

Research Questionnaires

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Outline

- What is a Research Questionnaire?
- Translations
- How do we review them?
- References

What is a Research Questionnaire?

- Data Collection Tool
 - Series of questions or items used to collect information from respondents
 - Intent is to standardize data
 - May be part of a study using mixed methods or not
- Reliability & Validity
 - Consistent results
 - Measures what it claims to measure
- Classifications:
 - Mode of Administration - Self-reported or Researcher/Interviewer reported
 - Mode of Format – structured, semi-structured, matrix

Matrix Example



EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

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Your birthdate (Day, Month, Year):

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Today's date (Day, Month, Year):

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	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4

What is a Research Questionnaire?

- Validated
 - Tested and published in the literature
 - Population/context/purpose for which it was developed matters
- Unvalidated
 - Not published
 - Usually custom to a given study

Translations

- Validated
 - Tested in the language into which it has been translated
 - Proven to be valid and reliable
 - Published
- Unvalidated
 - May have validated English (or other language) version
 - Not validated in other languages

Review - General Requirements

- Is what the questionnaire claims to measure relevant to the aims of the research?
- If validated, do not need to submit, but should give name of tool and specify that it is validated with appropriate reference
- If unvalidated:
 - Are the questions worded appropriately (respectfully)?
 - Are the questions eliciting information that is relevant to what the tool claims to be measuring?

Review of Translations

- Study must be approved to enroll non-English speakers
- If validated in language into which it has been translated, do not need to submit
 - Should specify name of questionnaire and that it is validated with reference
- If validated in one language but not validated in language into which it has been translated OR no language is validated/custom tool:
 - PI must identify a qualified translator
 - Translator must sign a letter of attestation or provide certificate of translation (commercial service)

References

- [21 CFR 56.111](#)
- [45 CFR 46.111](#)
- [OIA FAQs](#)