

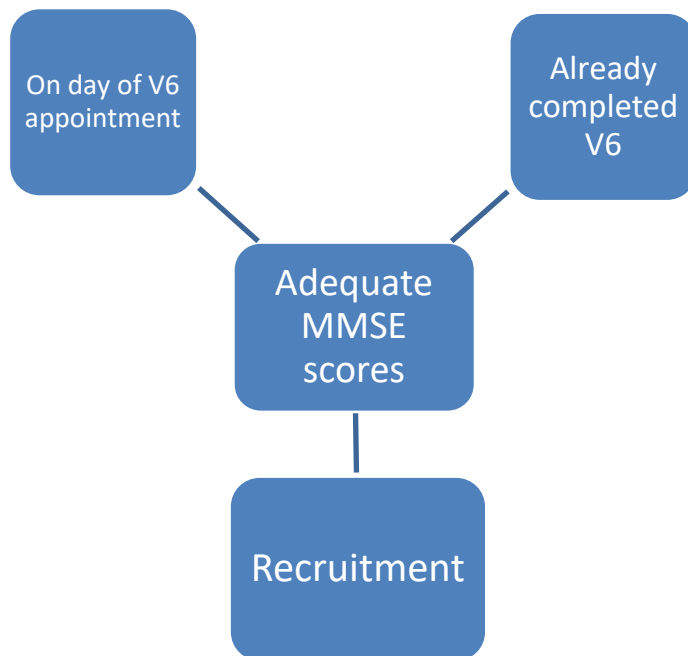


INSTRUCTIONS FOR THE EYE DOC RECRUITMENT TRACKING AND SCHEDULING (ERE) FORM



I. General Instructions

The Recruitment Tracking and Scheduling Form is completed by the staff recruiting for EyeDOC to track and document the status of each Eligible ARIC participant who is invited for EyeDOC. Eligible is defined as living ARIC participants with ARIC V6 MMSE scores of at least 24 in whites and at least 22 in blacks.



The form is opened and initiated when the recruitment process begins for a cohort participant. Ultimately, it is to be completed for all ARIC cohort participants who are eligible and for whom an attempt to give recruitment materials is made until recruitment goals are met. Only one record per invited participant is expected for this form. After goals are met, no more participants are invited for EyeDOC, and this form is NOT completed. The form is also NOT completed for participants not invited to participate in the EyeDOC study (i.e. for those for whom an attempt to give recruitment materials was not made). In cases where the participant could not be reached after numerous attempts or where the participant never explicitly stated whether or not they were interested in the study (item 0c), items 0a and 0b should be completed, and item 0c should be marked missing.

The purpose of the ERE is to allow field centers to track the scheduling status of invited participants, not to identify those who need to be recruited. Participants who are eligible to be recruited are identified using the 'EyeDOC Recruitment Report' available in CDART. The ERE form is intended to track the status of invited participants, from the start of recruitment through completion of the EyeDOC visit among those who come first to ARIC Visit 6. This form will serve as the basis for the real-time CDART 'EyeDOC Scheduling Report'. The EyeDOC Scheduling Report will provide real-time information on scheduled

participants (based on Section C and Question 2 – appointment date/time) but who have not yet completed the visit, and include information on their need for a proxy, transportation or other special needs.

The recruitment and scheduling for EyeDOC exam can be initiated at the conclusion of ARIC V6, or can be initiated via a telephone call following the ARIC Visit 6 NCS visit. The latter option may be used frequently over the first few months of the study to recruit participants who have completed V6 already, before the distribution of brochures began. All participants will be given time to review the EyeDOC brochure, which they will have received at Visit 6 or by mail (if recruitment was initiated by phone).

The ERE form is updated each time contact is made for recruitment, and that contact is recorded in Section A of the form, including new contacts made after a failed appointment. The expectation is that no more than 10 contacts will need to be recorded for a given participant.

