

## ISOQOL Good Practices Working Group – January 2006

The aim of the Good Practices Working Group, which was initially formed in 2002, was to explore and describe the accessibility of HRQL instruments. The objective of the group was to summarise and illustrate the (expected) wide range of conditions for obtaining permission to use an HRQL instrument (and indeed, to obtain the instrument itself). A second objective was subsequently proposed: to evaluate the situation and make some kind of recommendations, statement or proposal of Good Practices for accessing HRQL instruments, to be endorsed by ISOQOL's Board of Directors.

### **1. Access to HRQL Instruments: Current situation**

The focus of the review was on the terms or requirements for accessing the original instruments (and adapted versions) for end-users. Items that were considered of interest in the review were: costs, legal requirements, and how long it actually took to obtain an instrument.

In order to assess the current situation, a survey of 20 well-known instruments of different content areas, countries of origin, and age-groups was carried out. There were:

- 🚩 8 generic HRQL instruments:  
(SF-36, WHOQOL, EQ-5D, NHP, OARS, CHIP, CHQ, and Kindl),
- 🚩 9 disease-specific instruments  
(EORTC, FACIT, VF-14, SGRQ, AQLQ, QLI-Epilepsy, DUKE-AD, WOMAC, and QUALEFO),
- 🚩 3 instruments measuring psychopathology:  
(PWIBI, GHQ, and HADS).

#### Sources and collection of information:

The following data sources were consulted:

- 🚩 QOLID ([www.proqolid.org](http://www.proqolid.org))
- 🚩 Red IRYSS ([www.rediryss.net](http://www.rediryss.net))
- 🚩 Direct contact with developers or contact persons.

Data was collected by Sali Santed, Sarah Shiffert, Montse Ferrer, José María Valderas and Jordi Alonso.

The **Appendix** presents the following data for each of the instruments reviewed : Name of the instrument, Basic characteristics, Conditions of use; Copyright information; and Contact address.

#### Summary of findings:

Access to **generic and psychological** questionnaires is not free: fees are charged for the use of 6 out of the 8 instruments reviewed (with the noticeable exception of the WHOQOL). However, around half of these questionnaires requested fees from commercial/pharmaceutical companies only, whilst access is free for academics.

**Disease-specific** questionnaires are more accessible than generic instruments: access is free for half of them; the other half charge fees only for commercial/pharmaceutical companies: no instrument requires fees for academic/non-profit research.

It is current practice for an instrument's developers to request users to sign an **agreement or contract for the use** of their instrument.

We were unable to identify any formal description of specific policies for potential users from **developing countries**.

## **2. Good Practices in the access to HRQL measures: A proposal from ISOQOL**

Although the task described above may be incomplete, the group discussed the possibility that at some stage ISOQOL should produce a statement on Good Practices in accessing HRQL instruments, which would differ according to users. The statement would consider, amongst other things, the perspective of researchers working for non-profit bodies, or researchers working in a non-convertible currency country.

Another important issue to consider is whether or not the development of the instrument occurred with public financing.

Another issue for consideration is a general strategy that could extend to all types of instruments, and might be promoted in order to obtain a return of research costs. This issue falls outside the scope of this statement as it is decided by the demands of the marketplace.

Finally, the statement might devote attention to the following issues:

- a) The fees for use should vary by type of end-user (e.g. academics vs. industry or public bodies), as well as by economic context (i.e. more developed vs. less developed countries, etc.). It might be of interest to differentiate which items can/should be charged (e.g. the questionnaire vs. additional documentation such as scoring algorithm software, manuals, or additional data and documentation).
- b) The conditions specified in the agreement (or contract) signed by users may increase the feasibility of future research by developers of the questionnaire and include a guarantee of the rights of the study's original authors; and
- c) Intellectual property rights should be respected, and special considerations for versions adapted to other cultures and languages may be necessary.

