current workforce. Our goal is to provide a voluntary registry of firefighters for tracking cancer risk over time, to better understand the links between workplace exposures and cancer.

An important feature of the NFR is that it will be open to all firefighters, not just those that have had cancer. Additionally, we will enroll large numbers of women, minorities and volunteers—groups that have been understudied in the past. We are interested in not only structural firefighters but also wildland firefighters, instructors, fire investigators and other subspecialties. We strive to enroll 200,000 or more firefighters.

In our protocol, we outlined three primary objectives for the NFR. One, collect self-reported information on workplace and personal characteristics through an online web portal. Two, obtain records from fire departments or agencies, to track trends and patterns of exposure. And three, link with health information databases, including population-based cancer registries and the National Death Index, to detect cancers and deaths.

I'm now going to discuss how we plan to carry out these objectives. We're proposing two subgroups at the NFR, a targeted cohort and an open cohort.

The targeted cohort will be a sample of currently active firefighters from selected fire departments or states. We'll partly be able to use the targeted cohort to focus efforts on groups specified in the Act—women, minorities and volunteers. This subgroup will register through the web portal and will also contribute incident record information that we obtained from departments, states or other record systems.

The open cohort will include any members of the US Fire Service, including active, former, and retired members, paid and volunteer. All members of the open cohort will register through the same web portal.

The targeted cohort will provide the population at risk required for assessing cancer incidence rates. Because of the eligibility criteria implemented for this group, we expect reduced selection and participation bias. We'll also obtain some incident- and department-level information for this subgroup to complement self-reported information obtained in the web portal. We'll be able to assess response

characteristics of the open cohort using information from the targeted cohort as a comparison. But, obtaining the targeted cohort will be relatively cost- and labor-intensive and, because of cancer's long latency period, it may take over ten years to detect robust estimates of cancer risk.

The open cohort involves the non-probability sample for which all current and former firefighters are eligible. It's the best method for recruiting a large and inclusive sample that is diverse by firefighting characteristics. Recruitment for the open cohort will be much less resource-intensive than the targeted cohort. The open cohort's large and diverse sample will allow for many early analyses such as descriptive and hypothesis-generating investigation. But because there are no exclusion criteria, the open cohort is subject to selection bias. For example, firefighters that have had cancer may be more likely to participate. Additionally, the exposure information for a majority of this group will be limited to self-report.

We have proposed methods for recruiting firefighters into both subgroups. Our sampling design for the targeted cohort will involve a combination of two sampling frames: selecting fire departments, and selecting states that require some degree of regular recertification or training of all practicing firefighters in that state. Examples include Kentucky, Ohio and Georgia. Both sampling frames offer comprehensive rosters of current firefighters from which we can recruit. Only a handful of states require recertification of all firefighters, and we may be open to including any other rosters for active NFR recruitment. But because there are roughly 25,000 fire departments in the US, we need to have a strategy for which departments we invite to participate.

In sampling strategy, we'll need to ensure adequate representation from female, minority and volunteer firefighters, which is the reason for Phase 1 of the proposed sampling design. But the samples should also be diverse geographically and by department characteristics to maximize generalizability of the findings, which is the reason for a stratified random sample in Phase 2 of the proposed design.

In Phase 1, we will consult with stakeholder groups as well as data on workforce demographics, such as those available from NFPA, USFA and individual fire department statistics, to identify departments with large numbers of women and racial ethnic minorities. We will also work with stakeholder groups to identify departments with a large volunteer workforce from all four regions of the US.

In the Phase 2 stratified random sample, we will select departments from nine geographic divisions defined by the US Census Bureau. Within each of these regions, we will first select career departments with at least 100 fire personnel that are both large and small, based on a threshold of 100,000 population served. Second, we will select volunteer departments without size restrictions from each geographic division.

We use estimates for a hypothetical cancer incidence analysis to estimate

minimum sample sizes necessary for the targeted cohort. Minimum sample size benchmarks require at least 1,000 women, 6,500 non-white firefighters, and 5,000 volunteer firefighters at (least @ 00:19:22) to detect elevations in breast cancer or all cancers, and compare them to the general population after 30 years of follow-up. We estimate that we would need approximately 135 departments to participate in the targeted cohort to achieve these benchmarks. However, if one or more states contribute their certification rosters, we can reach these sample size benchmarks with less individual departments.

The open cohort will involve firefighters from a wider net, and will likely include many more firefighters than in the targeted cohort. The open cohort presents a great opportunity for enrollment of members from wildland, instructor, investigation, airport rescue, federal and other sectors. All participants will consent and enroll through the web portal just like the targeted cohort.

If there are groups of the open cohort that have high participation from active rosters, we may analyze them as part of the targeted cohort and potentially request incident records. For example, if a large department that wasn't selected as part of the targeted cohort has high participation in the open cohort, we could combine information from these members to those from the targeted cohort since selection bias may be limited.

We anticipate recruiting firefighters into the open cohort by disseminating material through departments, stakeholder groups, and online communications. We will also be presenting at professional meetings, and plan exhibits at some meetings where firefighters can obtain information and enroll on the spot.

Now I'm going to outline our proposed procedures for collecting information. Individual enrollment for firefighters in both subgroups will involve providing consent and self-reported exposure, demographic and lifestyle information in the web portal. NIOSH will be able to use the self-reported information to carry out the other necessary activities. These include periodically linking with state cancer registries and vital status databases to detect new cancers or deaths, administering follow-up questionnaires for more detail on workplace or risk factor information longitudinally, conducting continued engagement to keep participants informed and their information up to date, and, when applicable, potentially collecting additional exposure information from employment records, exposure tracking platforms, and other external sources of data.

To enroll as part of the open cohort, an individual firefighter will make an account, provide consent, and complete the questionnaire in the web portal. The process for enrolling individuals in the targeted cohort will be a little more complex. First, selected departments or states will provide NIOSH with contact information for their entire active roster. NIOSH will also request department incident records dating back to at least 2010 and preferably older, when available. The rosters and incident records don't need to be sent together, but the rosters are critical for the

next step.

Using this contact information for active rosters, NIOSH will assess if individual firefighters have already enrolled on their own; otherwise, NIOSH will contact individuals to invite them to enroll. Contacted firefighters will either consent and enroll through the web portal, or they will be unresponsive or choose not to consent. In the latter case, NIOSH will not use any of their individual information, and they will not be included in the NFR.

This process will be repeated for the targeted cohort every few years, to obtain updated incident records, and to recruit new firefighters since the last date records and rosters were shared. We anticipate enrollment being continuous for the open cohort.

In order to accomplish the goal of enrolling 200,000, we realized that we need to offer a concise but meaningful NFR registration experience. This involves an enrollment questionnaire that will be implemented through a web portal to collect information on demographics, work and exposure history, and lifestyle and health information. Registration through the web portal will be simple and accessible on multiple devices. The system will be secure through the use of multifactor authentication and login.gov. Content will be relevant for all firefighters, and clearly convey the privacy of participants' information, which is important because we will need to obtain Social Security Numbers in order to successfully match with cancer and vital status information. This platform will also be used in the future for important voluntary follow-up questionnaires.

For firefighters to enroll, they will complete four steps within the web portal: creating a login.gov account, providing informed consent, creating a user profile for basic contact and work status information that can be updated over time, and completing the enrollment questionnaire.

The Firefighter Cancer Registry Act states that we should ensure information in the NFR is publicly available as appropriate, while also protecting the personal privacy of participants. Therefore, we are obtaining an Assurance of Confidentiality, which is the highest level of protection allowed by the federal government, and will assure participants, fire departments and other institutions like state cancer registries that NIOSH will protect the confidentiality of NFR data.

We are also pursuing secure mechanisms for making deidentified data available to external researchers. One option might be through the use of a research datacenter, which is a federal data warehouse responsible for protecting the confidentiality of participants while providing access to restricted use data to external researchers for statistical purposes.

We are developing a robust communication plan to deliver clear and important messaging about the NFR purpose, expectations and privacy. This plan will include various messaging tools such as focus groups, social media, videos, presentations, a quarterly newsletter which we've already begun distributing, and

more. Websites for the NFR and NFR Subcommittee are already available and are listed here.
This year has been spent planning for and developing the NFR, but we plan to begin enrollment by the middle of 2021, with ongoing data collection, analysis and dissemination thereafter.
Now I'll pass it over to Grace and Pat for the Subcommittee perspectives.

PRESENTATION OF NATIONAL FIREFIGHTER REGISTRY SUBCOMMITTEE (NFRS) REPORT AND RECOMMENDATIONS

DR. LEMASTERS: Okay, very good. Thank you, Miriam, that was a very nice and thorough overview. We appreciate that, and I think that helped set the tone for this meeting, and gives the BSC a nice update on what has occurred.
So, I will start out by reviewing the process that the Subcommittee has undertaken to get us to this point, and it was pretty thorough and involved, beginning on March 20. The 39-page draft protocol and the 5 appendices that included the enrollment questionnaire were sent to all the Subcommittee members. Then, on May 6, we had to have our comments on the draft protocol were due to the DFO, who compiled all these comments, and on May 8, there were 12 pages of single-line comments were compiled and provided to the Subcommittee. Then, on May 15, the Subcommittee had its meeting, which lasted probably five to six hours, to discuss the draft protocol, and the minutes to the meeting, and additional questions that were raised by NIOSH and the co-chair. From this, we received 94 pages of minutes from that meeting, and on June 4, from these 94 pages of the minutes, as well as the initial 12 pages of comments, a report was drafted by Pat and myself, and it was sent to the DFO. So then, after that, June 19, the comments on the draft protocol were due, and then following that, the DFO, on June 21, compiled all the Subcommittee's comments and provided these to the co-chair. Then, on June 25, we did a revised draft report which was sent to the NFR—the Subcommittee—through the DFO. Everything was sent through the DFO then to the Subcommittee. July 14, we, the Subcommittee, had a meeting to make any final changes, and there were one or two made, and we approved the report at this point for submission to the BSC for deliberations, which brings us to today, to our special BSC meeting to review and finalize the report and recommendations for NIOSH and the NFR Program.
Our job today is to review the report, make any changes that we deem necessary to the report, and then vote on—and the BSC has the last say on this report, okay—and then vote on acceptance of the report after changes and the recommendations after any changes have been made. Then this report is sent to Dr. Howard for final review, and then the Program will be able, the NIOSH Program, will be able to review these non-binding recommendations and proceed

