



INSTRUCTIONS FOR THE CSCC DRIED BLOOD SPOT COMPLETION (DBS) FORM

I. General Instructions

The DBS form is used to record essential information related to participant recruitment and sample tracking. CSCC will provide a list of ARIC participants deemed initially eligible for recruitment, that is, excluding those who have withdrawn, are not included in follow-up calls any longer, or have known cognitive impairment. Field Center (FC) staff must complete at least part of the form in CDART for each participant on the CSCC list, updating the form as they obtain information.

If FC staff are certain an ARIC participant on the CSCC list would not be able to do the DBS collection, they should not attempt recruitment and record ineligibility as described below. For everyone else on the list, FC staff will perform multiple attempts to reach the participant by telephone, recruit them using the DBS script, and obtain consent.

If a participant initially is not interested in taking part in the Dried Blood Spot study, and then later decides to participate, simply update the existing DBS record with the new information, as though they were being recruited for the first time. There is no need to track this change of mind.

When multiple kits are being sent to a single household, it is imperative that the kits be marked in some way to clearly indicate which kit is assigned to which participant to ensure each individual completes the correct kit.

See page 4 for Instructions for the DBS Recruitment in the clinic at Visit 9.

II. Detailed Instructions for Each Item

0a. Enter the date on which the interviewer reads recruitment script, or else the date when the interviewer deems the participant ineligible or unable to be contacted. Enter the date using either the calendar function or by keying the date with MM/DD/YYYY format. Leading zeroes are not necessary in CDART but are acceptable.

0b. Enter the code number of the interviewer who initially started the DBS form in the boxes provided.

RECRUITMENT

0c. If the interviewer administered the recruitment script, record yes and continue on to 0d. If the interviewer deemed the participant ineligible prior to telephoning, never reached the participant after multiple attempts, or otherwise never read the script, record no and SAVE AND CLOSE the form.

0d. If the participant gave DBS consent, record yes and proceed to 0e. Otherwise, record no and SAVE AND CLOSE the form.

0e. If the participant consented, but the interviewer subsequently believes the participant could

not do the DBS, record yes and SAVE AND CLOSE the form. If the interviewer does not have this concern, proceed to 1.

THE FOLLOWING GRID SHOWS HOW TO COMPLETE QUESTIONS 0c, 0d, AND 0e FOR DIFFERENT SCENARIOS.

0c: Script	0d: Consent	0e: Concern	Status
Y	Y	N	Consented
Y	N		Declined
Y	Y	Y	Ineligible
N			Not Contacted
Y	Y	[blank]	Other

VACCINATION

Interviewers should ask the vaccination questions of consented participants using the DBS script, using the following instructions, and enter the answers here.

1. Using the script, ask the participant if they have received a vaccination for COVID-19. If a prompt is required, you may state that the vaccination is for SARS-CoV-2 or the novel coronavirus. Proceed to question 2 if YES. Otherwise, questions 2-4 will not be asked and be skipped in CDART.

2. Ask when the participant was last vaccinated for COVID-19. If the participant has received more than one dose, you may need to clarify that we are seeking the last (i.e., most recent) date. Ideally, it is important to get the exact date but realistically, if participants don't remember, probe for the approximate date or time of the month (e.g., early in the month, at/near the beginning of the month, late/late in the month, at/near the end of the month, around the middle of the month, etc.). Using relevant holidays if applicable might be useful (before or after Valentine's Day, St. Patrick's Day, Passover, Easter, Mother's Day, Memorial Day, Independence Day). If the participant reports being vaccinated early in the month, record the date using the 1st day of the appropriate month (e.g., a participant says they were last vaccinated in early February 2021, but they are unsure of the exact date, record February 1, 2021). If they were last vaccinated late in the month, record the date using the 30th day of the month. For February, use the 28th day. If the participant says they were last vaccinated around the middle of the month, record the date using the 15th day of the month. In these cases, always use either the 1st, 15th, or 30th (28th for February) day of the month. If the participant reports the month, but they cannot narrow it down at all (i.e., early, late, or middle of the month), record the date using the 15th day of the appropriate month.

In all cases, ensure a complete date is recorded. Do not enter a partial date.

For reference, COVID-19 vaccines and their corresponding number of doses is included:

COVID-19 Vaccine	# of Doses
Moderna*	2 doses

Pfizer*	2 doses
AstraZeneca	2 doses
Janssen (Johnson & Johnson)	1 dose
Novavax	2 doses

**Approved for use in the United States; table revised 2/26/2021*

3. Ask which vaccine they received. First allow them to respond without prompting. If they don't recall, read the names of all vaccines as a prompt. If the participant still does not know, selected unknown. If "other", probe for vaccine name and record the response.