## Appendix: ISOQOL Good Practice - Instruments

Name	Characteristics	Terms of Use	Copyright Information	Contact address/ person
<b>AQLQ</b> Asthma Quality of Life Questionnaire	<b>Specific</b> (Asthma, Adults, Canada)	<b>Conditions of use:</b> * with author's written permission * with fees for commercial/ pharmaceutical companies	<b>Copyright:</b> All questionnaires and translations are copyrighted. They must not be altered in any way, sold, translated or adapted for another medium (e.g., computer) without the written permission of Professor Elizabeth Juniper.	Professor Elizabeth Juniper QOL Technologies Ltd 20 Marcuse Fields Bosham, West Sussex P018 8NA, UK Telephone +44 (0) 1243 572 124 Fax +44 (0) 1243 573 680 Email: <a href="mailto:juniper@goltech.co.uk">juniper@goltech.co.uk</a>
<b>CHIP</b> Child Health and Illness Profile. Adolescent edition.	<b>Generic</b> (Adolescents & Children USA)	<b>Conditions of use:</b> * Licensing Fee For Profit Companies \$ 1,500 Research/ Evaluation \$ 250 Student Research \$ FREE upon approval * with the signature of a contract/agreement * Contact with Anne Riley	<b>Copyright:</b> John Hopkins Bloomberg School of Public Health	Anne Riley Associate Professor, John Hopkins University Bloomberg School of Public Health Dept of Health Policy and Management 624 N Broadway St., Baltimore, MD 21205, USA Phone: +1 (410) 955-1058, E-mail: <a href="mailto:ariley@jhsph.edu">ariley@jhsph.edu</a> Website: <a href="http://www.chip.jhu.edu">www.chip.jhu.edu</a>

Name	Characteristics	Terms of Use	Copyright Information	Contact address/ person
<b>CHQ</b> Children's Health Questionnaire	<b>Generic</b> (Children, USA)	<b>Conditions of use:</b> * free for <i>some</i> academic/non profit research (conditions apply) * with fees for commercial/ pharmaceutical companies * with the signature of a contract/agreement * all use requires purchase of the CHQ User Manual (135\$), and permission from Landgraf. Please see: <a href="http://www.healthact.com">www.healthact.com</a> for full licence and cost details	<b>Copyright:</b> 1996-2003 Landgraf and Ware. All Rights Reserved	Jeanne M Landgraf HealthAct, 205 Newbury Street, 4th Floor Boston, Massachusetts 02116, USA Phone: +1 (617) 375-7800 Fax: +1 (617) 375-7801 E-mail: <a href="mailto:jml@healthact.com">jml@healthact.com</a>
<b>Duke AD</b> (Duke Anxiety – Depression)	<b>Specific</b> (Anxiety & Depression, Adults, USA)	<b>Conditions of use:</b> For information on, or permission to use the original questionnaire, contact: Professor George R Parkerson	<b>Copyright:</b> Copyright: ©1994-2005, Department of Community and Family Medicine, Duke University Medical Center, Durham, NC, USA	Professor George R Parkerson Jr, MD, MPH Box 2914 Duke University Medical Center, Durham North Carolina 27710, USA Phone: +1 (919) 681-3043 Fax: +1 (919) 684-8675

Name	Characteristics	Terms of Use	Copyright Information	Contact address/ person
<b>EORTC</b> (QLQ 30 core) (European Organisation for Treatment of Cancer Quality of Life Questionnaire)	<b>Specific</b> (Cancer, Europe)	<b>Conditions of use:</b> * with fees for commercial/ pharmaceutical companies: rate to be determined, based on trial specifications * with the signature of a contract/agreement * other: Free access for academic/non-profit research after signature of user's agreement	<b>Copyright:</b> The QLQ-C30 and modules are copyrighted instruments, with all rights reserved. Written, prior consent of the EORTC Quality of Life Group is required for its use.	EORTC Data Center, Quality of Life Unit, Avenue E.Mounier 83, Bte 11, 1200 Brussels Belgium Andrew Bottomley, Head, Quality of life Unit email: <a href="mailto:Andrew.bottomley@eortc.be">Andrew.bottomley@eortc.be</a>
<b>EQ-5D</b> (EuroQol)	<b>Generic</b> (Adults, Europe)	<b>Conditions of use:</b> * free access * with fees for commercial/ pharmaceutical companies	<b>Copyright:</b> The Euroqol group	EuroQol Group Business Management Office PO BOX 4443 3006 AK Rotterdam The Netherlands Tel: +31 10 408 1545 Fax: +31 10 452 5303 E-mail: <a href="mailto:userinformationservice@euroqol.org">userinformationservice@euroqol.org</a> <a href="http://www.euroqol.org">www.euroqol.org</a>
<b>FACIT</b> (Functional Assessment of Chronic Illness Therapy)	<b>Specific</b> (US, Chronic illness)	<b>Conditions of use:</b> * with the completion of a user's agreement * Fees – free for English language version, licence fees apply to some translated versions. See Registration and Request section in <a href="http://www.facit.org">www.facit.org</a>	<b>Copyright:</b> © 1998 FACIT Measurement System, owned and copyrighted by, and the intellectual property of David Cella, Ph.D.	FACIT.org 328 Myrtle Avenue Elmhurst, IL 60126 USA Tel: +1) 630.279.9464 (voice mail only) Fax: (+1) 630.279.9465 e-mail: <a href="mailto:d-cella@northwestern.edu">d-cella@northwestern.edu</a> Web: <a href="http://www.facit.org">www.facit.org</a>