II. Detailed Instructions for Each Item

Participants completing ARIC visit 6 may be asked in person or later by phone about potential EyeDOC participation. The receipt of the recruitment materials at visit 6 or verbal (phone call) agreement to have information about the study mailed to them is considered agreement to be recruited (Question 0c of the form). **Unsolicited, blanket mailing to a group of eligible participants does NOT meet criteria for “Participant agreed to recruitment”**. The outcome of subsequent recruitment calls should be recorded in Section A of the form.

Immediately following the ARIC visit 6, ask the eligible participant the following:

We are recruiting for a new ARICsub-study at [Johns Hopkins University/The University of Mississippi] called the Eye Determinants of Cognition or EyeDOC study. Briefly, this study involves an eye exam to see if looking in your eye will help us understand related processes occurring in the brain, such as dementia. May we give you a recruitment brochure [and consent form] for the EyeDOC study? If you are interested we can follow-up later with a phone call after you have had time to read the material”

If YES, then:

ERE 0c. Check “Yes” box and tell the participant “We look forward to talking to you after you have reviewed materials for the EyeDOC study. We will give you a call soon. Good-bye”

If NO, then:

ERE 0c. Check “No” box and tell the participant “We want to thank you for your time today and your participation in ARIC. Good-bye”

If attempts to invite a participant to take part in the EyeDOC study were made, but contact was never established or the participant did not explicitly state whether or not they were interested (e.g., they asked for time to think about it, requested a phone call back, etc.), mark 0c as missing. A notelog may be added to explain the situation.

When calling the participant who has received recruitment materials about scheduling (box 0c is checked "Yes"), ask the participant or their proxy:

"I am calling [I am contacting you again] about a new ARIC sub-study at [Johns Hopkins University/The University of Mississippi]. Do you recall receiving the recruitment brochure [and consent form] for the Eye Determinants of Cognition or EyeDOC study at your ARIC visit?

If YES, then skip to Instructions for Section A. FOR PARTICIPANTS WHO HAVE RECEIVED RECRUITMENT MATERIALS

If NO, then ask them the following: "Briefly, this study involves an eye exam and helps us understand if eye findings are related to processes occurring in the brain, such as dementia. Shall we send you another recruitment brochure [and consent form] for the EyeDOC study through the mail?"

If YES, then: skip to Instructions for Section A. FOR PARTICIPANTS WHO HAVE NOT YET RECEIVED RECRUITMENT MATERIALS

If NO, then ask "Would you be interested in hearing more about the study over the phone and possibly scheduling an appointment?"

If YES, then skip to Instructions for Section A. FOR PARTICIPANTS WHO HAVE RECEIVED RECRUITMENT MATERIALS

If No, then skip to Instructions for Section A. FOR PARTICIPANTS WHO HAVE RECEIVED RECRUITMENT MATERIALS- under the subheading: If respondent is unwilling to schedule an EyeDOC visit

When calling the participant who has NOT YET received recruitment materials about scheduling (box 0c is unchecked), ask the participant or their proxy:

"I am calling [I am contacting you again] about a new ARIC sub-study at [Johns Hopkins University/The University of Mississippi]. Briefly, this study involves an eye exam and helps us understand if eye findings are related to processes occurring in the brain, such as dementia. May we send you a recruitment brochure [and consent form] for the EyeDOC study through the mail and call back to possibly scheduling an appointment?"

If YES, then:

ERE 0c. Check "Yes" box and skip to Instructions for Section A. FOR PARTICIPANTS WHO HAVE NOT YET RECEIVED RECRUITMENT MATERIALS

If NO, then:

ERE 0c. Check "No" box and skip to III. CLOSING on QxQ.

ERE Form Section A. Recruitment Attempts (Completed by the ARIC/EyeDOC Interviewer or Recruiter).

i – x. . Each time contact is made for recruitment, that contact is recorded in the next row of the recruitment log and the appropriate columns a.-e. are completed.

FOR PARTICIPANTS WHO HAVE NOT YET RECEIVED RECRUITMENT MATERIALS

Record the date on which the recruitment call was made in MM/DD/YYYY format, complete a, c, d and e as specified below, and skip to III. CLOSING on QxQ.

i – x a. Record the result code B

i – x c. Record the code number of the staff who made the contact attempt

i – x d. Record whether the participant was contacted or a proxy. Record the name of the Proxy and/or the relation of the Proxy to the participant.

i – x e. Record that the participant had not yet received recruitment information and a followup call would be needed after materials were received through the mail. Record convenient times for a followup call if provided by the participant. Note that recruitment materials need to be mailed.