4. If they respond yes to question 1 (received a vaccine), ask how many doses they have received. This might have been indirectly answered in question 2.

COMPLETION

After consent, FC staff send DBS kits to participants and help participants, as needed, to collect the DBS. FC staff complete the remaining questions if, and as soon as, the information is available.

If a replacement kit is sent to the participant, because the initial one was lost, then create a new occurrence of the form to track the new kit with its new C4R DBS ID number. This is expected to happen very rarely. The form will allow 2 occurrences. It is not recommended to send more than 2 kits to a single participant.

5. Scan (or carefully record) the C4R DBS ID from the DBS kit assigned to this consented participant. It is **imperative** that the C4R DBS ID that is scanned into this field is the kit that gets mailed to the participant.

6. Record the date the DBS kit was mailed (or taken) to the participant.

7. If applicable, record additional participant interactions your field center wants to keep track of by answering yes to 7 and completing 8-10 as needed. For instance, this may include documenting a participant's decision to withdraw from the study after receiving a DBS kit. If this occurs, FC staff should answer yes to 7, complete items 8-8c3, and for item 8c3a mention in the note log "changed mind, now refusing". If the field center has no interactions they want to track, answer no to 7 and skip to 11.

11. If the participant mails the kit themselves, 11 will remain unanswered. If the field center mails the kit, enter the date mailed.

12. If the lab provides information to the FC about the date the lab received the kit, the FC may record the date here if they wish. Otherwise, this can remain blank.

13. Enter the date the results letter is mailed. **This step is key to closing the loop in results reporting.**

INSTRUCTIONS FOR DBS RECRUITMENT IN THE CLINIC AT VISIT 9

Starting June 1, select participants who have not already mailed a DBS kit to the lab and come in for the clinic visit can be approached and asked if they would like to participate in the C4R Dried Blood Spot protocol. These select participants fall into one of five categories:

- A) Have not yet been contacted for DBS and therefore do not have a DBS Tracking Form in CDART.
- B) Have a DBS Tracking form in CDART, but have a status of 'Not Contacted', as indicated by a response of 'N' to item DBS0c.
- C) Have been contacted for DBS, and consented for DBS over the phone, but have not yet collected the sample and mailed it to the VT lab. These will be indicated initially by responses of 'Y' to DBS0c, 'Y' to DBS0d and 'N' to DBS0e. Further, these participants must be asked if they mailed their card in yet. Those who say no are considered for participation at the clinic visit.
- D) Declined the DBS by telephone, as indicated by a response of 'N' to item DBS0d. (They may now be willing since they do not need to prick their finger and mail in the kit themselves.) These participants can be gently asked if they would like to now take part. Those who say 'Yes' are considered for participation at the clinic visit.
- E) Had a DBS Results Letter with either 'Indeterminate', 'Invalid' or 'Test Canceled' results and want to try again.

For those considered still eligible for recruitment to DBS, follow the recruitment script on page 5. For those participants who consent, the contact status, vaccination status and most importantly the new C4R DBS Biospecimen ID will need to be recorded in CDART, according to these instructions:

- A) For participants in category A above, **create** the first occurrence of the DBS form in CDART.
- B) For participants in category B above, **update** the existing first occurrence of the DBS form in CDART.
- C) For participants in category C above, **create a new second** occurrence of the DBS form in CDART.
- D) For participants in category D above, **update** the existing first occurrence of the DBS form in CDART.
- E) For participants in category E above, **create a new second** occurrence of the DBS form in CDART.

ARIC Phlebotomists: For instructions on how to collect the blood spots, please read on.

Trained phlebotomists should know what to do by reviewing the slides shared previously and the YouTube video starting at 21:53 at <https://www.youtube.com/watch?v=EqrWv8b8OgA>

Additional DBS cards and mailers should be ordered from the lab for the purpose of in-clinic collection, so as not to waste materials.

ARIC-C4R (COVID-19) Clinic Dried Blood Spot Recruitment Script

Instructions: First determine whether the participant falls into one of the categories A to D above. If so, after the main Visit 9 consent, please read the following script to ask the participant if they would be willing to participate in the C4R blood collection in clinic for testing of past exposure to SARS-CoV-2, the virus that causes COVID-19. If they agree, please obtain verbal consent.