with the Program.
Are there any questions about what went on?
Okay, well, hearing none, then I think we are ready to actually review the report of the Subcommittee, and we're bringing that up, and I hope you've all had a chance to read it before today. So, Pat and I are going to be doing a tag team on this. I'll be reviewing part of it with you, and then he will be reviewing parts of it that have direct representation to the firefighter service, and then it'll come back to me for some issues related to the science, and then back to him.
So, if you have that in front of you, you see it up on your screen. The history, we have just gone over that, and Miriam's presentation of the protocol and what the Subcommittee went through to get us to this point. You will note on the last line of that first paragraph, we did say it is advised that a NIOSH team review all the provided comments and make changes to the protocol and dependencies as they deem appropriate. That was from those 12 pages of written comments that the Subcommittee provided back to the NIOSH team, and I think, after Miriam's presentation, I see a few things already in the queue from that 12 pages of written comments that we gave them.
Then, the meeting overview, you want to scan down a little bit further and get all that on there, Emily? Yes, right there is good. The meeting overview, again, was to review the comments that the Subcommittee had, and also, NIOSH provided a list of six overarching questions. The co-chair added three for additional consideration at this meeting. These questions included issues related to communication and enrollment of participants, estimating lifetime exposure—somebody has, if somebody can mute their phone. I'm hearing a little background. If you could do that, please. Use of protective equipment, cancer risk factors, possible additional information needed for linking with state and territorial cancer registries, pilot testing elements of the protocol and approach to implementing recruitment of the targeted and open cohorts. We would like to say, after the last sentence, after "Review and final approval of the report by the NFRS and NIOSH boards," us—this group—will review it and discuss it in the open meeting, which is what we're doing today.
Now, the progress of the NFR—and I would just like to draw your attention, we talked about the Assurance of Confidentiality, which Miriam has discussed also in her introduction—but I'd like to draw your attention to the last sentence and give the project team some kudos as to NFRS was quite impressed by the progress made by the NIOSH team, as well as the overall study design and approach. We thought it was an elegantly designed project, with two very strong elements of, if you go on to "Overall study approach", Emily, yes, that as was just presented to us, there is a targeted and an open cohort to try to incorporate as many, as much diversity in the population, and to have as many people participate as possible, to get to that 200,000 point. And I'll draw your attention to that last line, last sentence

of the "Overall study approach" that says, "A question by some Committee members was the feasibility of including sufficient wildland firefighters in the open cohort approach to ensure reliability of findings." Now, our Subcommittee was comprised of nine members of the Fire Service, so I would say this was raised by a couple of people. So we thought that was important to leave in there.

Pat, are you able, in your current situation, is your computer onboard?

MR. MORRISON: I am doing the best I can on my phone, yes. So I am—all right.

DR. LEMASTERS: Oh, because we—

MR. MORRISON: Go ahead.

DR. LEMASTERS: Do you see—I just wondered if you saw, we're at the "Department eligibility requirements, communicating to targeted fire departments, overcoming participation barriers and increasing enrollment." Do you see that on your screen?

MR. MORRISON: I do, I have got that now, Emily. I mean, Grace.

DR. LEMASTERS: Okay. Okay, then I will turn it over to you to review that section.

MR. MORRISON: Okay, so thanks. Yes, and that's the overview, I guess, and then we'll go into recommendation number 1 I guess is the case there. So, for us, the biggest, I think, hindrance of making sure that firefighters participate in this registry would be, one, would they be willing to do the questionnaire with some of the key identifiers that we know, that we might have to use for identifying the individual firefighter. And I think one of those key identifiers really would be the—Grace, I'm getting a little, because I'm not seeing it all here because I've got my phone that I'm using, but I've got the section up here. Are we talking about here, when we went over this, so we're talking about the use of the Social Security Number here, in this one here, or?

DR. LEMASTERS: Pat, would it be better, do you want me to just—is this too…? I can (inaudible @ 00:40:11).

MR. MORRISON: Yes, do this one here, yes. Because I'm just trying to follow on my phone right now, because I'm kicking it back and forth here too, so I'm not too—so I think I just lost my place here.

DR. LEMASTERS: That's hard to do, you know. My phone broke yesterday, went kaput. And so I had to run out and buy a new phone so I'd have one for this meeting today, so I certainly understand these unexpected trials we experience. So, the next section that I'd like to go ahead and discuss with you is the department eligibility requirements, communicating to targeted fire departments, overcoming participation barriers, and increasing enrollment.

So, one consideration that the Subcommittee brought up was that the information from the fire departments may be protected by the Family Education Rights Protection Act, FERPA. And some states such as New York are very restrictive. Fire chiefs also may have privacy concerns and be very reluctant to provide information pertaining to their firefighters. Plus, departmental leadership are frequently changed, changing, and it is unknown if records are maintained in any

consistent manner. So if you look at the last sentence, we state, “It is suggested that the NIOSH team explore the restrictions that may be applied to their requests to anticipate the degree of resistance and non-compliance that may occur.”

Now, you will notice in this report that, at times, we use “suggested” and “advised”. Those words do not have to be voted on, but any time we use the word “recommendation”, those, that has to be voted on either individually or as a whole. But it doesn’t mean that we don’t, that we can’t change any of the wording that we, as the BSC, deem necessary.

So, it was also felt by members of the fire service that it is going to be very important to identify key opinion leaders in each department, and maybe develop a webinar for the targeted departments to, again, inform them and encourage them to participate.

Two issues that the Committee thought of paramount concern for participation by both the fire departments and firefighters are data security and confidentiality. So, NIOSH is seeking to offer an Assurance of Confidentiality, and we describe that, but there may need to be some education of to what—what does that Assurance of Confidentiality provide for them. And we state that, in the last part of that paragraph, “Most participants will need a clear and specific explanation of how the AOC protects their privacy. This explanation may be included in informational and in promotional materials, informed consent documents, and the enrollment questionnaire.” But there will be a fair amount of concern about privacy.

But, as you see, regardless of the AOC, the Committee felt that there was still going to be considerable reluctance of providing the complete Social Security Number. So, we went on to say it’ll be important to explain why that is necessary, and that the need for Social Security Numbers should be highlighted in all communications, and even a suggestion was made to headline it in trade magazines.

It was also a concern that possibly maybe the last four digits of the Social Security Number would be considerably easier to obtain and less likely to decrease participation, and I think NIOSH plans that if they can’t get the whole one that they're going to ask for the four-digit one in a second element.

And enrollment will require that individuals understand that their participation will provide an overall benefit to the profession, as well as contribution to science, and it’s going to be necessary to have a very good explanation to how, in the long run, it will benefit future firefighters and the profession.

So do you want to go over Recommendation 1, Pat?

MR. MORRISON: Yes, I can, and I’ll just add a couple of things here on this, really the eligibility requirements, communicating to target fire departments, and really overcoming participation barrier. And I think that probably is in a lot of studies, that individuals actually do, an increase in the enrollment. But one of the important parts about getting fire departments on board will be, one of the components of this will be

matching of firefighters' exposure records. In other words, a firefighter that has run a number of calls—those records are usually kept electronically by the fire departments. They have control over those records. They know how many calls the individual firefighter had run. They know, perhaps, the amount of fires. And that's going to be extremely important for us when we do the exposure matching of the cancer registry. It's not just the cancer but what is the story telling us? What is different from one group to another group? Are these firefighters—why were they more exposed, and how were they more exposed? So that's going to be, that key opinion, getting the leaders in here, is going to be very, very important for us, to make sure that we have the information and we really can get fire departments to understand the critical nature of this.

But really, recommendation number one was, because the importance of obtaining the Social Security Number for the National Death Index and the cancer registries, it is recommended that NIOSH should pilot test with several individuals to learn the most compelling approach for explaining the purpose of both the assurance of the confidentiality and the rationale for requesting the SSN. Also, NIOSH may want to explore exactly what will be lost if only the last four digits are gathered, especially when they have other identifiers such as date of birth.

So Grace, that is our first sort of recommendations to the Board with that. Do we want to open up questions about that recommendation, Grace, now or do we want to move forward on some other areas?

DR. LEMASTERS: Terry, I see that we're supposed to do the presentation and then the discussion at 2:15 but I think we could do it either way. What is your preference?

DR. BUNN: I could go either way but maybe it would be best to stick to the agenda just in case there are members of the public that join at different times during the meeting and during the agenda. So it might be best to stick with the—how it's outlined in the agenda, the presentation first then the discussion.

DR. LEMASTERS: Okay.

MR. MORRISON: Okay, that sounds fine. I can go—let me go over this next section with you. That was one of the recommendations. Lots of debate on that, as you, everybody here on this call, would imagine, especially with the breach of so many different confidential information in people's personal lives that, would that be a barrier that we get excited about getting this registry out and then all of a sudden, we have a slowdown because we didn't really address it, and we're really in deep discussion.

The next thing that we really wanted to do, and we really felt—and this was something that the Subcommittee group did bring—the fire service is made up of a lot of national organizations. That includes that professional firefighters, the International Association of Firefighters that I was part of for my whole career as a firefighter, and I still work with them in the health and safety section. You have the International Association of Fire Chiefs. You have the International Association of Black Professional Firefighters, the Association of Hispanic Firefighters, and you

have Women in Fire Association.

And really, what was suggested, and this really is how the fire service sort of works, if these lead organizations really understand and get the information out to their members, and every one of those groups that I've talked about, their members rely upon those organizations to really give it the credentialing and the credibility that this project we are involved in, we are involved in every step. We know how this information is going to be used, how it is going to help the firefighters into the future, and especially with cancer in the fire service, which is probably the number one health issue that are facing firefighters today.