FOR PARTICIPANTS WHO HAVE RECEIVED RECRUITMENT MATERIALS

Tell the participant:

As detailed in the recruitment brochure, we are now recruiting and scheduling people to be part of this new study focused on vision and memory. This EyeDOC clinic visit will be similar to an ARIC visit, as it will take place at the [Johns Hopkins University/University of Mississippi] facilities where you have previously had your ARIC visit. We expect it will take 1.5 to 2 hours, and all study procedures can be done in a single visit at a convenient time for you. We will reimburse you for your travel, or we can provide taxi services. In addition, we will give you a monetary compensation for your participation in this study. Our appointment times are at [TIMES]. Is there a day or time that would be best for you?"

If the appointment is scheduled, record the date on which the recruitment call was made in MM/DD/YYYY format, complete a, c and d as specified below, record the date and time of the appointment in Section B Question 1, and go to III. CLOSING on QxQ.

i – x a. Record the result code A

i – x c. Record the code number of the staff who made the contact attempt

i – x d. Record whether the participant was contacted or a proxy. Record the name of the Proxy.

ERE 1. Record the date and time of the appointment

If respondent is unable to schedule an appointment at this time, record the date on which the recruitment call was made in MM/DD/YYYY format, complete a, c, d and e, and skip to III. CLOSING on QxQ.

i – x a. Record the result code B

i – x c. Record the code number of the staff who made the contact attempt

i – x d. Record whether the participant was contacted or a proxy. Record the name of the Proxy and/or the relation of the Proxy to the participant.

i – x e. Record reason and prospects for re-contacting or scheduling later

If respondent is unwilling to schedule an EyeDOC visit, record the date on which the recruitment call was made in MM/DD/YYYY format, complete a-e as specified below, and ask the participant about reasons for not participating (see script below)

i – x a. Record the Result Code C

i – x b. Record the reason for refusal

i – x c. Record the code number of the staff who made the contact attempt

i – x d. Record whether the participant was contacted or a proxy. Record the name of the Proxy.

i – x e. Record the Reason for Refusal Code and prospects for re-contacting or scheduling later if participant is amenable after reading scripts below

“Is there a specific reason you are not willing to participate in the EyeDOC study?”
[Do not read responses unless the participant does not offer a reason]

REASON FOR REFUSAL CODES

A. Too busy? Highlight that the participant will receive a number of benefits including a vision exam to detect vision threatening disease and refraction to determine if glasses could help them see better. If still does not agree to complete full exam, see 3 below

B. Exam requires too much time? Highlight that the participant will receive a number of benefits including a vision exam to detect vision threatening disease and refraction to determine if glasses could help them see better. If still does not agree to complete full exam, see 3 below

C. Not interested? Highlight the value of the knowledge that will be gained from the study and how a simple noninvasive image of the eye might someday be used to detect early signs of Alzheimer’s disease. Try to work out a way that it will work.

D. Fearful of study procedures? Read the following: “All the examinations and sub-studies done by ARIC are considered safe. The procedures for EyeDOC are the same as those given during routine visits to your eye doctor. Some tests may cause minor discomfort, but you can always withdraw from the study at any moment without negative consequences. Do you have any additional concern?” Answer questions from the participants. If the participant agrees, go back to section A and schedule appointment.

E. Because of their, or a family member’s, health? “We understand that 1.5 to 2 hours is long. Would a later date work better? We could call again at another time to schedule. If YES, try to schedule a follow-up call.

F. Unable to travel? Remind the participant that we offer transportation arrangements.

G. Distance “We might schedule the appointment at some other time, before the end of the study, when you are in the area. Do you expect to come back to the area soon?” If YES, try to schedule a follow-up call closer to the date or schedule visit. If NOT, try to negotiate travel arrangements.

