



Quality of Well-Being Manual of Procedures

May 1, 2021 Version 8.0

GRADE QWB Reading Center

QWB-SA Procedures

- I. Introduction: Quality of Well-Being Scale–Self-Administered (QWB-SA)
- II. Accessing QWB-SA Questionnaires
- III. Administration of the QWB-SA
- IV. Processing of the QWB-SA Shipment
- V. Communications with QWB-SA Reading Center
- VI. Certification Process

Appendix – Frequently Asked Questions

I. Introduction: Quality of Well-Being Scale – Self-Administered (QWB-SA)

The QWB-SA is a measure of health related quality of life and can be scored to provide a wellness score ranging from 0.0 to 1.0. The scale also provides clinical information.

Participants will self-administer the questionnaire, to be completed at baseline and during each annual follow-up assessment. This document describes procedures in detail from first accessing the questionnaires to completing shipment of QWB-SA to the QWB Reading Center.

II. Accessing QWB-SA Questionnaires

Clinics are responsible for printing the QWB-SA questionnaires as they are needed throughout the study. *It is important that the questionnaires are printed and not photocopied so the alignment is the same each time.* A master copy of this document in PDF format is provided on the GRADE study website under Documents/Form Packets by Study Visit (CRFs)/Annual Visit/Individual Visit Forms/QWB-SA V1.04_09.15.04.pdf and QWB-SA V1.04_05.08.16_Spanish.pdf. Login information will be provided by the GRADE Study Coordinating Center. In the event of an updated version, the clinics will be notified and an updated link will be provided on the website.

III. Administration of the QWB-SA

It should take the patient approximately 10-15 minutes to complete the QWB-SA. To ensure high quality data, the trained clinical staff should collect the forms and review all pages for completeness for the following:

1. Make sure the participant ID label matches the ID assigned to the participant who completed the form.
2. Verify that the “Visit date” is the date the participant came to the clinic.
3. Review Headers: all 4 pages should have *complete* and *identical* information for each field in the header:

Site:	Participant ID:	GCode:	Visit #:	Visit date (mm/dd/yyyy):
<input type="text"/> <input type="text"/> -	<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>

4. For all questions under part 1(a-k) and part 2 (a-g) of Question 1, review each page to make sure that a Yes or No box is clearly checked for each question. If neither of the boxes or both boxes are checked, please ask the participant to answer the question at that time. These are chronic symptoms and should not change since the “date completed”.

5. For Questions 2 and 3, review each page to make sure that each question was answered with “No Days” or any combination of “Yesterday”, “2 days ago”, or “3 days ago”. However, if “No Days” is checked, no other boxes should be checked for that individual question.
6. For Question 4, Symptom A and Symptom B, make sure a description of the problem is provided if “Yesterday”, “2 days ago”, or “3 days ago” are endorsed.
7. For Question 5a through 8c, the same rules apply as step #5 for the response choices “No Days”, “Yesterday”, “2 days ago”, or “3 days ago”. **However, Page 4, follow up to Question 7h should be blank, unless the participant reported that they spent all or most of the day in a wheelchair in the previous question (Question 7h). If 7h is “No Days” then the follow up should be blank.**
8. Provide initials and date to show that form was reviewed.

If corrections are made to a response, a single line should be drawn through the incorrect answer and initials written next to that questionnaire item.

Additionally, clinics may detach QWB-SA pages from each other if they were attached after printing. It is not required that the pages are attached when administered to the participant or when sent to the QWBRC. Ensure that all pages for a patient are sent in order.

IV. Processing of the QWB-SA Shipment

Shipping Log: A QWB shipping log (generated via MIDAS) should be included with each monthly batch which indicates Clinical site number, Participant ID, GCode, Visit Date, Visit type, and Date Mailed for each questionnaire included in the batch. The report is accessible through MIDAS by clicking on ‘Study Reports’ on the left hand side, then ‘QWB Shipping Log’ in the middle of the screen. Populate the 4 fields and click “Create Report”. Print and include with the questionnaires or email to the QWB Reading Center Data Coordinator ahead of shipment.

Send Original QWB-SA: Clinics should send the *original* QWB-SA questionnaire and keep a copy locally. Clinics are asked to batch QWBs and send to the reading center **monthly**, on the first of each month. These should be sent according to the clinic’s preferred shipping method (e.g., USPS, Fed-Ex, etc.).

Confirmation: Confirmation of arrival at the reading center will be provided via email within 2 business days of receipt. The clinic should file these confirmation emails in a secure location so they may be referred back to. If the clinic does not receive confirmation of receipt from the QWB Reading Center within 2 business days of expected arrival, they should send an email to the QWB Reading Center Data Coordinator.