Name	Characteristics	Terms of Use	Copyright Information	Contact address/ person
<b>GHQ</b> (General Health Questionnaire)	<b>Psychopathology</b> (Adults, Psychopathology, UK)	<b>Conditions of use:</b> * all customers must register with nfer-Nelson * with variable fees for academic/non profit research. * with variable fees for commercial/pharmaceutical companies.	<b>Copyright:</b> Yes	NFER-NELSON, The Chiswick Centre, 414 Chiswick High Rd, London W4 5TF, UK. Tel: +44 (0)208 996 8444 Fax: +44 (0) 208 996 3660 E-mail: <a href="mailto:international@nfer-nelson.co.uk">international@nfer-nelson.co.uk</a> Web: <a href="http://www.nfer-nelson.co.uk">www.nfer-nelson.co.uk</a>
<b>HADS</b> (Hospital Anxiety and Depression Scale)	<b>Psychopathology</b> (Adults, Psychological, UK)	<b>Conditions of use:</b> * all customers must register with nfer-Nelson * with variable fees for academic/non profit research. * with variable fees for commercial/pharmaceutical companies.	<b>Copyright:</b> R.P. Snaith, A.S. Zigmond 1983, 1992, 1994	NFER-NELSON, The Chiswick Centre, 414 Chiswick High Rd, London W4 5TF, UK. Tel: +44 (0)208 996 8444 Fax: +44 (0) 208 996 3660 E-mail: <a href="mailto:international@nfer-nelson.co.uk">international@nfer-nelson.co.uk</a> Web: <a href="http://www.nfer-nelson.co.uk">www.nfer-nelson.co.uk</a>
<b>KINDL</b>	<b>Generic</b> (Children, Germany)	<b>Conditions of use:</b> * with fees for commercial/pharmaceutical companies. * For academics, free access is granted with the condition of sharing data for psychometric analysis with the authors	<b>Copyright:</b> Copyright: U Ravens-Sieberer, M Bullinger 1997	Dr. Ulrike Ravens-Sieberer MPH Head Research Group Robert Koch Institute Stresemannstr. 90 D-10963 BERLIN, Germany Tel: +49-30-4547-3436 (3434 Secretary) Fax:+49-30-4547-3531 E-Mail: <a href="mailto:ravens-siebereru@rki.de">ravens-siebereru@rki.de</a> Web: <a href="http://www.catscreen.de">www.catscreen.de</a>

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<b>NHP</b> (Nottingham Health Profile)	<b>Generic</b> (Adults, UK)	<b>Conditions of use:</b> Contact S McKenna for permission for use	<b>Copyright:</b> The Nottingham Survey: Sonja M. Hunt, J. McEwen & S. P. McKenna, 1982	Dr. Stephen McKenna, Galen Research, Enterprise House, Manchester Science Park, Lloyd Street North, Manchester M15 6SE, UK. E-Mail: <a href="mailto:100663.1650@compuserver.com">100663.1650@compuserver.com</a>
<b>OARS</b> (Older Americans Resources and Services Schedule)	<b>Generic</b> (Elderly Adults, USA)	<b>Conditions of use:</b> * with author's written permission * with fees for commercial/ pharmaceutical companies * with the signature of a contract/agreement	<b>Copyright:</b> © 1975, 1988 Duke University Center for the Study of Aging and Human Development. All rights reserved. The use of the OARS questionnaire is restricted. Persons wishing to use it should obtain permission by contacting Dr. Harvey Jay Cohen.	Dr. Harvey Jay Cohen Director, Center for the Study of Aging and Human Development Box 3003, Duke University Medical Center, Durham, NC 27710, USA. Tel +1(919) 660-7502 Fax: +1 (919) 684-8569 E-mail: <a href="mailto:betty.ray@duke.edu">betty.ray@duke.edu</a> Web: <a href="http://www.geri.duke.edu">www.geri.duke.edu</a>
<b>PWIBI</b> (Psychological General Well-Being Index)	<b>Psychopathology</b> (Adults, Psychological, Well-being, USA)	<b>Conditions of use:</b> * with fees for commercial/ pharmaceutical companies: 250€ (access cost to the scale per study), plus 50€ per language version. * with the signature of a contract/agreement	<b>Copyright:</b> Harold J. Dupuy, PhD Originator	Mapi Research Institute 27, rue de la Villette 69003 Lyon, France. Phone: +33 (0)4 72 13 66 67 Fax: +33 (0)4 72 13 66 82 Web: <a href="http://www.mapi-research.fr">www.mapi-research.fr</a>