"As part of your participation in the ARIC study, you have the opportunity to participate in a national research study to help us understand the health of study participants during the COVID-19 pandemic and to understand the relation of COVID-19 to cardiovascular disease. To do this, we ask if you would be willing to have us take a few drops of the blood from the tubes we will draw today for testing for antibodies to the virus that causes COVID-19. We may have invited you over the phone to prick your finger and mail a drop of blood in, and you may or may not have been interested at that time. Because taking the blood from the tubes we will draw today makes the process simple, we wonder if you would consider taking part now.

Antibodies provide information about whether you have ever had COVID-19 in the past. We will mail you the results of the antibody testing along with other visit results.

Please be aware that we will keep the dried blood spots indefinitely for use in approved research, and that you are donating the blood sample and will not own the sample or data or benefit financially from any future research.

Taking part in this blood spot collection is entirely voluntary and your decision to take part or not would not otherwise affect your ongoing participation in ARIC. Do you have any questions about what ARIC is inviting you to do?"

If Yes - > [Answer any questions following the Q*Q (refer to PI if necessary) then proceed to next item.]

If No - > [Proceed to next item.]

"I now would like to ask, then, do you **consent** to letting us to take a few drops of blood for this, or do you not want to take part?"

If Yes - > "Great! Thank you."

If No - > "Thank you for considering it."

ARIC-C4R (COVID-19) Finger-prick Blood Collection (Dried Blood Spot) Recruitment Script

Instructions: Please read the following text to the participant to ask if they would be willing to participate in the C4R finger-prick blood collection (dried blood spots) at home for testing of past exposure to SARS-CoV-2, the virus that causes COVID-19. If they agree, please obtain consent, send a collection kit via mail and schedule a time to guide them through the procedure if necessary.

[If participant is already on the phone for other reasons, skip to the appropriate next step, below] "Hello, my name is [interviewer name]. I'm calling from [institution name's ARIC Study, to speak with [participant name]. Is [participant name] available?"

If no -> "When would it be convenient to call back?
_____ Thank you, I will call again."

If yes -> "Hello, [participant name], this is [interviewer name] with the ARIC Study. You are used to hearing from us about once a year to talk about your cardiovascular health, but today I am calling about a new ARIC request that has to do with Coronavirus Disease (COVID-19). Do you have a few minutes to speak on the phone?"

If no -> "May I call you at a later date to provide you with information about the study on COVID-19?"

If yes - > "When would it be convenient to call back?
_____ Thank you. I will call again."

If no - > "Thank you for your time. We appreciate your participation in the ARIC Study!"

If yes - > "Great! As part of your longstanding participation in the ARIC study, you have the opportunity to participate in a national research study to help us understand the health of study participants during the COVID-19 pandemic and to understand the relation of COVID-19 to cardiovascular disease. To do this, we ask if you would be willing to provide a small blood sample for testing for antibodies to the virus that causes COVID-19. Antibodies provide information about whether you have ever had COVID-19 in the past. Because of the pandemic, we'd like to have you do this at home instead of in the clinic. It involves a finger-prick blood test at home, similar to the finger-prick that people with diabetes do to test

their sugar. The finger prick is mildly uncomfortable and there is a small risk of bruising or infection at the site of the finger prick. To minimize any risk, we'd send you a small kit with everything needed and instructions on proper sanitizing prior to blood collection. You would then mail the sample to the lab using a prepaid and pre-addressed envelope that we provide. The kit will include written instructions, but we can walk you through what you need to do by phone when you get the kit or you could follow a video on how to do it. You can ask a friend or relative to help you, if you want. A few weeks later, we'd mail you the test result along with reimbursement for your effort of \$40. Taking part in this blood spot collection is entirely voluntary and your decision to take part or not would not otherwise affect your ongoing participation in ARIC. Do you have any questions about what ARIC is inviting you to do?"

If Yes - > [Answer any questions following the Q*Q (refer to PI if necessary) then proceed to next item.]

If No - > [Proceed to next item.]

[If the interviewer has concerns about the participant's understanding or ability to consent, the interviewer may use the ARIC UBACC questions and if still concerned, end the interview by explaining that after going through the material ARIC is concerned that the protocol may be too difficult for the participant and we apologize for bothering them about it. Otherwise proceed.]

"I now would like to ask, then, do you **consent** to doing the finger-stick, or do you not want to take part?"

If Consent - > "Great! Thank you."

If Consent-> [Note willingness to proceed in participant's study records and explain when to expect the kit. If they want help by phone for collection, set this up. Before closing jump to vaccination questions below.]

If no Consent -> "May I call you at a later date to see if you might be interested then?"

If yes - > "When would it be convenient to call back?
_____ Thank you. I will call again."

If no - > "Thank you for your time. We appreciate your participation in the ARIC Study!"