Shipments should be sent to the following address:

UCSD Health Services Research Center
5440 Morehouse Drive, Suite 3500
San Diego, CA 92121

V. Communications with QWB Reading Center

For any questions regarding the QWB-SA, sites should contact the QWB Reading Center Data Coordinator by email or phone.

UCSD Health Services Research Center main line: 858-622-1771.

VI. Certification Process

Clinic staff will be trained in QWB-SA procedures during a 1-hour webinar which will be scheduled prior to the study launch date. The clinical coordinator should track which staff at their clinic attend the webinar and send this information to the QWBRC. Upon completion of the webinar training, the clinic staff in attendance will receive an email notification to keep in their records that they are certified in the QWB-SA for the GRADE study.

For new staff hired later in the study, or those who could not attend the live webinar, the clinic coordinator should first have the new staff member review the Power Point presentation given at the webinar, read this manual, and fill in one practice QWB-SA questionnaire. Completing a QWB-SA is meant to give the coordinator greater understanding of the measure so they can assist participants with the response options. The completed form should not be sent to the QWBRC and may be destroyed once completed. Once these are completed, the coordinator should submit the staff member's name and contact information to the QWBRC coordinator. The staff will be contacted to schedule a brief call with the QWBRC staff. The purpose of the follow-up call will be to give the newly trained clinical staff the opportunity to ask questions and verify their understanding of the QWB-SA questionnaire and procedures. Once the call is completed, the QWBRC will send a certification email to the new staff member and the clinical coordinator. At this time, the clinic should update their records of certified personnel at their site.

To re-certify existing study staff, the coordinator should review the training power point on the website and fill in one practice QWB-SA questionnaire. Once these steps are completed, the coordinator should contact the QWBRC for written confirmation.



Appendix A

Quality of Well-Being (QWB-SA)

Frequently Asked Questions

(Last updated 2/19/16)

FILLING IN THE QWB QUESTIONNAIRE

Q: How much help can be given by coordinators to participants on the questionnaire?

A: The QWB-SA is a self-administered questionnaire, so ideally the coordinators should not assist or prompt the participants as this may bias their responses. The participant should be encouraged to answer the question to the best of their ability. If the participant truly doesn't understand a question, the coordinator can carefully provide synonyms for a word or re-word a phrase. This is not recommended, though. If a situation arises that the coordinator is not sure about, they can contact the QWB Reading Center data coordinator.

Q: How should participants be prompted to answer questions left blank?

A: Start by reviewing the entire questionnaire after the participant has completed it. Verify with the participant that the question was intentionally left blank by asking "did you mean to leave this question blank because you are refusing to answer?" If they say they did, then leave blank. You may mark the QWB if you would like to track how often this happens at your site, but the markings will not be factored into questionnaire scoring. If they did not mean to leave it blank, ask them to fill in a response at that time.

Q: How should participants be prompted to correct conflicting responses?

A: Same procedure as blank responses. You should review all pages before the participant leaves and ask, "it looks like you have marked two answers that conflict, could you please select one or the other?" They can be instructed to mark a line or an "X" through the incorrect answer. You should then initial and date in the column near the response.

Q: Question 3L which asks if participant takes any medication including OTC remedies, how should participants respond if they are taking their daily study medications, like metformin?

A: Any medication that has been taken should be included. If the study medications are prescribed daily and they are taken as prescribed, the participant should fill in all three bubbles for "Yesterday", "2 days ago", and "3 days ago".

PROCESSING QWB FORMS FOR GRADE

Q: How often should I send QWBs to the QWB Reading Center?

A: Sites should batch forms for one calendar month (e.g., 4/1/2015-5/1/2015) and send on the first of the month at the end of this range (e.g., 5/1/2015). All forms for a month should be included in one mailing unless fitting them into an envelope is an issue.

Q: I accidentally printed the QWB two-sided and realized this after the participant filled it out – what should I do?

A: Print pages 2 and 4 again and transcribe the participant's answers onto the new copies. Cross the old pages out by drawing a line all the way across the page. Add your initials and the date to the crossed out page.

Q: I accidentally punched holes in one of the QWB's thinking it was the copy. Will that affect your machine's ability to read it?

A: Hole punches cause slight difficulties for the scanning program to read the QWB data. As long as the holes are not punched through the header information, please send anyway though sites are encouraged to not punch holes in the originals if possible. If holes are made through header information, please transcribe all responses to a new print-out of the QWB.

Q: MIDAS records one date per visit. How should a form be handled that is completed as a split visit, as in, the Final Run-in was on one date, and the participant returned at a later date to do the questionnaires including QWB?

A: Please contact your assigned Protocol Management team member at the Coordinating Center who will provide guidance and instructions on how to enter the form in MIDAS.