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<b>QOLIE</b> (Quality of Life in Epilepsy Inventory)	<b>Specific</b> (Adults, Neurology, USA)	<b>Conditions of use:</b> * free access	<b>Copyright:</b> Copyright:1984 and 1998 (USA) by Carol Estwing Ferrans and Marjorie Powers	Carol Estwing Ferrans, Dept. Medical-Surgical Nursing, College of Nursing, University of Illinois 845 South Damen Avenue, 7th Floor, Room 746 Chicago, IL 60612-7350. Fax: +1 (312)-996-4979 E-mail: <a href="mailto:CFerrans@uic.edu">CFerrans@uic.edu</a> Web : <a href="http://www.uic.edu">www.uic.edu</a>
<b>QUALEFO</b> (Quality of Life Questionnaire of the European Foundation for Osteoporosis)	<b>Specific</b> Rheumatology	<b>Conditions of use:</b> * with the signature of a contract/agreement <a href="http://www.osteofound.org">www.osteofound.org</a>	<b>Copyright:</b> Copyright: © International Osteoporosis Foundation	International Osteoporosis Foundation 71, cours Albert-Thomas, 69447 Lyon Cedex 03, France, Phone: +33 472 91 41 77 Fax: +33 472 36 90 52 E-mail: <a href="mailto:info@ioflyon.org">info@ioflyon.org</a> Web: <a href="http://www.osteofound.org">www.osteofound.org</a>
<b>SGRQ</b> (Saint George's Respiratory Questionnaire)	<b>Specific</b> (Adults, Respiratory disease, UK)	<b>Conditions of use:</b> * with fees for commercial/ pharmaceutical companies: 250€ (general administrative expenditure) plus 50€ per version requested paid to Mapi Research Institute. Other fees have to be provided to St George's Hospital Medical School * with the signature of a contract/agreement	<b>Copyright:</b> St George's Hospital Medical School	Paul W. Jones Division of Physiological Medicine St. George's Hospital Medical School Cranmer Terrace London SW 17 0RE England Fax: +44(181)-767-5559 E-mail: <a href="mailto:pjones@sghms.ac.uk">pjones@sghms.ac.uk</a>

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<b>SF-36</b>	<b>Generic</b> (USA)	<b>Conditions of use:</b> * with fees for academic/non profit research * with fees for commercial/ pharmaceutical companies * with the signature of a contract/agreement	<b>Copyright:</b> The Medical Outcomes Trust (MOT), Health Assessment Lab (HAL) and QualityMetric Incorporated. <a href="http://www.sf-36.org">www.sf-36.org</a>	640 George Washington Highway, Lincoln, RI 02865, USA. Tel +1:(800) 572-9394, Fax: +1 (401) 334-8801, Toll Free: +1 (800) 572-9394 <a href="http://www.qualitymetric.com">www.qualitymetric.com</a>
<b>VF-14</b> (Visual Function)	<b>Specific</b> (Adults, Cataracts, US)	<b>Conditions of use:</b> * with author's written permission * with the signature of a contract/agreement	<b>Copyright:</b> Johns Hopkins University (JHU) owns the copyright to the RSVP questionnaire.	Johns Hopkins University School of Public Health 615 North Wolfe Street Baltimore, MD 21205-2179 Tel: 410-955-1680
<b>WHOQOL</b>	<b>Generic</b> (Most countries)	<b>Conditions for use:</b> * with the signature of a contract/ agreement * In order to obtain permission for use of the various language versions it is necessary to contact the collaborating sites directly. The national WHOQOL centres are at: <a href="http://WHOQOL">WHOQOL</a>	<b>Copyright :</b> The World Health Organisation	WHOQOL Department of Mental Health World Health Organization 1211 Geneva 27, Switzerland Tel: +41 22 791 36 34 Fax: + 41 22 791 41 60 E-mail:whoqol@who.ch The WHOQOL instrument: <a href="http://WHOQOL-BREF">WHOQOL-BREF</a> WHO instruments web: <a href="http://www.who.int">www.who.int</a>

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<b>WOMAC Index</b> (Western Ontario and McMaster Universities Osteo-Arthritis Index)	Specific (Adults 55+ years Osteoarthritis, Australia)	<b>Conditions of use:</b> * Complete e-form at the Womac website	<b>Copyright:</b> Copyright : Professor N. Bellamy	Professor N. Bellamy, Centre of National Research on Disability and Rehabilitation Medicine (CONROD), University of Queensland, Mayne Medical School, Herston Road Herston, Queensland 4006, Australia Phone: +61 7 3365 5560 Fax: +61 7 3346 4603 E-mail: nbellamy@medicine.uq.edu.au or n.bellamy@mailbox.uq.edu.au Web: <a href="http://www.womac.org">www.womac.org</a>