INSTRUCTIONS FOR EYEDOC RESULTS AND ALERT REPORTING FORM (ERA)

ALERT CODES:

PAP	Papilledema
RRD	Rhegmatogenous retinal detachment

I. General Instructions

The results and alerts reporting form is designed to track the date when participants were notified of any alert value as well as track when study findings were reported to participants.

Notifications of alert values can occur under different circumstances:

- While the participant is at the field center (very high eye pressure is the only reason for such an alert).
- When alerts are communicated to the field center following clinical review of retinal images and completion of the retinal image review form (ERR).

The Alert Report should be run **daily** from CDART by the data manager. All new alerts that show up in the report should be processed and resolved in a timely manner. The high IOP alert occurring at the visit will be resolved by reporting this alert to the participant on the After Clinic Report, which is expected to occur immediately following the EyeDOC visit, though this alert will still appear in ARIC alert summaries. Alerts that are triggered from the review of acquired study retinal images will be resolved when the participant or proxy is contacted by phone, as appropriate and customary for other ARIC alerts.

The 'Alerts Report' on CDART will list all reported and unreported alerts, and the corresponding alert code for each one. Data managers should run the Alerts Report for all alerts (resolved or not) for a given participant, to assure alert values were reported to the participant in a timely manner.

Field center staff are responsible for notifying the participant of both alerts and abnormal findings through the After Visit Report and Photo Findings Letter. For alerts triggered by the retinal photo review, the field center will contact the participant within 3 days of the completion of the retinal image review (ERR form); the participant's physician or eye care specialist may also be notified, as appropriate given participant's informed consent and provided physician contact information on the (Question 17 on the EOH form). If contact is not made with the participant within the 3 day time period, the Field Center PI must be notified on the 4th day. After Visit Reports and Photo Findings Letters should be provided within two weeks of the EyeDOC visit and the completion of the retinal image review (ERR form), respectively.

Study participants who do not have an eye care personal physician can contact the field centers to get a list of local eye care professionals.

This form may need to be accessed more than once, since alerts may occur at different times and reports/letters will be sent at different times. Similarly, it is possible that notification may take place on a different date than the date of receipt of the alert. Note, only one occurrence of this form is allowed.

The study participant does not need to be present when this form is completed. The information required is gathered both at the time of the study visit and after the retinal images are reviewed.

Alerts will continue to appear in the CDART Alerts Report until the participant is notified and the notification details (Alert Code and Date Participant Notified) are entered in this form. Consequently, field center staff should make every effort to notify participants as soon as possible.

II. Detailed Instructions for Each Item

The ERA is organized into three sections:

A: DURING VISIT ALERTS – alerts and reporting. This section concerns the occurrence of a high IOP alert during the Eye DOC visit and the reporting of summary findings from the EyeDOC visit. The After Clinic Report should be run at the end of the visit, following data entry from the EVS form. The expectation is that the occurrence of a high IOP is reported to the participant through the After Clinic Report following the EyeDOC visit while the participant is still present at the field center. Thus the date of the alert resolution will most often be the date of the visit and the same as the date the After Clinic Report is handed to the participant, but the system will allow for later dates.

1. Record whether there was a high IOP alert (IOP≥35) during the visit. If no, skip to item 2
   If the participant's IOP is 35 mmHg or greater tell the participant after the visit:

   "Your eye pressure is high today. Eye pressure at the level noted today can worsen your vision, so we strongly recommend you make an appointment and see your eye doctor. You should see an eye care specialist within the next 3 days. If you start to experience any eye pain or redness in the eye, you should go to the emergency room right away. If you do not have an eye doctor, we can help you find one."

1a. Record the date on which the high IOP alert was resolved, which in most cases will be the date the After Clinic Report is handed or mailed to the participant.

2. Record whether or not a copy of the After Clinic Report was handed to or mailed to the participant.

2a. Record the date on which the After Clinic Report was given to the participant.

B. AFTER VISIT ALERTS – these alerts occur after the participant's visit following the review of retinal images and completion of the ERR form. See the Alert Codes table at the top of this QxQ for a list of the possible alert triggers.

3. Record whether there were any alert notifications reported following the retinal image review. A post retinal image review reporting of rhegmatogenous retinal detachment or papilledema (defined by answers of "Right" or "Left" to answers 8 or 9 on the ERR form) indicate the presence of an alert. If no, skip to item 4.

   If the participant has any post retinal image review alerts, use the codes at the top of the QxQ for alert triggers.

   If the Papilledema (PAP) alert is triggered, the field center should contact the participant by phone and tell the participant:

“There are signs that the fluid inside your skull has high pressure. There are many things that can cause this, several of which are very dangerous. We strongly recommend you go to the emergency room or see your primary medical doctor right away.”

Participants unaware of their condition will need brain imaging, and possibly a lumbar puncture. If they are able to see their primary medical doctor right away, they may coordinate their care through them as long as they can get an appointment urgently, and the primary doctor is comfortable coordinating their care. Alternately, they may be sent to the emergency room for urgent brain imaging and, if necessary, lumbar puncture. Participants aware of a history of this finding should be directed to their primary medical doctor to ensure that it is indeed being adequately cared for.

If the Rhegmatogenous retinal detachment (RRD) alert is triggered, the field center should contact the participant by phone and tell the participant:

“There are signs that you have a retinal detachment, in which the retina (the “film” part of the eye) is not where it usually sits. We strongly recommend you make an appointment and see an eye care professional in the next 3 days. If you do not have an eye doctor, we can help you find one.”

Assistance should be given to participants to ensure that they see an appropriate eye doctor within 3 days. Retinal detachments are best handled by a retinal specialist, and if they do not have such a specialist, a list of them may be provided for them. Alternately, if participants are more comfortable seeing their primary eye doctor, they may do so with the understanding that this doctor may need to refer them on for further care.

3a. Record the date on which the alert was resolved, which will be the date the participant is called by the field center and told of the alert.

C: Results Reporting – Whenever possible, it is preferable (mainly from an operational standpoint) to send the Photo Findings Letter one time with complete results. This means ensuring that the final OCT and fundus photo results are available and complete before the report is sent, with completion determined when the reviewing ophthalmologist records the date the report is ready to be sent to the field center. This date will remain blank on the ERR form until the photo review is finalized.

4. Record the date the Photo Findings Letter was mailed to the participant.