So we really did reach out, and the group really felt that we really needed to rely on these organizations. We really needed to rely on how could they communicate to their members. So in the beginning when we discussed about the Program and how the Program was going to roll out, the marketing is going to be incredibly important, for two reasons. One is to make sure the firefighters understand this is not a registry just for firefighters that have cancer or who have had cancer in their, during their career, but this is—we need to enroll a number of firefighters, you know, the healthy firefighters. Those that do have cancer, yes, you can enroll in this, but we needed to make sure that they understood that. The best way for us to get this information to a large, large audience is through these organizations, and that was really talked about a lot at that meeting. It was—because a lot of individuals on our Subcommittee belong to these different organizations. So that is an area that we're really going to have to focus in. You think you have the best product, but you don't have the best product until you really look at these organizations and have they been educated, have they been updated? Do they understand all the different aspects of this registry, and how can they help NIOSH completing their task, with making sure that we do have a representative sample included in this registry from the very beginning? So I'll turn it back to you, Grace.

DR. LEMASTERS: Okay, thank you. Very good. I think that really hit the high point of what the Committee felt.

Then the next issue that was discussed in detail was linking with cancer registries, and we had two people on the Committee that that was their specialty, our cancer registry. So that was very advantageous. And the NIOSH team's question was, "Are any crucial details missing from the protocol or consent form that would be needed for linking with population-based state and territorial cancer registries?" "How soon after initial enrollment should NIOSH seek to conduct registry linkages necessary?"

So we learned at this meeting from the two members of this Subcommittee that the entire nation has been covered by state-based cancer registries since 1995. And then there was a lot of discussion about the recent transformative developments to link individual identifiers with cancer registries. Then there is the North American Association of Central Cancer Registries that has created a

virtual national cancer registry called the Virtual Pooled Registry. To date, 38 states have agreed to a single point access where a data file can be submitted with identifiers. The file is then submitted through a secure mechanism to link with each state, with each state's cancer registry, and then the deliverable to NIOSH would be a report of the number of matches by state that occurred. However, no personal identifiers will be released in this phase. Then, NIOSH can negotiate with the state to receive patient identifiers, which will be needed for data analysis of course. It was reported that it is possible to do minimal risk linkage studies using cancer registry with an IRB-approved waiver of consent.

So that leads us to Recommendation 2, if we could—yes. So, Recommendation 2 is for, "We state that currently, changes are underway with the NAACCR to facilitate and streamline linkage between research groups and state cancer registries via the Virtual Pooled Registry. We think that NIOSH should begin the groundwork for establishing the framework for linking the firefighter cancer information, both past and ongoing, to facilitate future easy access to the state cancer registry data." In other words, to get started on finding out what's going to have to be done to facilitate that when you have the data, and you want to go to the state cancer registry, that it's a streamlined process by the time you're ready to do it, that all the back work has been done.

Okay, so the next issue has to do with estimating lifetime exposures and use of protective equipment. Pat, is that—shall I go on or do you want to do that? You may not be able to see it. Pat?

MR. MORRISON: Let me take it off of mute. I'm slow on the uptake right now, so anyway. And this was probably, you know, any time you have a report, you say, "This is the most critical," "This is the most critical." But really, estimating lifetime exposures and the use of protective equipment really captures the complete picture of an individual that's going to be part of the registry. And really, that is a difficult thing to do; that is not easy. When we had other cancer studies done, the exposure, overlaying and mapping out of firefighters' exposures over a career is not only important but it is difficult sometimes.

So the group really, we spent a lot of time talking about this, because there was another issue on here. I think, I haven't met a researcher that doesn't want to add another question into a project, that—and it has to be added. So we really had to, we started this discussion, we started with, you know, how long is this question—the enrollment questionnaire going to be, and that can be a barrier too, as to if you make it so long, will a firefighter sit to complete the enrollment questionnaire? And we'll get into that in a little bit.

But the cancers that we really are looking at that will be reported in the next ten years or so with the Registry are going to be related to exposures that occurred 15 or 20 years previously. And we do know that. We do know that with some of the history that we have now. We do know that with the latency of the cancers that

firefighters are getting. So we do know that we have to go back, when we're looking at to capture a complete picture, we have to go back and find out when that firefighter started their occupation. What was actually going on? What was in place? There was a time 20 years ago that a lot of firefighters did not use personal protective equipment after the fire, we called that, you know, when we go in, we've knocked the fire down, and then you'll have salvage and overhaul, and you're actually in the overhaul process. And we had so many firefighters that were needlessly exposed to harmful gases during that period of time, but there was no policy. We didn't really have a complete understanding of the cancers that would be related to that. But you really have to take a look at that. Does that firefighter have that in their exposure records?

So we really wanted to make sure that we had taken a look at that, and looking at the other question that is really relevant to that is that if I'm a firefighter and I'm going to be compared to a lot of other firefighters in this registry, it really is going to depend upon, a lot of times, geographical areas and difference, from an urban/suburban firefighter. How many runs—runs and shifts—what we meant here is how many calls did I actually run. How much, yes?

MS. NOVICKI: Pat, I'm so sorry to interrupt. I just want to—2:00 p.m. was just our public comment time, so I'm just going to state for the record that we have not received any requests for public comment, and so we are just going to move right along, and you can continue with your discussion. Thank you.

MR. MORRISON: Okay, thanks, Emily. You scared me to death there. Anyway, I—

MS. NOVICKI: Oh, I'm so sorry. I just wanted to—there are so many FACA rules, we just have to—

MR. MORRISON: No, I'm just—I'm just kidding, Emily. I'm just kidding. I thought maybe I'm really well off-base here, but anyway.

MS. NOVICKI: Not at all.

MR. MORRISON: Okay, thank you. But really, what we wanted to make sure that we did have enough and sufficient time for this, because—and the other is the frequency. I might have worked at a station but I didn't have that many calls, it was a very slow area, didn't have many fires, didn't have many exposures. So the frequency of not only the calls but what type of calls, and what was done, into the exposure. And then I did talk about the frequency of wearing the respiratory protection, and currently today, if you went into a firehouse today, and you went into a firehouse, and if we had the ability to go back in time, you would see an enormous difference in the way, the cultural aspect of firefighters looking at their PPE, wearing it, taking care of themselves, washing their gear. It used to be a badge of honor that you could have this gear and make it as dirty as possible, because that made you look like a really seasoned, seasoned firefighter, and we are really moving away from that. You are seeing a complete difference in the way that we are taking care of ourselves, coming back from calls, removing the smoke and the soot on the skin,

getting showers right away. So really, we need to compare that. I mean, this is going to be part of this data collection, and why were there differences? You know, researchers are going to say, "Well, why is this group showing this, and this group not showing that?" So we want to make sure that we actually put that, and we get those questions in place, and we have those, and making sure that we know what those common practices were during that period of time.

The other thing that we are seeing is a real switch in the movement of firefighters from one fire department to the other fire department. You'll have a lot of firefighters that start as volunteers in some areas, go to paid fire—they want to be a career firefighter so they go to that. And then we have a lot of firefighters that will move from department to department. So we really have to capture the movement of those firefighters. It wasn't that they were just in one fire department. They were really in a lot of different fire departments. And what was actually happening? What—did they have SOP, standard operating procedures, for that PPE and all of those different departments, or were they all different? And that is going to allow us to really look at the total exposure picture from all these individual firefighters.

And then, we really wanted—and this is going to be difficult for us, because when you sit down and you're filling out something, you're trying to go back and recall, how many firefighters did I—I mean, how many fires did I fight? How much exposure did I have? So we had a lot of discussion about that, and then we really wanted to make sure that—we can't capture all this information. The report might be too long. So where is that balance? And really, this question is going to go to NIOSH, is how do we balance the necessary information that they are going to need for this exposure based on the firefighter's history and based on, a lot of it is the recall for that firefighter. How much did they understand, and can we give them information that could trigger, basically, some information that they would need, that they don't currently have?

So with that, I don't know where I'm at right now, so are we at—I guess we're at Recommendation 3.

DR. LEMASTERS: Yes.

MR. MORRISON: Let me, I'll just go through this and then I'll turn it back over to you. So Recommendation 3, it was recommended that one or two approaches be used to characterize exposure. One approach could be the use of strategic questions regarding the approximate year that the individual firefighter started each protective action, such as self-contained breathing apparatus, other respiratory protections during overhaul, types of turnout gear used, storage, cleaning, showering. Then the second approach would be to ask—and these are the questions that are in the EQ—for each job held. Further, it is recommended that both approaches be assessed in a pilot study to determine how much time is added to the total time for collecting the information for the enrollment questions.

Several of our Committee members felt that 30 minutes or less may be ideal for completing the enrollment question, but that this exposure protection information was vital for success of the study, hence it is recommended that different versions of the questionnaire be piloted—be pilot-tested—to have a better understanding of which approach is more reliable, valid, and acceptable to the participants.
And that, we did feel, that group did feel that this would, the pilot approach could not only assist us but could really kind of focus in on exactly how we should be writing these questions down, that firefighters are going to be filling in. And I did talk about how much time before you lose the interest of the firefighter, and we don't get a completed sample.
So with that, Grace, I'll turn it back to you.

