



**Title:** EuroQol IP Protection Policy

**Authors:** Legal Team EuroQol Office

**Date of issue:** 07 January 2021

**Version number** 2.0

## Table of contents

1.	IP Protection Policy .....	3
1.1	General.....	3
1.2	Definitions.....	3
1.3	Policy.....	4
1.3.1	Written permission/ license agreement .....	4
1.3.2	Reproduction of EuroQol instruments in a publication or on a website .....	4
2.	Categorization.....	4
2.1	Category A: Approved Version.....	4
2.2	Category B: Beta Version .....	5
2.3	Category C: Experimental Version .....	5
2.4	Category D: Modified Version.....	6
2.5	Category E: Disapproved Version.....	7
3.	Legal team actions .....	7
3.1	EuroQol instrument use without permission.....	7
3.2	Publication of EuroQol instrument without permission.....	7

## 1. IP PROTECTION POLICY

### 1.1 General

The EuroQol Research Foundation (hereinafter: “**Foundation**”) manages the intellectual property rights of all instruments owned by the EuroQol Group Association (hereinafter: “**EuroQol Group**”). The Foundation is thus entitled to distribute and commercialize these instruments, including, but not limited to, the family of EQ-5D and EQ-HWB instruments. This includes negotiating license agreements. Therefore, as part of the Foundation the [EuroQol Office](#) (hereinafter: “**EQ Office**”) is entitled to protect the IP rights of EuroQol instruments.

### 1.2 Definitions

- A. EuroQol instruments** are instruments developed or co-developed by the EuroQol Group, of which the IP Rights are held by the EuroQol Group, and which are managed by the Foundation.
- B. EQ-5D** is a family of standardized measures of health-related quality of life developed by the EuroQol Group to provide simple, generic questionnaires for use in clinical and economic appraisal or population health status surveys. Available in several versions, including EQ-5D-3L, EQ-5D-5L, and EQ-5D-Y.
- C. EQ-HWB** is a family of standardized instruments measuring aspects of both health outcomes and well-being. The instrument is currently under development by the EuroQol Group. Initial work was done by a team at the School of Health and Related Research (SchARR) at the University of Sheffield, in collaboration with researchers from the EuroQol Group. All IP Rights in EQ-HWB were transferred to the Foundation.
- D. Legal Team** of the EQ Office is the team responsible for handling requests for use of EuroQol instruments. Furthermore, the Legal Team manages licenses and performs legal research on behalf of the EQ Office. This team consists of a Legal Team Leader, Legal Counsels and a User Support Officer.
- E. Intellectual Property Rights** (hereinafter: “**IP Rights**”) means copyrights, neighboring rights, patents, design rights, trademarks, service marks, database rights, know-how, trade or business names, rights in confidential information and all other intellectual property rights and rights of a similar nature, whether registered or unregistered and wherever in the world such rights arise. The Intellectual Property Rights include the aforementioned rights regarding or in connection with EuroQol instruments (any version) and the brand names of EuroQol instruments (any version). The IP Rights do not include data collected with EuroQol instruments, nor value sets estimated for EuroQol instruments.

### 1.3 Policy

Prior written consent from the EQ Office is required to use, test, reproduce, alter, amend, convert, transfer, translate, publish, or otherwise make EuroQol instruments available, regardless of mode of administration (self-complete, interview, etc.), language, or form (digital, hard-copy, etc.).

The Foundation is the single point of distribution of EuroQol instruments.

#### 1.3.1 Written permission/ license agreement

For the use of EuroQol instruments, an online registration is required at the Foundation's website: <https://euroqol.org/eq-5d-registration-form/>. Written permission will be provided, or a license agreement will be arranged, in accordance with the applicable [User License Policy](#).

The Foundation's permission and licenses are only provided for use of EuroQol instruments to the parties explicitly accepting the provisions of the applicable documentation, wherein the scope is indicated as well.

#### 1.3.2 Reproduction of EuroQol instruments in a publication or on a website

A request to display (parts of) a EuroQol instrument in a publication (book, article, dissertation, thesis, etc.) or on a website should be submitted via the EuroQol registration page. In general, permission is provided for non-commercial purposes and for the English (UK) sample versions only. Upon acceptance of the Terms of Use Reproduction for reproducing a EuroQol instrument, a sample version will be provided for use in the publication.

## 2. CATEGORIZATION

The applicable IP protection policy is based on five different categories described below:

### 2.1 Category A: Approved Version

A EuroQol instrument is classified as an Approved Version on the recommendation of the [Executive Committee](#) (hereinafter: "**Exec**"), a governing body of the EuroQol Group. There must be adequate evidence supporting the sufficient quality of the EuroQol instrument for this progression to take place. In most cases, the Exec will have approved funding of the scientific studies necessary for the final development of this EuroQol instrument. Once the Exec has signed off on this EuroQol instrument, it is made available to the wider public as an approved EuroQol instrument. The Foundation makes the Approved Version available to users upon registration at the EuroQol website in accordance with the applicable User License policy.

Approved Versions are listed on the Foundation's website as available versions. These versions have been reviewed by the [Version Management Committee](#). This EuroQol committee is responsible for the quality of the translation process of all EuroQol instruments.

