

	Title:	Vision – Visual Acuity		
	Version Date:	2014-JUL-10	Document Number:	SOP_DCS_0025
	Effective Date:	2014-OCT-15		
Data Collection Site (DCS)	Version:	2.1	Number of Pages:	4

1.0 Purpose:

The purpose of this document is to provide the standardized procedure for administering the visual acuity test.

2.0 Scope:

DCS staff must use this document to administer the Visual Acuity Test with an ETDRS Chart.

3.0 Responsibilities:

DCS staffers are responsible for performing the procedures as described in the current and approved version of the standard operating procedure.

4.0 Related Documents:

Not applicable

5.0 Definitions:

Not applicable

6.0 Equipment:

Not applicable

7.0 Supplies:

- ETDRS Chart; and
- Multi-hole occluder with handle (black).

8.0 Procedure Steps:

Contraindications:

- There are no contraindications for the Visual Acuity test.

ETDRS Chart

ETDRS vision chart: if participants wear glasses or contacts, then do the test with participants wearing the glasses or contacts;

Step 1: Place the ETDRS chart two meters from the participant's eyes and make sure the light on the chart is turned on.

Participants will be asked to read successively smaller sets of letters. The vision score corresponds to the smallest complete set of letters they can read, plus the number of letters they can correctly identify on the line following the last line where they read a complete set of letters.

Step 2: At the *Interview Tab* in Onyx, look for the “Visual Acuity” measurement in the list of stages and select **Start** in the “Actions” in that row.

Step 3: **Answer** the question about whether the participant is wearing glasses. Ask the participant if they are wearing contacts if they do not have glasses on. Click **Next**.

Step 4: The “Visual Acuity using ETDRS Chart” page is shown, and **Answer** if the test was performed. This step will be repeated for each measurement (ie: right eye, left eye, pin hole, both eyes.)
If **No**, indicate **Why not?** and give details as required. Then choose **Next**.
If no is answered for both eyes proceed to **Step 13**.

If **Yes**, click **Next** and proceed to **Step 5**.

Step 5: Hand the participant the black multi-hole occluder with handle. They will be using this to cover one eye while reading the chart with the other eye.
NB: Never give the participant a hint about what they are reading. Giving them help will affect their results.

Step 6: Begin with the ‘Right eye’ - hold the occluder so that the left eye is covered and the right eye can see the chart.
Add the value into Onyx for the last row where the participant correctly identifies **all 5 letters**: 20/ __

Then **add** the number of letters they can identify correctly in the line below.
NOTE: If a participant cannot read the first line completely (20/200), but can read some of it, then place a zero to answer the first question (last row where all five letters are correctly identified) and enter the number of letters read on the second line.

Step 7: Repeat the test for the ‘Left eye’. Have the participant turn the occluder over to cover the right eye and complete the information as above in Onyx. Click **Next**.

Step 8: Next, test the ‘Right eye with pinhole’. Move the pinholes into the viewfinder of the black occluder by flipping the pinholes into the viewing area of the occluder and ask the participant to hold it so that the left eye is completely covered.
Add the value into Onyx for the last row where the participant correctly identifies all 5 letters 20/ __

Add the value for the number of letters correctly identified past the last row __

Step 9: Repeat the test for the ‘Left eye with pinhole’. Turn the occluder over to cover the right eye and complete the information as above in Onyx.

Step 10: Repeat the test for 'both eyes'. Have the participant read the chart without covering their eyes and complete the information as above in Onyx. Click **Next**.

Step 11: The Visual Acuity using ETDRS Chart Score Results screen appears. Click **Next**.

Step 12: Add any Comments. Ensure that comments do not contain any personal identifying information or check **None**. Click **Next**.

Step 13: The Conclusion screen appears, click **Finish**.

Step 14: Click **Continue** to return to the status page.

ETDRS Scoring Method

For each of the five readings, a decimal acuity score can be determined. **This is typically done in Onyx** but for manual calculation this is how it is done;

- Determine the last row where the participants can correctly identify all 5 letters on the row.
- Determine the log score for that row (these scores are shown in the margin of the ETDRS test, e.g. the 20/25 line has a log score of 0.1).
- The formula used in calculating the score is:

ETDRS Acuity Log Score = Log value of the best line read – (0.02 * X) (X = number of letters correctly identified beyond the last row where all of the letters are correctly identified)
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9.0 Documentation and Forms:

- **CRF_DCS_0025** - Visual Acuity Case Report Form

10.0 References:

- <http://webvision.med.utah.edu/book/part-viii-gabac-receptors/visual-acuity/>
- Visual Acuity Scales

Foot	Meter	Decimal	LogMAR
20/200	6/60	0.10	1.00
20/160	6/48	0.125	0.90
20/125	6/38	0.16	0.80
20/100	6/30	0.20	0.70
20/80	6/24	0.25	0.60
20/63	6/19	0.32	0.50
20/50	6/15	0.40	0.40
20/40	6/12	0.50	0.30
20/32	6/9.5	0.63	0.20
20/25	6/7.5	0.80	0.10
20/20	6/6	1.00	0.00
20/16	6/4.8	1.25	-0.10
20/12.5	6/3.8	1.60	-0.20
20/10	6/3	2.00	-0.30

Revision History:

New Version #	Revision Date	Revision Author	Content Approval
2.1	2014-JUL-10	Lorraine Moss	Mark Oremus
Summary of Revisions			
Removed scoring directions from Step 5. Clarified scoring directions in Step 6.			
SOP formatting updated.			
Wording of Scope, Purpose and Responsibilities updated and clarified.			
New Version #	Revision Date	Revision Author	Content Approval
2.0	2013-Jan-31	Lorraine Moss	Mark Oremus
Summary of Revisions			
Step 1 in section 6.0 changed to read "Place the ETDRS chart 2 meters from the participant's eyes and make sure the light is turned on."			
Various formatting updates			
Added CRF number in section 7.0			
Step 3 re-worded to read " Answer the question about whether the participant is wearing glasses. Ask the participant if they are wearing contacts if they do not have glasses on. Click Next ."			
Step 4 re-worded to read "The "Visual Acuity using ETDRS Chart" page is shown, and answer if the test was performed. This step will be repeated for each measurement (ie: right eye, left eye, pin hole, both eyes.) → If No , indicate Why not? And give details if required. Then choose Next . ○ If answered no to both eyes proceed to Step 13 . → If Yes , click Next and proceed to Step 5 ."			
Removed "Each letter has a score value of 0.02 log units. Since there are 5 letters per line, the total score for a line on the LogMAR chart represents a change of 0.1 log units;" from section 7.0			
Step 6, 2 nd bullet point re-worded to read " Add the value for the Number of letters correctly identified past the last row NB: If a participant cannot read the first line completely (20/200), but can read some of it, then place a zero to answer the first question (last row where all five letters are correctly identified) and enter the number of letters read on the second line."			
In section 6.0 under the ETDRS scoring module deleted "To calculate the decimal acuity score, follow the guidelines below."			
Added " NB: Never give the participant a hint about what they are reading. Giving them help will affect their results." under step 5			