DR. LEMASTERS: Okay, thank you. So, you'll see, starting at the comment, "Another important point raised was that the fire departments may share the same name, and a way to distinguish these would be to capture the Fire Department Identification, FDID." Every fire department has a unique FDID, we found out, which may be key to understanding how protective gear was handled, by the individual fire department. Knowing the FDID may be especially important when individuals worked at multiple fire departments. The FDID numbers are standard. All fire departments registered with the NFIRS system used the FDID. It is advised that—and we say the word "advised"—that the NIOSH team explore how to incorporate the FDID numbers, but understand that individual firefighters may not even know the department's FDID. So that's a question that has to probably be explored, to see how prevalent the understanding of the FDID may be amongst the fire departments—the individual service, the firefighters providing the work out there in the field may not know these FDIDs. But the Committee was uncertain about that.
Now, the next issue was assessing cancer outcomes, and identifying risk factors. So, the NIOSH team asked the NFRS to address what other important variables related to cancer risk should be collected as part of the enrollment process, and what should be included in follow-up surveys. The Subcommittee did note that the key risk factors had been well-identified and included the use of tobacco products, but maybe more specific information needed to be added about including cigars, chewing tobacco and snuff. I mean, humidors are in a lot of fire departments, we found out.
Alcohol use, exercise, strength training, use of indoor tanning devices, and having annual medical evaluations are in the current protocol, but it was suggested that some type of measurement of the amount of use of tobacco products should be added, such as, for calculating pack years, not just say yes or no, but the amount specifically. The Subcommittee also felt that for the follow-up questions, when they go back to the questionnaire, there might be, it might be important to ask about sleep and stress, how is that currently happening for them, how well are

they sleeping. The recall of past sleep and stress may not be good, but if we're getting it currently, like how well did you sleep in the last six months or the last month, and issues related to how much stress they're under might be added.
In the written comments to NIOSH, it was also advised that questions be asked in order of lower sensitivity to those of greater sensitivity, sort of starting with the exercise first and ending with alcohol use. As it is now, we start with the alcohol question.
And so, there was just some more questions were raised about the profile questionnaire should be updated with a new cancer diagnosis or exposure information. It was also stated that regarding cancer diagnosis, that it is critical that the residence where the individual was living at the time of cancer diagnosis, and not the state where the diagnosis was made, be made.
And one person mentioned, after about asking if any of the children, their children had developed cancer, which would be related to bringing workplace exposures to the home or possible spermatogenic effects as well as genetic effects.
Those were, that was, some of those were new items that were brought to the forefront, in the realm of advising or suggesting rather than as formal recommendations to be voted on.
Next, we'll go to communicating the findings to participants. Well, the Committee, we had a lot of discussion on this also, and the Committee felt additional considerations should be given to communicating the start-up of the study as well as ongoing communication of the findings. For example, at time of signup through the web portal, the individual could request to receive regular updates. At least every six to twelve months, each participant might receive a summary of how—just simple things—how many have been registered, what regional areas have been included. Just some basic statistics to know, on an ongoing, continuous basis, that progress is being made. There could be an ongoing visual as to how the enrollment has come forward for the goal of 200,000, like you know, how high the thermometer is going is just a funny example.
And the Committee wondered if it was possible for participants to refer other people to the NFR, as it's always good for other firefighters to encourage each other.
Communication of a study's findings is the ultimate, ultimate tool—I can't emphasize that enough—for maintaining interest and follow-up participation, this constant, ongoing communication with newsletters to keep—because this is such a long study, and there's going to be so many follow-ups, there needs to be follow-up, having the firefighters just not forget about you, you know, interviewing them and then waiting two to three years before you contact again, that's probably too much timeframe that has passed by, and there's the other means of newsletters, updates, that can be sent out to the participants.
Okay, I think that's it. It's 2:09 so we pretty much kept within our timeframe. Emily,

I'll turn it back to you and Terry. And I guess I would just add that, you know, what we're looking for in this report is substantial issues or substantial wording or changes, but not, you know, not minor wording and changes, you know. I might prefer to say something one way; you might prefer to say it another way. But really substantial issues that we need to pass on to Dr. Howard as well as the research program. Okay.

DR. BUNN: All right, thank you so much, Grace and Pat, for your really well-done synthesis of all of the minutes from your Subcommittee meetings, as well as the input that was provided by the stakeholders. So now is where we—I think I would like to start with the discussion starting with recommendation number one, and is there a way to bring that back up, where we're actually looking at recommendation number one so that we can discuss the contents of that recommendation?

MS. NOVICKI: Sure thing, hold on just a second.

DR. BUNN: Okay, so I'll just read it here. It says, "Because of the importance of obtaining Social Security Numbers for the National Death Index and the cancer registries, it is recommended that NIOSH do pilot tests with several individuals to learn the compelling approach for explaining the purpose of both the Assurance of Confidentiality and the rationale for requesting the Social Security Number. Also, NIOSH may want to explore exactly what will be lost if only the four digits of the Social Security Number are gathered, especially when they have other identifiers such as date of birth available."

So let's begin with that recommendation. I have some questions myself, but I would like to open it up to the members first, to see and listen to their questions and suggestions for this first recommendation. If everyone could wave their hands when they speak, that would be great, and then I'll know who to call on first.

MS. NOVICKI: We have a question. Lauren Barton has raised her hand, and—

DR. BARTON: Yes, I have. I have. I think that the request for the Social Security Number is going to be one of the main barriers towards getting participation in this registry. And so I was interested in knowing, when you say that developing the most compelling approach for explaining the purpose of the AOC and the rationale for requesting the Social Security Number, number one, do you have any idea of what approaches you're going to use yet? And my second question is, do you have any idea, is there something that will be lost by using the last—using only the last four of the Social Security, Social Security Number, if you have the date of birth as well. And I'm going to go on mute since my other phone is ringing, sorry.

DR. LEMASTERS: This is Grace, and I think that should go back to Miriam or Kenny for their thoughts on it.

DR. SIEGEL: So, related to—I guess I missed little parts of that question, but I would like to address using the last four digits. You know, we know that using full SSN is obviously going to provide much better and more accurate and comprehensive matches than using partial or no SSN. But we know that cancer registries can

match using last four digits. One problem with this population compared to maybe the general population, doing just general population studies, is that research shows that matching with no SSN or fewer digits of SSN is a problem for people with common names. And we have heard that this is a population where you can expect to see common names and similar names, with similar demographics and even within similar—even within the same city, same department, same region. And so that will be one problem with just linking with the last four digits of SSN. And we know that for linking with—can you all hear me okay? It seems my connection was lost.

DR. BUNN: Yes, you're fine.

DR. SIEGEL: Okay. Okay, thank you. For linking with death data from NDI, you can only link with a full SSN or no SSN. You can't link with partial SSN. So that's another consideration.

DR. BUNN: So do you have any idea about approaches that were mentioned, the best approach was mentioned to explain this?

DR. SIEGEL: I know we're working on some communication messaging, and I'm going to ask the rest of my team to jump in, but we're being sure to put the messaging on all aspects of our communications, not just in the questionnaire but also in other forms of messaging.

MS. WILKINSON: Hi, this is Andrea from NFR team. One of the messaging ideas was actually brought to us that perhaps we should work with our Fire Service partners on some sort of video that would be very brief, and just explain the importance, and this is something that we're hoping to reach out to someone like Pat Morrison to help us out with, to find out the right people to represent this cause so that the message is coming from someone that they trust and that is in the field with them.

MR. WEPSALA: And this is Will from the NFR team. Also, kind of in regards to that, and kind of the messaging that we're trying to do, we are also having, facilitating some discussions with firefighters to see what kind of assurances they would respond to, and what would be a compelling argument for them for providing the full SSN. And so we're hoping to use that feedback that we get from firefighters to tailor the messaging as we need to.

DR. BUNN: I had a question to Miriam. In accessing the NDI, if you have things like date of birth and where they've died, and date of death, aren't you pretty able to get the information from NDI? I mean, we've been fairly successful with it, and I just wondered how—you would still, if you don't get this full Social Security Number, you will still try to get it, right, with date of birth, date of death, and state where they died, right?

DR. SIEGEL: Well, we'll need vital status information to ascertain date of deaths and place of deaths, but we absolutely will still, you know, do pursue linkages if we don't have access to full SSN through NDI. You know, we're still going to have date of birth, full name, and other identifying information that we can locate to pursue these

matches. We have some analyses that have been done in the past that we've looked at, or that I've reviewed, that show varying degree of looking with NDI, using no SSN but other linkages. And usually, it's pretty successful, for the most part, overall, estimates range, you know, between 91 and 99 percent. But again, for people with common names, their linkages can be poor, be as poor as, you know, less than half, for example, of correct matches made. So, you know, it's a give-and-take. We'd work with the information that we have and the more information, the better. But when you don't have SSN at all, then the more important the other identifiers become and, you know, we won't always have access to, you know, completely accurate of those identifiers and so on.

DR. LEMASTERS: It looks like we have a question—

DR. BUNN: Right, thank you very much.

DR. LEMASTERS: Michael Foley has a question.

DR. BUNN: We have a question from Michael Foley.

MR. FOLEY: Well, it was kind of similar to the previous person's question. I just think you need to have the answer to the question from the candidate, when they ask you, "Well, you have my name and you have my date of birth, why do you need my SSN?" then you need to have a compelling answer to that question. So I think that's probably going to be where most people think that, "Well, that should be enough to identify a person," especially if you already—also have location information, as well.

DR. BUNN: Okay, thank you, Michael. That kind of brings – wraps into my own question, which is regarding the actual content of this recommendation. My question for the group is, you know, you say pilot testing in the recommendation, but I'm wondering if you might want to consider including the performing of—which I think has already kind of been mentioned, but maybe really describe it—performing targeted stakeholder interviews as well as pilot testing. Well, first, targeted stakeholder interviews to inform the development of the Assurance of Confidentiality and rationale document, then pilot testing them.

DR. LEMASTERS: I'm fine. Pat, are you with adjusting — well, can you give us the wording? I mean, what we would like to do is get the recommendations in a form that then we can vote on, and I'm fine with that comment, Terry.

DR. BUNN: Okay. So...

MR. MORRISON: Grace, I—yes.

DR. BUNN: This adjustment, and this may be up for more discussion is it is recommended that NIOSH should perform targeted stakeholder interviews to inform the development of the Assurance of Confidentiality and rationale document, then pilot tests with several individuals which brings me into my next question about the definition of individuals. Who is the target audience for the pilot testing? I assume it's the firefighters.

DR. LEMASTERS: So then you would be comfortable with instead of saying several individuals, say

several firefighters or stakeholders, which I think that's a different issue.

DR. BUNN: Preferably firefighters/stakeholders.

DR. LEMASTERS: Firefighters/stakeholders. Emily, can you make that change so we can see what it looks like and see if we like it as a group? Oops, I've just lost the whole thing.

DR. FENT: So this is this is Kenny Fent. I think, perhaps, if we're going to be more specific, I think it has more to do with the language that we should use to explain the Assurance of Confidentiality to firefighters, because we already have a pretty good draft of the AOC, and I don't know that it would, you know, meeting with individual firefighters or stakeholders isn't going to necessarily change the AOC, but how we explain the AOC to firefighters is something that we would definitely want feedback from different stakeholders on that.

MS. NOVICKI: Terry, could you please repeat the phrase that you wanted to put here?

DR. BUNN: That NIOSH should perform targeted stakeholder interviews to inform the development of the Assurance of Confidentiality and rationale documents, then pilot test informs the development of the Assurance of Confidentiality and rationale documents, then pilot test with several firefighters/stakeholders. Which I'm glad to hear that you are developing a draft one and that would be great even for those stakeholder interviews, that there is a draft developed. I do see that we have a question from Steve Lerman as well regarding this recommendation.