J. Another reason? Try to work out a way that it will work.

If respondent is still unwilling to schedule an EyeDOC visit, record the reason Section A part b and go to III. CLOSING on QxQ. If a participant has previously indicated that they are “not interested” in a recruitment call, or indicate that they do not wish to be contacted again, result code “I- Hard Refusal- Contact Not Attempted” should be used. This result code is reserved for participants who are not contacted by any means. If a participant that has indicated “not interested” is contacted in some way (mail or email, for example), but has not responded in an appropriate amount of time, then user status “J- Hard Refusal- No Response to Recruitment Attempts.”

If respondent is willing to schedule an EyeDOC visit, offer dates and times, and record appointment in Section B Question 1, then go to III. CLOSING on QxQ.

1. Record the date and time of the appointment

If respondent is not reached, record the date on which the recruitment call was made in MM/DD/YYYY format, complete i a and i c, and END. A maximum of 10 recruitment attempts are available in this section of the form. Option ‘D – Reported alive, will continue to attempt to contact’ is used for contact attempts in which the participant or his/her proxy could not be reached.

If an appointment is canceled and then rescheduled, record the initial appointment in the first row with the initial recruitment date (Row 6 for example), using code 'A= Contacted and Scheduled' for the result code. Then, record the date in which the appointment was cancelled using code 'F=Cancelled' in the next row (Row 7 for example). Finally, record the rescheduled appointment in the next row with the rescheduled recruitment date (Row 8 for example), again using 'A= Contacted and Scheduled' for the result code, and including the new appointment date and time in item 2. The process for recording ‘no-shows’ (missed appointments) is similar, but instead of using code ‘F=Cancelled’, the staff recording the missed appointment should use code ‘G=No-show’.

ERE Form Section B. Recruitment Result

1. Record the result of the recruitment attempt.

If the participant agrees to the study, check yes, and offer available appointment dates. Go to Section C.

If the participant does not agree to study, check no and go to Section III Closing on this QxQ.

ERE Form Section C. Appointment

2a & 2b.. Record the date of appointment using the format MM/DD/YYYY and the 24 hour
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time format HH:MM. If the participant needs to reschedule, record the rescheduled date in item 2a & 2b.

A proxy may be considered necessary for the exam. If the participant is already established as needing a proxy, this information will be provided in the CDART EyeDOC Scheduling Report.

At the time of recruitment, it will be necessary to assess the participant's transportation and special needs. As the EyeDOC exam will occur at the field center, read the following:

"To help us prepare for your visit to the ARIC center for your EyeDOC exam:"

"Do you need assistance in arranging for transportation?"

If YES, record in the ARIC central CIU form and/or in the RTS from Visit 6: CIU0g or RTS5a.

"Do you need any kind of assistance reading, hearing questions, walking or in getting on an examination table?"

If YES, record in the ARIC central CIU form and/or in the RTS from Visit 6: CIU0g or RTS5a.

This information will also be provided in the CDART EyeDOC Scheduling Report.

Go To Section III Closing on the QxQ.

ERE Form Section D. Date of Informed Consent

3. Record the date of informed consent using the format MM/DD/YYYY. **Only complete this section once informed consent has been obtained.** If the participant schedules an appointment but does not attend or reschedules, then this section remains blank until the informed consent is obtained.

III. CLOSING

If participant DID NOT RECEIVE recruitment materials:

"We want to thank you for your time today. We look forward to talking to you after you have received and reviewed materials for the Eye Determinants of Cognition study which I will mail to you today. We will give you another call soon. Good-bye"

Remember to mail recruitment materials.

If participant DID AGREE to EyeDOC:

"We want to thank you for your time today. We look forward to seeing you for your EyeDOC visit. We will give you a reminder call the day before your scheduled visit. Please remember to bring your eyeglasses and any details about your previous eyecare history such as eyedrops, eye surgeries and name of your eye doctor. Good-bye"

If participant DID NOT AGREE to EyeDOC or to receiving recruitment materials:

"We want to thank you for your time today. We look forward to talking with you at your next regularly scheduled ARIC telephone interview. Good-bye"