## 2.2 Category B: Beta Version

A Beta Version of a EuroQol instrument refers to a category given by the Exec to designate a EuroQol instrument that is under development. The Exec can decide that instrument development has sufficiently advanced to merit granting a EuroQol instrument the status of Beta Version. This status implies that the body of evidence on this EuroQol instrument has not yet reached the level where the Exec can decide to make the EuroQol instrument available as an Approved Version.

The Exec may decide to make Beta Versions available to users under the following conditions:

- A Beta Version will be provided on an 'as-is' basis. As this is not a final product, updated versions may be released, which may differ substantially from the previous version.
- The Foundation will not support users of a Beta Version to the same levels as users of an Approved Version. For example, user guides will not be made available and the Version Management Committee may not provide support to the same level as for Approved versions.
- The Foundation may charge a licensing fee for using a Beta Version. Alternatively, it may charge a fee for using the Approved Version on which the Beta Version is based. The applicable User Licence policy will determine if a fee is required.
- The Foundation cannot be held liable for any damages resulting from use of a Beta Version.

## 2.3 Category C: Experimental Version

(Note that in a previous version of the IP Protection Policy an Experimental Version was defined as "an EQ-5D version or format that has been created for the purpose of a methodological research study and/or publication". In this current version of the IP Protection Policy such an EQ-5D version falls under the category of Modified Version, See section 2.4)

An Experimental Version is a category used exclusively to designate EuroQol instruments in an early stage of development by the EuroQol Group that are not sufficiently advanced to be classified as a Beta Version. Experimental Versions are not made available to users. However, the EQ Office can share Experimental Versions with researchers who are conducting Exec-approved research. The following conditions apply:

- Researchers are not allowed to distribute Experimental Versions beyond study sites participating in the study.

- Separate written permission must be obtained if the researcher wants to display (parts of) an Experimental Version in a publication.
- The Foundation cannot be held liable for any damages resulting from use of an Experimental Version.

## **2.4 Category D: Modified Version**

(Note that in a previous version of the IP Protection policy an EQ-5D version or format that had been created for the purpose of a methodological research study and/or publication was designated as an Experimental Version. In this current version of the IP Protection Policy such an EQ-5D version falls under the category of Modified Version, see below. the Experimental Version category is now used exclusively to designate EuroQol instruments in early stages of development.)

A Modified Version is a category used to designate a modified version of an Approved Version or a Beta Version of a EuroQol instrument. Researchers interested in assessing the effect of adding or removing a dimension, changing the layout, or changing the wording of any part of a Beta or Approved Version of a EuroQol instrument should contact the EQ Office. In line with our Policy, as described in section 1.3, a request for permission to modify a EuroQol instrument should be submitted via the registration page on the EuroQol website. The Legal Team will set up a Permission to Modify agreement, in which the following points are described:

- Explicit written permission to modify a EuroQol instrument can be given for use in a specified study only.
- The researcher is not allowed to distribute a Modified Version beyond study sites participating in the study.
- Separate written permission must be obtained if the user wants to display (parts of) a Modified Version in a publication.
- As part of the permission to modify agreement, IP Rights on a Modified Version will be automatically transferred to the EuroQol Group.
- The Foundation does not provide any support on the use of a Modified Version.
- The Foundation cannot be held liable for errors in a Modified Version or any damages resulting from use of a Modified Version.

Once the Permission to Modify agreement has been signed, the requested Approved or Beta Version of the EuroQol instrument will be provided, which the user can then modify as described in the agreement.

Note that the Foundation will generally not make Modified Versions available. However, permission can be obtained from the Foundation to modify a EuroQol instrument as described in an existing scientific publication. The Legal Team will then determine if a transfer of IP rights is needed as well.

## **2.5 Category E: Disapproved Version**

A Disapproved Version is a category used to designate modifications or versions of EuroQol instruments that were created without the Foundation's explicit permission. After Board approval, the Legal Team and the EQ Office's Executive Director will decide on appropriate action.

## **3. LEGAL TEAM ACTIONS**

Upon a notification of potential use or publication of EuroQol instruments without written consent, the Legal Team will contact the user to request additional information about their use or publication of the EuroQol instrument and their obtained permissions. Based on this information, the Legal Team will take the appropriate action.

### **3.1 EuroQol instrument use without permission**

The following cases will trigger action by the Legal Team:

- Use of a EuroQol instrument without written consent of the Foundation;
- Sharing the EuroQol instrument with parties not covered in an agreement or for which the Foundation did not give written consent.

In these cases the Legal Team will request the user(s) to do the following:

- a. Retroactively register the EuroQol instrument use via the online EQ registration form and provide information about the use (e.g. number of respondents).
- b. Forward the used version(s) to the Legal Team.
- c. Provide information about the use (e.g. number of respondents).

The Legal Team, in consultation with the EQ Office's Executive Director, will then determine if further action is required.

### **3.2 Publication of EuroQol instrument without permission**

The following cases will trigger action by the Legal Team:

- Making a EuroQol instrument available to, or accessible by, the public (outside a study) without written permission;
- Displaying a EuroQol instrument in a publication (book, article, dissertation, thesis, etc.), partially or in full, without written permission;

The Legal Team will contact the website owners, journal editors or authors to notify them of the infringement of EuroQol IP rights. The Legal Team, in consultation with the EQ Office's



Executive Director will then determine which action is required. In case of illegal distribution of EuroQol instruments, the Legal Team will send a takedown notice to the website owners or journal editors to remove the EQ instruments from the internet.