DR. LERMAN: Yes. So the last sentence the "Also, NIOSH may want to explore...," my initial proposal was going to be that's not really a recommendation, let's make that Recommendation number 2, but hearing the discussion, actually, it sounds like NIOSH has a pretty good understanding of what they lose, and I think we could just strike it. If we don't strike it I think it should become a recommendation. But, I guess, my primary thought right now is just strike it.

DR. LEMASTERS: Yes. I think given what we just heard, I'm fine. I think NIOSH has a pretty good understanding of this and we don't necessarily need that last sentence in there. I'm in agreement with you, Steve. How about you, Pat? Are you okay?

MR. MORRISON: Yes, I am. I'm okay with that.

MR. LEMASTERS: But, Kenny, I don't think we addressed your comment, did we or did we?

DR. FENT: Well, I mean, you know, I certainly appreciate the guidance, the recommendations that you're providing. I don't want to sway it one way or the other. I think what I wanted to just convey is that the I don't know how much we would change the AOC based on interviews—I'm looking at the words right now—but interviews with stakeholders. I don't know if it would change the AOC because the AOC is intended to protect data that's collected from release without written permission from individuals. I mean, it's pretty black and white in that sense. I mean, we do have some ways of sharing data built into the AOC, but that's still a very confidential sort of process that we have built in.

What I see as a real advantage of meeting with stakeholders is how do you explain the AOC to regular firefighters? How do you explain what it's for and what

it intends to do? So that's what I would see as being the most beneficial recommendation that you could provide.

DR. LEMASTERS: So it is recommended that NIOSH should perform targeted stakeholder interviews to what, Kenny? To...

DR. FENT: Inform the communication of the AOC to firefighters or explain the purpose of the AOC to firefighters.

DR. LEMASTERS: To explain. Instead of inform, to explain the purpose of the AOC.

MR. MORRISON: And, Kenny, this is Pat. I tend to agree with you on that path there. And I think that, really, the simpler, the better, but you're really trying to get the firefighters to understand why do we need your SSN, is what you're trying to do. And does the explaining of that persuade the firefighters to say, "Oh, I understand this. Yes, I'm going do it?" Is that correct, Kenny? Am I paraphrasing right?

DR. FENT: Yes. Yes, I mean, why we need the SSN, but then, also, how we're going to protect your SSN. That's really the purpose of the AOC, is how are we going to protect the data that you provide to us.

MR. MORRISON: Right. And that's what they're going to want to know. Yes. Go ahead, Grace.

DR. LEMASTERS: Yes. Go ahead, Pat.

MR. MORRISON: No, that's all right. I understand, Kenny, exactly what you're saying. I think like a couple of the questions earlier, a firefighter not wanting to put it in. They're saying you've got my name, you've got my date of birth. But if you can explain to the firefighter that this is how we would like the SSN. Because you have to you have to say, "Well, why is that piece so important for this project," and then after you say that, how is it protected. And if the firefighter knows that hey, listen, this is a project that really is, you know, the SSN will enhance it and they feel confident enough that it is going to be productive, I think that's what you will get in the final outcome of your of explaining the AOC on that.

DR. LEMASTERS: So since the Subcommittee, Kenny, you did not have the AOC finished at the time we did our reviews. The AOC then discusses the Social Security Number, in particular? Does it discuss it, in particular, specifically, the Social Security Number? That's the question.

MR. MAYER: Hello. This is Alex. I'm part of the registry team and I helped draft the AOC. And, yes, we specifically mentioned the Social Security Number in the Assurance of Confidentiality.

DR. LEMASTERS: And so, you feel like your wording is such that you have the right wording, but you could—so stakeholder interviews would be done regarding the AOC, right?

DR. SIEGEL: So this is Miriam. Could I make one quick clarification? So the Assurance of Confidentiality itself is a document that we prepare to send to the CDC in order to be granted that kind of protection of our data. It's not a messaging document. So I think the recommendations that are being made right now are great for the communication about that protection, not the document itself. Does that make sense?

MR. MAYER: Yes. In the communication, including in the informed consent and enrollment questionnaire. So the language that we're using in those documents is some of the language that we'll be looking for in addition to other communication products that go out to the fire service.

DR. SCHENKER: This is Marc Schenker. Can you hear me?

DR. LEMASTERS: Yes, Marc.

DR. SCHENKER: Yes. I mean, what we're talking about is, basically, focus groups which, I think, have two purposes. One, is to see is the requesting of an SSN a barrier to participation, and that has to clearly be addressed because if it is, it has to be somehow modified. And the second is the issue of communication, how to communicate this and reassure the workers. And I think both of those could be purposes of focus groups of firefighters or other participants. And then the second stage would be to actually pilot test, which can be done pretty efficiently. You can send out requests of two different formats and look at the response rate, if it comes to that. So I do think that the feedback is really important. That we get the feedback from the participants. You know, no, this sounds invasive; no, I understand and I would participate if it were requested this way.

MR. MAYER: This is Alex, again. And we are holding virtual focus groups at this time with some firefighters, discussing a few different things. But one of the main topics is the language regarding the Social Security Number. So that's perfect. We're right in line with this recommendation at this time.

DR. LEMASTERS: Okay. And thank you, Marc. And, Steve, I see your hand is up. Did you have another comment?

DR. LERMAN: Yes. So I apologize if this is what you asked not to do, which is wordsmithing, but I think based on this discussion, we can de-jargonify this. It's not to explain the purpose of the AOC, it's to explain why Social Security Numbers are needed and how they're protected, and that's much more plain English.

DR. LEMASTERS: Well, I think the Assurance of Confidentiality is—okay. Someone from the NIOSH team, are you actually going to present the Assurance of Confidentiality to the firefighters or is that only going to the CDC?

DR. SIEGEL: That goes to the CDC. What we would communicate is that the data are protected by an AOC, and defining and explaining what an AOC is.

MR. MAYER: And in that language would be communicated in the informed consent and the enrollment questionnaire, you know, parts of the AOC, but the whole assurance statement will not be provided to the firefighters.

DR. FENT: I like the suggested change, the wordsmithing that was proposed because I do think that's a much simpler, but it's factual, that is what we need to do.

DR. SIEGEL: I agree.

DR. LEMASTERS: Okay. Do we have it changed?

MS. NOVICKI: Yes. This is Emily. Does this look right to you all? Are there any more edits needed?

DR. LEMASTERS: Well, can you accept all this, and then we can see what it reads, how smoothly it reads? Okay. So going through it again. "Because of the importance of obtaining SSN for the National Death Index and the cancer registries, it is recommended that NIOSH should perform targeted stakeholder interviews to learn the most compelling communication approach for explaining why the Social Security Number is needed and how it would be protected, then pilot test it. What's pilot tested? It sort of hangs off at the end. And how it will be protected. What about pilot testing? What are we...

MAN: Then the communication approach.

DR. LEMASTERS: Then pilot test, then the communication approach should be piloted. Okay. Period. Does that work for everybody? Are there any other changes? If not, then we have to...

DR. BUNN: From members, I don't see any hands up. Any more discussion of Recommendation number 1?

DR. LEMASTERS: What happened here? I lost something. Oh, there we go. So, Terry, should we vote on this?

DR. BUNN: I think I will refer to Paul as to whether we vote now on each recommendation as we go through it or whether we save the voting to the end of the discussion.

DR. LEMASTERS: Emily, Paul, is it either...

MS. NOVICKI: Both options are acceptable, either way. I'd probably suggest that we do one vote at the end on all three recommendations just to be more efficient, but we could do it either way.

DR. BUNN: Okay. Why don't we wait till the end once we can see all three of them together then.

DR. LEMASTERS: Okay. Very good. Shall we move on...

DR. BUNN: Okay. So let's move on to Recommendation number 2. If you could put that up, please, Emily.

MS. NOVICKI: Sure.

DR. LEMASTERS: I just lost you guys.

DR. BUNN: Okay. So that says, "Currently changes are underway with NAACCR to facilitate and streamline linkage between research groups and state cancer registries via the Virtual Pooled Registry. NIOSH should begin the groundwork for establishing the framework for linking the firefighter cancer information, both past and on-going, to facilitate future easy access to the state cancer registry data."
So, again, I will turn it over to our board members to provide input into this recommendation and the content within the recommendation. Okay. Jessica, I see your hand up.

DR. GRAHAM: Yes. I just have a quick question. Does the state cancer registry data have any indication of trade, like does that mention whether someone had a role of a firefighter?

DR. LEMASTERS: NIOSH team, have you checked into that?

DR. SIEGEL: You're asking about the state cancer registry records?
DR. GRAHAM: Right. Are there occupations as part of that state cancer registry?
DR. SIEGEL: Some of them do and there's varying degrees of information that is collected and recorded, and there is some research out of Florida looking at the accuracy of this information for firefighters, and from what we understand it's less than perfect.
DR. GRAHAM: Okay. Thanks.
DR. BUNN: Do we have any other questions or comments? Okay. So to start the discussion—and thank you, Jessica—or to continue the discussion, I was wondering myself is probabilistic linkage a possibility in the event that the participants do not agree to share their Social Security Number?
DR. SIEGEL: Would you like me to answer that as well? Do you want NIOSH to address that question?
DR. LEMASTERS: Oh, yes, I think so.
DR. BUNN: Yes, NIOSH.
DR. LEMASTERS: Yes.
DR. SIEGEL: Okay. Yes. The answer is yes.
DR. BUNN: Okay. My next question is, is there a possibility where a hash number might work for identification of firefighters in the registry and linking to these other data sources?
DR. LEMASTERS: Hash numbers? Could you clarify that, Terry?
DR. BUNN: Yes. That's, basically, after they're linked in order to be able to share information even internally to create a hash number instead of the use of Social Security Numbers. So you just use the Social Security Number for the initial linkage, but what you come up with is the hash number that every single individual would have their own unique number.
MS. RAUDABAUGH: Hi. This is Jill Raudabaugh from the NFR team. Can you guys hear me?
DR. BUNN: Yes.
DR. LEMASTERS: Yes.
MS. RAUDABAUGH: Okay, good. So I'm the NFR team member. Yes, we're familiar with hash numbers. If you want to get really geeky, actually, encryption at a 128 level is even better than a hash. But, anyways, yes, there are techniques and things that we are going to be doing internally and we're certainly working with our ISSO Bill Brinkley, and we have a number of helpers experienced in encrypting at the column level or Social Security Number on other databases that we have. So, yes, we do, do that. Yes. And we will be doing that on this database as well.
DR. BUNN: All right. Thank you very much. And, I guess, hopefully, to continue the conversation more is—and this is for the board members. Should the basic elements of the framework be described, do you think, within the recommendation?
DR. LERMAN: This is Steve Lerman. I think that NIOSH probably knows better than we do exactly how to lay that groundwork.

