Attachment 5 – Adult informed consent for in-person (5a) and virtual (5b) focus groups

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Road
Hyattsville, Maryland 20782

Attachment 5a: Adult informed consent for in-person focus groups

Adult Informed Consent Form for In-Person Focus Group Participation

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to sign this form.

- **Purpose of the Research**

The National Center for Health Statistics (NCHS) uses surveys and other tools to collect information on the health and wellbeing of Americans. Findings from these surveys and other research efforts help to develop programs to improve the health and health care of people living in the United States.

One important aspect of the work at NCHS is understanding the use of new diabetes medications known as GLP-1 receptor agonists (GLP-1 RAs) and how the public understands and thinks about these medications and potential barriers to their use. If you agree to take part in this test, we will ask you to participate in a focus group where you and others will discuss how you understand and talk about topics related to new diabetes medications including awareness, perceptions and stigma, clinician advice and use, and affordability and access. This focus group will give us insight into peoples' experiences and understandings of new diabetes medications and the appropriate language to use in developing survey questions about them.

Procedures

A member of the CCQDER research team, either a staff member or a contracted interviewer from Research Support Services (RSS), will lead you and a group of other participants in a discussion. A variety of topics will be covered, and the facilitator will do his or her best to make sure everyone in the group has an equal opportunity to contribute to the discussion.

The focus group will last no more than 90 minutes, and we will give you $100. You will also be asked to fill out a personal information sheet. The information sheet will be stored on a secure server and only NCHS researchers (and NCHS contractors) working on the study will have access to it. Your information will be kept for up to 5 years and you can decide at any time to be removed from our database. Email recruitmentteam@cdc.gov to request removal.

You may choose not to participate in any section of the focus group for any reason. If you do not want to answer a question the facilitator poses, say so, and they will move on to the next participant or question. You may also stop participating at any time.

While the focus group is going on, NCHS researchers and contractors who are working on the project may watch or listen to the focus group.

If you have questions about how the project works, contact CCQDER by email at recruitmentteam@cdc.gov.

Recordings

We would like to audio and video record this focus group. The recording allows us to more carefully study and improve future survey questions. At the bottom of this form, you will be asked if you are willing to have the focus group recorded. If you agree, you may still ask to stop the recording at any time, and we will turn off the machine. If you decide to stop

recording, we will ask your consent to retain the portion already recorded. When the focus group is finished, you may watch/listen to the recording.

If you agree to record the focus group, we will keep it in a locked room either in a secure storage cabinet or on a password-secured computer that is not connected to the internet. Only researchers from the CCQDER, RSS contractors, National Center for Chronic Disease Prevention and Health Promotion/Division of Diabetes Translation (NCCDPHP/DDT) and NCHS's Division of Research and Methodology (DRM) will be allowed to watch the video recording in a secured room. When in use all recordings will be in the safe keeping of a staff person from the CCQDER. In accordance with the CCQDER Data Storage and Access Policy, upon project completion, the video of the focus group will be destroyed. Audio recordings will be retained for a minimum of 5 years and may be used for question evaluation research that is not directly related to this project.

You may decide at any time after the focus group that you don't want us to keep a recording of the focus group. In this case, you may contact CCQDER by email at recruitmentteam@cdc.gov. When we receive your request, the recording of your focus group will be immediately destroyed.

Privacy

We are required by law[1] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

Video recordings are stored on CCQDER's Local Area Network (LAN), not connected to the internet, and located in a locked room that only CCQDER staff can access. All recordings are labeled by a code number, date, time, and project title. The recording is never labeled with your name or other personal facts.

Materials with personal facts (such as names or addresses) are also stored on a password secure server and will be kept up to five years in a locked room. Only CCQDER staff has access to this material. Any hardcopies of these materials will be destroyed upon completion of the focus group. Project related information will be stored in our database for up to five years, located on password protected and secure server. You may decide at any time after the focus group that you don't want us to keep your information. In this case, you may contact CCQDER by email at recruitmentteam@cdc.gov to request removal. When CCQDER receives your request, your personal information and recording of the focus group will be immediately destroyed.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project or those viewing the video recording, however, may recognize you or your voice.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

- **Benefits and Risks**

There are no direct benefits to you from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the focus group. You may also stop at any time and still receive the full $100. For you to take part in the study today, we agreed to meet at this location. We will protect any materials that contain your personal information and transport them to the National Center for Health Statistics.

Attachment 5 – Adult informed consent for in-person (5a) and virtual (5b) focus groups

If you have any questions about this study, please call the office of the Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Project ID-XX [Note: The project ID will be inserted into the form once CDC IRB approval has been received]. Your call will be returned as soon as possible.

Please Read and Sign Below if You Agree

- I freely choose to take part in this research study.

I allow NCHS to video record my focus group . I also allow NCHS to play my video recording to researchers from NCHS, DRM, NCCDPHP/DDT, and NCHS contractors working on this project on-site at NCHS CCQDER.