DR. BUNN: Okay. Is there any more discussion of Recommendation number 2? Jessica, I see you still have your hand up. Do you have another comment? No. Okay. All right. Well, there's no further comment on Recommendation number 2, why don't we move to Recommendation number 3. Okay. So this one says, "It is recommended that one of two approaches be used to characterize exposure. One approach could be the use of strategic questions regarding the approximate year that the individual firefighter started using each protective action such as self-contained breathing apparatus, other respiratory protection during overhaul, types of turn-out gear used, storage and cleaning of turn out gear, showering etc. The second approach would be to ask questions for each job held. Further, it is recommended that both approaches be assessed in a pilot study to determine how much time is added to the total time for collecting information for the enrollment questionnaire. Several Subcommittee members felt that 30 minutes or less may be ideal for completing the enrollment questionnaire but that this exposure/protection information was vital for the success of the study. Hence, it is recommended that different versions of the questionnaire be pilot tested to have a better understanding of which approach is more reliable, valid, and acceptable to the participants."
So I'd like to open that up for discussion now among the board members. And I think I will start with you— oh, Tiina, yes, let's start with you.

DR. REPONEN: Yes. Yes, I do agree, totally agree that it's important to look at like the past history also on the use of the personal protective equipment and other factors that affect the exposure. I was just wondering if it's a sub-question should be—like a follow-up question should be added to the respiratory protection because currently it looks like it's only asking how frequently do you use respiratory protection in certain activities, but it doesn't ask about the type of the respirator, and that's actually affecting quite a lot of the exposure. So just suggest, then, to potentially add a question. I do understand that there is a balance between brevity and the scientific reasoning, but I think the type of the respirator is an important factor.

DR. BUNN: Okay. I'll leave that to NIOSH to answer.

DR. FENT: So this is Kenny Fent. I mean, I think we're certainly open to that suggestion. Right now we're in the process of revising our questionnaire and trying to gather more information on different control measures that are implemented throughout the fire service. That's another one we can consider.

DR. BUNN: Thank you, Kenny. I see, Marc, your hand's raised now.

DR. SCHENKER: Yes. This is, of course, always the dilemma if you want more information, but is it overloading the questionnaire. And I think exposure is critical, but you have to be careful not to overdo. I seem to recall from, at least, one study that acute overdose of smoke exposure was a predictor of significant risk, and I didn't know if that was one of the questions that had been asked.
And my other comment or question is that the exposure should be able to look at

some dose response. So, ultimately, the findings are going to be stronger if you have a dose response and that's dependent on having the dose be categorically measured as low, medium, high, or however you want to classify it.

DR. LEMASTERS: Marc, this is Grace. Are you suggesting any wording change for the recommendation or, Tiina, are you suggesting some wording changed for the recommendation? Things can be also put above. It doesn't have to be in the recommendation, it could be up above in the sort of leading up to the recommendation. So...

DR. REPONEN: Yes, I think it could be added on top when you talk about the questions, frequency.

DR. LEMASTERS: So...

DR. REPONEN: Frequency of wearing respiratory protection may be there. Adding frequency and type of respiratory protection.

DR. LEMASTERS: Yes, that's where I thought it could go too so can you add that for us, please, Emily? After "29 (Frequency and type of wearing respiratory protection)".

MS. NOVICKI: Yes. Hold on a second. I got it.

DR. SCHENKER: Well, I don't know how to ask it, but is it possible to have something about smoke overdose or acute smoke exposure? In other words, you have frequency of smoke exposure, but if somebody needs to get first aid or be hospitalized or have significant smoke exposure that seems to be qualitatively different.

DR. LEMASTERS: Like number of times?

DR. SCHENKER: No. It currently asks frequency, but I'm getting at acute smoke overdose. I'm blocking on the right terms, but...

DR. BUNN: I think high intensity, right? High intensity exposure?

DR. LEMASTERS: High intensity/smoke?

DR. SCHENKER: Or maybe smoke exposure requiring first aid or something.

DR. LEMASTERS: Yes. Frequency of smoke exposure and smoke exposure requiring first aid, right there. Okay. I think that's a good addition.

DR. BUNN: Okay. Thank you, Marc. Do you have anything else, Marc, before I move on to Steve?

DR. SCHENKER: No.

DR. BUNN: Thank you. Steve, I know that you had also posted a comment to NIOSH. I didn't know if you wanted to go over that now and if you have any other additional questions or comments.

DR. LERMAN: Well, so I can do that, but I wanted to chime in on this first. I think first aid, what the definition of that is and what the threshold for that is, is very variable, and I would propose, instead, requiring evaluation in an emergency room or hospitalization as opposed to first aid. If you cough twice and if there's somebody there they might administer first aid, but an emergency room is a little bit more objective. Somebody thought you were sick enough or you thought you were sick enough to actually be taken off the scene and evaluated.

DR. LEMASTERS: Well, that would be extreme. Are we only concerned about extreme smoke exposure? I mean, coughing...

DR. LERMAN: So, I said if I understand Marc's concern correctly, then I would share that there is concern that, yes, that a significant—that, you know, that even a one-time bad enough exposure can have long-term consequences whereas you're concerned about relatively high ongoing periodic exposures or one massive exposure. Marc, am I mischaracterizing what you said?

DR. SCHENKER: No, you're exactly right. And, I think, I recall vaguely some study where this has been a significant predictor of the outcome was, and I don't remember exactly how it's quantifies, but it was extreme smoke exposure or smoke exposure requiring medical care or something to that effect. And I share your concern, first aid is ambiguous.

DR. LERMAN: So I think, at least, emergency, I mean, if you're in the emergency room and released I'm not even sure if that qualifies as extreme, but I think that would be, at least somewhat higher for it.

MR. MORRISON: This is Pat. On the fire ground that's exactly what would take place, extreme smoke inhalation, that would take place either a firefighter running out of air having to remove his respirator to get out. That would be cause to be transported to the emergency room for evaluation. It's not as commonplace, but that does happen. So what you're talking about is exactly being treated at the hospital for smoke inhalation or a high degree of smoke inhalation. It definitely does happen on the fire ground.

DR. LERMAN: You might take out "or hospitalization" and just make it emergency room evaluation?

DR. BUNN: All right. Thank you, Steve. Before we get into the discussion of the comments that you submitted to NIOSH, Steve, do we want you just following the agenda, take a 15-minute break, and then come back to the discussion of Recommendation number 3?

DR. LERMAN: Sure.

DR. BUNN: All right. Thanks, everyone. So we will reconvene at 3:15. Thank you.

DR. LERMAN: Do we call up again?

DR. BUNN: I'm just going to leave my phone on and mute it.

DR. LEMASTERS: So just to clarify, are we still working on Recommendation 3 when we come back?

DR. BUNN: Yes.

DR. LEMASTERS: Okay.

MS. NOVICKI: Okay. Thanks, everyone. We'll see you at 3:15, and we'll do another roll call.

DR. BUNN: Okay. Thank you.

[Break.]

DISCUSSION OF NFRS REPORT AND RECOMMENDATIONS

MS. NOVICKI: So to meet the FACA requirements we need to do a roll call and make sure that everyone is back so we meet quorum. So I'll just run through that quickly and if you could just tell me if you're present that would be great. So we'll start with our Chair Terry Bunn.

DR. BUNN: Present.

MS. NOVICKI: Thank you. Lauren Barton

DR. BARTON: Here.

MS. NOVICKI: Thank you. Cristina Demian. Cristina, are you back? Okay. Let's keep going and we'll come back. Mary Doyle.

MS. DOYLE: Present.

MS. NOVICKI: Thank you. Michael Foley.

MR. FOLEY: I'm here.

MS. NOVICKI: Thank you. Jessica Graham. Jessica, are you back online? Okay. Jessica's here in the chat. Steven Lerman.

DR. LERMAN: Present.

MS. NOVICKI: Thank you. Grace LeMasters.

DR. LEMASTERS: Present.

MS. NOVICKI: Thank you. Pat Morrison.

MR. MORRISON: Present.

MS. NOVICKI: Hello to someone's cat. Tiina Reponen.

DR. REPONEN: I'm present.

MS. NOVICKI: Robert Roy. Robert, are you back on the line? Okay. What about Judith Su?

DR. SU: Present.

MS. NOVICKI: Thank you. Okay. Let's go back to Cristina. Are you on the line yet? Okay. So even without Cristina and Roy, I count 10, so we still have quorum. So we can continue.

(Inaudible @ 00:02:48)

MS. NOVICKI: Yes?

MS. NOVICKI: Pauline, did you have a comment?

MS. BENJAMIN: Yes. I just wanted it to be noted that Tony Cox joined us late, but he is on the call.

MS. NOVICKI: Oh, great. Thank you.

MS. BENJAMIN: Okay.

MS. NOVICKI: Thank you so much. I appreciate that.

DR. SCHENKER: This is Marc Schenker. I'm on the call.

MS. NOVICKI: Okay, perfect. Thanks, Marc. Okay, what about Kyle Arnone? Still no. Okay.

DR. BUNN: Anyone else going—who has not said that they are present yet who is a member of the Board?

MS. NOVICKI: Okay. Well, we definitely have quorum. So I am going to turn it back over to you, Terry.

DR. BUNN: All right. Thank you, Emily. If you wouldn't mind putting Recommendation 3 back up for discussion. I wanted to bring it back to the members to see if—you now had 15 minutes to chew on this recommendation, so I was just wondering if there was any input into the content of this one. Okay. Well, I do see that there is no mention. I guess, my own question is this recommendation, is this applied to the whole cohort, the targeted cohort, the open cohort? I'm just wondering if we might want to add as to whose approach will be pilot-tested with.

DR. LEMASTERS: Well, the questions, themselves, will be on this for both cohorts, the open cohort and the targeted cohort, because they all will go to the web portal in order to answer the questions. So it's applied to everybody because the portal will be used by everyone, correct, Miriam?

DR. SIEGEL: That's correct.

DR. BUNN: Okay. All right. Thanks for the clarification. And then I see that most of that recommendation is geared towards protection or protection interventions as opposed to exposures. Question for the Board, do we want to clarify this recommendation to be specific towards protection or do you think that we need another recommendation, splitting out protection and exposures? I just wanted to receive feedback from everyone.

DR. LEMASTERS: Just speaking on behalf of the Subcommittee, we felt that the exposure question goes hand in hand with protective equipment or not using protective equipment. And so that's why the Subcommittee decided to include it as one recommendation rather than two, that it is about both the exposure and the protection because if you aren't using any protective equipment you're being more exposed. Does that answer your question?

DR. BUNN: Yes, yes. And thank you very much I guess, the last thing that I have is that a letter was forwarded to the NIOSH docket from the American College of Occupational Environmental Medicine, and they had a few questions within their letter, that this might be a good time to maybe address that. Also, might inform the wording or the content of this recommendation. So the first question they asked is if the era of fire service should be included—that it be included in the protocol to assess the effectiveness of intervention.

DR. LEMASTERS: So the era of fire service. Well, I guess, my response would be, and maybe Miriam or Kenny might have another response, would be that when we're collecting dates that they did different job positions, that really gets at being able, then, to look at in the analysis phase different eras. You see what I'm saying? That if you have the dates on the job then you can break out eras once you know when each firefighter was working. By definition dates will lead you to eras unless I'm interpreting the question wrong. I could very well be.

DR. BUNN: No, that answers the question in my mind anyway, so thank you.

DR. LEMASTERS: I think it's an analysis question, really.

DR. BUNN: Yeah, yeah. They also suggest that there is significant bias when participation is

voluntary, and I guess this pertains to the open court cohort. So they suggest that rather than using national cancer data that local or regional data be used to correct for original differences in cancer rates and types.

DR. LEMASTERS: Well, state data are being used, so that is regional. That would be my answer to that. State cancer registry data, correct, Miriam?

DR. SIEGEL: Yes. We'll be using state information.

DR. LEMASTERS: So they're not using national, only when the data are put together so you can access it much easier, but you can break it down by state. So that should not be a problem at all. That's not an issue as I see it. Anybody else?

DR. BUNN: Okay. And then the last couple of comments is, do you look at age as a firefighter when they began service and will the study follow the participants into retirement?

DR. LEMASTERS: Project team? Miriam?

DR. SIEGEL: Yeah, we're getting age. We're getting dates of different years of when things happened during their work history as well as their date of birth, so we can extrapolate age based on that information for a lot of the work history stuff. And we hope to get comprehensive work history for people no matter where they are in their career at enrollment, so that will include retired fire personnel that enroll. And we'll also be collecting information longitudinally. So for participants that remain engaged and participating in follow-up questionnaires, we hope to obtain future work information into retirement.

DR. LEMASTERS: All depends on how long the study is. National funds are provided, too. That's up to our government.

DR. BUNN: All right. Well, thank you very much. It sounds like based on your answers the content will not be changed for Recommendation number 3. So I wanted to give everyone a last chance to provide input into Recommendation 3.

MS. NOVICKI: Terry this is Emily. Did we get to Steve Lerman's comment? I think we didn't.

DR. BUNN: Oh, yes. Steve, sorry. Can we go back to the comment that you have submitted to NIOSH, if you would like to discuss that.

DR. LERMAN: Sure. If we're done with Recommendation number 3, I'm happy to talk about that. And, actually, if you don't mind, one other comment that occurred to me as we were having this discussion that isn't directly in one of the recommendations, but was discussed. So let me do that one first because I think it's simpler. There was some discussion, I don't think it formed a recommendation, about how much detail should go into the lifestyle questions, as the smoking and the drinking, and so on. I think that was something less than a recommendation, so it doesn't need a vote. But, one, because we're trying to keep the questionnaire to 30 minutes or less and, two, because this sort of information is notoriously the more detail you ask, the less reliable it is. I would make them pretty simple like for smoking currently past or never, not try to get down to pack years and something similar to that for alcohol, do you drink more than seven drinks a week or something along those lines, not try to get too detailed there because you won't get good

information and could make the questionnaire much longer. So I don't remember exactly where that fit in, but I know we had that discussion, and that would be input on that.

But the larger issue, in my mind, at least is that it wasn't clear to me, and it may just be that I didn't understand the protocol completely, is how the open cohort is going to be analyzed. And you acknowledge selection bias. I think there's also, potentially, a lot of recall bias since you're not going to be validating, I think, most of the open cohort exposure data with fire department records, whereas in the targeted cohort you will. So for those reasons I think you have to be really careful on what you try to do in the analysis of these. So, for instance, I think, in my view, with the open cohort it should probably be strictly a prospective cohort and you shouldn't, retrospectively, accept, possibly, to use it as an exclusion criteria, actually, for further analysis. If someone had cancer in the past they say, well, I'm going to have cancer in the future. For whatever variety of reasons, it could be a recurrence, they could be prone to it, it could be because of the same exposure that caused the past going forward. But that's only one of several possibilities. And if you don't make an exclusion criteria, certainly make it a factor in the analysis. So, anyway, so those are my thoughts and there's partly a question there, what are you planning to do in part, and if those sorts of issues aren't being addressed then it turns into a recommendation, and I'll stop.

DR. SIEGEL: Would you like NIOSH to respond?

DR. LERMAN: Please.

DR. SIEGEL: So, yeah, we share your concerns related to different biases affecting the open cohort, and we do recognize that will be less of a problem for the targeted cohort which is why the targeted cohort is our prospective cohort that we'll be using to calculate cancer incidence rates. We realize that it's not feasible to do this with the open cohort because of those biases. We do feel that the open cohort can be used for a lot of descriptive and hypothesis generating analyses or those cross-sectional in nature, not necessarily related to cancer risk, particularly, incidence rate, but to get a good idea of practices in the fire service in general. And one of the very first steps we'll be taking, once we get to the analysis stage, is comparing the two cohorts to understand the degree of potential selection bias among the open cohort.

DR. LERMAN: Thank you. In that case I think that you—I think you're addressing my concerns before I raised them, so I don't think there needs to be a recommendation there.

DR. SIEGEL: Thank you.

DR. BUNN: Any other comments or suggestions regarding any of the three recommendations or for the protocol itself?

DR. SCHENKER: I have some comments on the risk factor issue, and I slightly disagree with Steve. I think that you need to prioritize the important risk factors for the cancers of concern. And I would be uncomfortable with just cigarette smoking as ever, never

X. I mean, it's such a potent risk factor, particularly, for the smoke exposure cancers that I would prioritize my effort in that as opposed to strength testing or sleep or stress or some of these things which are less well established and less significant.

I mean, that brings me to my other point which is, and I'm sorry if I've missed this, but does NIOSH have its a priori cancers of concern? Because I think those are important to identify prior to the data analysis. And, similarly, cancers which would have no exposure, no risk with firefighting and could be used as controls to look at them in relationship to exposure in the two cohorts.

So my two points are, one, to prioritize the other risk factors to those of most risk for the cancers of concern. And, second, to spell out the a priori cancers of concern versus those which have no potential exposure association with firefighter exposures.

DR. BUNN: Thank you, Marc. So do you think that we need to amend this recommendation, develop a new recommendation, just add it to the report, or what would you recommend?

DR. SCHENKER: I think it could go into the text where you talk about identifying risk factors. I mean, obviously, it's ultimately the questionnaire creator's decision in what to put in and I don't think we can wordsmith that, but it's a balancing act and I think it would be deficient if we didn't recommend adequate data on known risk factors. Maybe we can just clarify a little in that paragraph on assessing cancer outcomes and identifying risk factors. I don't know it needs to be another recommendation.

DR. BUNN: Okay. Emily, would you mind going to that paragraph, please? Where do you think it should be submitted, Marc…?

DR. SCHENKER: Well, sleep and stress might be added. I don't know what that's about, to be honest with you. It sounds like somebody's pet risk factors. Somehow we could add in the questionnaire should prioritize exposure to no risk factors for cancers of interest of a priori cancers of interest.

DR. LEMASTERS: There are, Marc, if you recall, many cancers of interest because the various studies have shown, including NIOSH's study and my study, that because of, I think, because of the multitude of exposures that the firefighters have to agents, all kinds of agents, it's just not one exposure, that what has come out is that there are many cancers that the firefighters are exposed to. And there may be some top ones, but once you get into risk factors by cancer there's probably six to eight cancers that we have concerns about here.

DR. SCHENKER: Well, I think that filling out those—

DR. LEMASTERS: So it's hard to drill down that list a bit, if you see what I'm saying.

DR. SCHENKER: Yeah. No, and I think that's an important process and the reason for the study, or one reason. I'm just a little concerned that this becomes an open-ended sleep and stress. Are you really going to have enough information to use that in any analysis?

DR. LEMASTERS: I'm sorry, I can hardly hear you. All of a sudden you've — can everybody else hear Marc. I can't.

(Inaudible @ 00:24:16)

DR. SCHENKER: I'm not sure what I have to do to…I have to come back.

DR. LEMASTERS: Okay. Okay. I got you. You're back. I think it was me, not you. So you're suggesting that that paragraph might be changed to selective risk factors depending upon the cancers of primary interest?

DR. SCHENKER: Something like that, yeah. Prioritize the information on risk factors for cancers of interest instead of...

DR. LEMASTERS: Okay.

DR. LERMAN: So, Marc, as others just said, it's not quite so straightforward. If breast and prostate cancer are on the list of cancers of concern, I think at least breast cancer is, shift work is likely a risk factor, and firefighters do shift work. And so, that is a sleep connection. I don't think it's as far-fetched as, perhaps, you implied or think.