°Yes ° No

IF YES:
I allow NCHS to retain my video recording for future research on how people think about and understand new diabetes medications; peoples' experiences with these drugs; and words that can be used to write new survey questions and response choices about them. I also allow NCHS to play my video recording to internal NCHS CCQDER staff. I understand that the recording of my focus group will be kept for as long as it is of interest to researchers for a minimum of 5 years.

° Yes ° No

_____	_____	_____
Respondent Signature	**Print Name**	**Date**

[1]The Public Health Service Act provides us with the authority to do this research (42 U.S.C 242k). We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) and the Confidential Information Protection and Statistical Efficiency Act or CIPSEA (44 U.S.C. 3561-3583). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition to the above cited laws, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015 (6 U.S.C. §§ 151 and 151 note) which protects Federal information systems from cybersecurity risks by screening their networks.

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Attachment 5 – Adult informed consent for in-person (5a) and virtual (5b) focus groups

Attachment 5b: Adult informed consent for virtual focus groups

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Adult Informed Consent Form for Focus Group Participation

You are being asked to take part in a research study. This consent form tells you about the study and what you will be asked to do. You can choose to take part in the study or not. If you choose to take part, you will need to read this entire form.

- **Purpose of the Research**

The National Center for Health Statistics (NCHS) uses surveys and other tools to collect information on the health and wellbeing of Americans. Findings from these surveys and other research efforts help to develop programs to improve the health and health care of people living in the United States.

- One important aspect of the work at NCHS is understanding the use of new diabetes medications known as GLP-1 receptor agonists (GLP-1 RAs) and how the public understands and thinks about these medications and potential barriers to their use. If you agree to take part in this study, we will ask you to participate in a focus group where you and others will discuss how you understand and talk about topics related to new diabetes medications including awareness, perceptions and stigma, clinician advice and use, and affordability and access. This focus group will give us insight into peoples' experiences and understandings of new diabetes medications and the appropriate language to use in developing survey questions about them.

- **Procedures**

This focus group will be conducted virtually through videoconferencing software. NCHS secures all information we collect, process and store on our systems as required by Federal regulations, Executive Orders, and NCHS confidentiality statutes. However, NCHS cannot secure and protect your personal computing devices, such as personal computer or smart phones, used to complete the NCHS focus group. During the focus group, a member of the CCQDER research team, either a staff interviewer or a contracted interviewer from Research Support Services (RSS) who works on this project, will ask you some questions.
The focus group will last no more than 90 minutes, and we will email you the link to your [$100 electronic gift card]. You will also be asked demographic questions from a personal information sheet.

You may find that some of the questions we are testing are sensitive. You may choose not to answer any question for any reason. If you do not want to answer a question, say so, and we will move on to the next one. You may also stop participating in the focus group at any time.

If you have questions about how the project works, contact CCQDER by email at recruitmentteam@cdc.gov.

- **Recordings**

We would like to audio and video record your focus group. The recording allows us to more carefully study and improve the questions. If you agree, you may still ask to stop the recording at any time, and we will stop recording. If you decide to stop recording, we will ask your consent to retain the portion already recorded.

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We will keep the recording of your focus group in a locked room either in a secure storage cabinet or on a password-secured computer. Only researchers assigned to this project from the CCQDER, RSS contractors, National Center for Chronic Disease Prevention and Health Promotion/Division of Diabetes Translation (NCCDPHP/DDT) and NCHS's Division of Research and Methodology (DRM) will be allowed to watch the recording in a secure room. When in use all recordings will be in the safe keeping of a staff person from the CCQDER. In accordance with the CCQDER Data Storage and Access Policy, upon project completion, the video of the focus group will be destroyed. Audio recordings will be retained for a minimum of 5 years and may be used for question evaluation research that is not directly related to this project.

You may decide at any time after the focus group that you don't want us to keep a recording of the focus group . In this case, you may contact CCQDER by email at recruitmentteam@cdc.gov. When we receive your request, the recording of your focus group will be immediately destroyed.

- **Privacy**

We are required by law[1] to tell you what we will do with the recording. We must also tell you how we will protect your privacy.

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Materials with personal facts (such as names or addresses) are also stored in a locked room or password protected. Only CCQDER staff has access to this material.

Your name or other personal facts that would identify you will not be used when we discuss or write about this study. People working on this project or those viewing the audiovisual recording or audio recording, however, may recognize you or your voice.

If you have questions about National Center for Health Statistics privacy' laws and practices, contact the NCHS Confidentiality Office by phone at 888-642-4159 or 301-458-4601, or by email at nchsconfidentiality@cdc.gov.

- **Benefits and Risks**

There are no direct benefits to you from taking part in this study.

The possible risks of taking part in this study are minimal. We will take all possible steps to protect your privacy. You do not have to give us any information that you do not want to, and you can choose not to answer any question in the focus group. You may also stop at any time and still receive the full [$100]. NCHS secures all information we collect, process and store on our systems as required by Federal regulations, Executive Orders, and NCHS confidentiality statutes. However, NCHS cannot secure and protect your personal computing devices, such as personal computer or smart phones, used to complete the NCHS focus group.

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