DR. SCHENKER: Yeah. No, I mean, it's a challenge, and then you put in keep the questionnaire to a half an hour, and it's a rock and a hard place.

DR. LERMAN: Yeah. You're right. There's no straightforward answer. And I'm not dead set on it, but that's why I suggested keep the environmental, the personal factors relatively simple, but I hear it, but I don't disagree with you that smoking is important and knowing the difference between three packs a day and the occasional cigarette. So it's hard.

DR. LEMASTERS: Well, are we comfortable, then, of saying the survey should prioritize risk factors for select cancers for primary cancers of interest?

DR. LERMAN: Or a priori or primary, yeah. Primary would be fine.

DR. SCHENKER: One of the challenges is having a little information about a risk factor. So have you ever used a tanning lotion or tanning device, and then you don't know anything more about it. And it's almost a liability because you don't have any dose response, you don't know how to fit it in.

DR. LEMASTERS: I think the concern was skin cancers.

DR. SCHENKER: Sure. No, I understand. I'm just...

DR. LEMASTERS: Yeah, I don't know how many people...

DR. SCHENKER: I'm just... You know, one option...

DR. LEMASTERS: You don't have... Well, if you don't have a lot of people exposed to tanning beds then there's hardly any reason to ask the question. But I bet a lot of the firefighters are exposed to sun.

DR. SCHENKER: Yeah.

DR. LEMASTERS: What about sunscreen, right? I mean, at least their face, neck.

DR. SCHENKER: Well, things where you can't quantify it, like alcohol use and tobacco, I would say those are known risk factors and if the answer is yes then there should be some kind of quantification. Other things I'm a little less clear about like strength testing and stress, and sleep deprivation.

DR. LEMASTERS: Well, the issue about sleep and stress was brought up by the Subcommittee members who are on the fire service. So I think they felt that chronic sleep and stress, you know, it can have all kinds of chemical effects. So (inaudible @ 00:29:13). I don't know. So just to wrap this up, are you okay with how the question says the survey should prioritize risk factors for primary cancers of interest? Can you live with that? Is that good?

DR. SCHENKER: Yeah. Yeah, I think that's good.

DR. LEMASTERS: Okay. Then we can move on.

DR. BUNN: Okay. So are there any last questions and comments before we recommend to vote on the report and the recommendations? Marc, you still have your hand raised. Do you have another question or...

DR. SCHENKER: It's down.

DR. BUNN: All right. I guess we have a couple of different choices. We can either vote to accept the report as it is with the recommendations included or we can vote on each recommendation itself. I guess I would request input from the members to see how they would like to vote.

DR. LEMASTERS: Well, personally, I think we can, given that we've gone over each recommendation separately and we've reviewed the protocol page by page, I feel comfortable with voting to accept the proposal as written and the recommendation as one body. Anybody else have any other ideas?

DR. COX: This is Tony, and I think that's an excellent suggestion.

DR. LEMASTERS: Any disagreements?

DR. SCHENKER: So moved.

DR. BUNN: So we will vote. Emily, can you kind of explain to us the process for virtual voting, whether everyone needs to raise their hand, so that we can count the votes or what is the process since this is a virtual meeting?

MS. NOVICKI: Yeah. So, for sure, we need to come up with a motion. I'll type it up on screen so everyone can see what it is that they're voting on. And so the motion might be something like we move to accept this report with the track changes below, and these are all the things that we've talked about today. So we agree on a motion, then we need someone to do the first one and then we need a second. And then we'll go person by person and do a yea or a nay, verbally.

DR. BUNN: Okay. Okay. Thank you. All right.

MS. NOVICKI: We need a motion.

DR. BUNN: So do we have a motion to accept the report as it is right now with the amended recommendations and to vote for the document as one entire whole document?

DR. SCHENKER: (Inaudible @ 00:32:51) so moved.

DR. BUNN: Do we have a second?

DR. BARTON: Second, Lauren Barton.

DR. BUNN: Thank you, Lauren. All right. So now we will move to vote. And I believe, Emily, will you be going one by one or do I or...

MS. NOVICKI: Yeah. So I'll go through as DFO and just like we did roll call, I'll just need a yea or a nay on the motion. Okay. So, Terry, we'll start with you.
DR. BUNN: I vote to accept the report as written with the amended recommendations as one whole document.
MS. NOVICKI: Okay, great. All right. That's a yes. All right. Lauren Barton.
DR. BARTON: Yea.
MS. NOVICKI: Thank you. Tony Cox.
DR. COX: Yea.
MS. NOVICKI: Thank you. Cristina Demian.
DR. DEMIAN: Yea.
MS. NOVICKI: Thank you. Mary Doyle.
MS. DOYLE: Yea.
MS. NOVICKI: Michael Foley.
MR. FOLEY: Yes.
MS. NOVICKI: Jessica Graham.
DR. GRAHAM: Yea.
MS. NOVICKI: Steve Lerman.
DR. LERMAN: Yea.
MS. NOVICKI: Grace LeMasters.
DR. LEMASTERS: Yea.
MS. NOVICKI: Patrick Morrison.
MR. MORRISON: Yea.
MS. NOVICKI: Tiina Reponen.
DR. REPONEN: Yea.
MS. NOVICKI: Robert Roy. Are you on mute, Robert? Okay. Let's just move on to Marc Schenker.
DR. SCHENKER: Yea.
MS. NOVICKI: And Judith Su.
DR. SU: Yea.
MS. NOVICKI: Okay. One last time. Robert Roy. I can't see the chat, if he's typed anything in.
DR. MIDDENDORF: No, he hasn't typed anything in.
MS. NOVICKI: Okay. Well, I believe the motion still passes. We have a unanimous vote, so I think we're good on that. Thank you, all.
DR. BUNN: Yeah, and I just want to really thank all of the Subcommittee for their hard work on the preparation of this report and the recommendations, and especially the co-Chairs, Grace and Pat, thanks for all your hard work into this report itself.
DR. LEMASTERS: Our pleasure. Thank you.
DR. BUNN: Okay. So, I guess, the next—which we've already done that. As far as the summary goes, well, we now have an approved report that will be submitted to Dr. Howard for his review and approval, I believe. And then I'm not sure, I would assume, that this just moves on to the implementation phase, then, once it's

approved and reviewed by Dr. Howard?

MS. NOVICKI: Yes, yes. So this will go on to Dr. Howard and the program, and then they will, as they continue on, decide which of these recommendations and suggestions that they're going to adopt. And so, this is kind of the end of our work on this for the moment, and I'm sure we'll be hearing updates along the way, but we can consider this particular task completed. So job well done, everyone. Thank you.

DR. BUNN: Thank you very much. And our next meeting will be at the end of September where maybe the co-chairs might provide us an update on where you are in the implementation process for the document. Does everyone have the next meeting on their calendars?

DR. LEMASTERS: I just want to comment. Once this goes to Dr. Howard then it goes back to the program, and we don't have any knowledge of really what's happening at that point until our next meeting which isn't for a year.

DR. BUNN: Oh, okay. Thank you very much for clarification on that, Grace.

DR. MIDDENDORF: It would be possible to add a short update to the upcoming meeting, if the BSC would like that.

DR. LEMASTERS: From NIOSH?

DR. MIDDENDORF: Yes, from NIOSH, from the program team.

WOMAN @ 00:38:13: Yes, I think that...

DR. LEMASTERS: Well, I think that would be nice.

Dr. LERMAN: You mentioned end of September meeting. I don't seem to have it on my calendar. Could a updated meeting notice go out or could I get a another copy of it, if I just lost it?

DR. BUNN: I believe that...

MS. NOVICKI: Yes.

DR. BUNN: ...Pauline sent the invitation, but I have it on my calendar on September 29th from 11 a.m. to 4:15 p.m. That's Eastern Daylight Time.

MS. NOVICKI: Who was that that needed the invitation?

DR. BUNN: I think Pauline usually sends those invitations.

DR. LEMASTERS: I don't have it at 11 a.m.

MS. BENJAMIN: This is Pauline. I sent an e-mail, but not a calendar invite.

MS. NOVICKI: Yeah. This is Emily. I did send a calendar invite. It's starting at 11 a.m. Eastern. Depending on your time zone it might have a different start time.

DR. LEMASTERS: Okay. 11 a.m. Till when?

MS. NOVICKI: 4:15 p.m. Eastern.

DR. BUNN: 4:15 p.m.

DR. LEMASTERS: Okay. Thank you.

DR. BUNN: If you did not receive the invitation could you let Emily know or me know, and then we'll make sure that you receive that? Okay. Are there any other questions or comments before we close this meeting?

DR. FENT: This is Kenny Fent. I just want to thank the NFRS and the BSC for all your

feedback and advice. It will really make a difference and make the registry so much stronger. So we really appreciate the time and effort that you put into it.

DR. BUNN: Well, thank you. Yes. And I neglected to mention the internal NIOSH project team in addition to the co-chairs and the Subcommittee. So thank you for all your hard work. And I can see a lot of hard work in establishing the registry. So kudos to NIOSH on that.

DR. SIEGEL: Thank you.

DR. BUNN: All right. Well, if there are no more comments or questions then I guess the meeting is ended. Thank you, everyone.

[Adjourn.]

GLOSSARY

AOC	Assurance of Confidentiality
BSC	Board of Scientific Counselors
CDC	Centers for Disease Control and Prevention
DFO	Designated Federal Officer
DFSE	Division of Field Studies and Engineering
FACA	Federal Advisory Committee Act
FDID	Fire Department Identification
HHS	US Department of Health and Human Services
IAWF	International Association of Wildland Fire
IRB	Institutional Review Board
NAACCR	North American Association of Central Cancer Registries
NFIRS	National Fire Incident Reporting System
NFPA	National Fire Protection Association
NFR	National Firefighter Registry
NIOSH	National Institute for Occupational Safety and Health
NVFC	National Volunteer Fire Council
PPE	Personal protective equipment
SOP	Standard operating procedures
USFA	United States Fire Administration

Certification Statement

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the August 4, 2020, meeting of the NIOSH Board of Scientific Counselors, CDC are accurate and complete.

_____08/28/20____ _____Terry Bunn_____

Date Terry L. Bunn, Ph.D.

Chair, NIOSH Board of Scientific Counselors