



EQ-5D User License Policy

Procedure and fee structure

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The information in this document is subject to change without notice and shall not be deemed as a warranty by the EuroQol Research Foundation.

EuroQol Research Foundation
Marten Meesweg 107
3068 AV Rotterdam
The Netherlands
T: +31 88 202 6890
<https://user.euroqol.org/support>

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www.euroqol.org

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1. Using EQ-5D

1.1. General

The EuroQol Research Foundation manages the intellectual property rights of all instruments owned by the EuroQol Group Association (hereinafter: 'EuroQol Group'). The EuroQol Research Foundation distributes and commercialises the EuroQol Group instruments, including, but not limited to, the family of EQ-5D instruments. If you would like to use the EQ-5D, written permission from the EuroQol Research Foundation must be obtained.

The EuroQol Research Foundation is a registered charitable institution in the Netherlands and serves as the single point of distribution of the family of EQ-5D instruments. The EuroQol Office Team processes all incoming requests for using EQ-5D. The vast majority of requests to use the EQ-5D result in free-of-charge use. In instances where license fees are charged, this source of income allows the EuroQol Research Foundation to fund activities in line with the EuroQol's Vision and Mission as described on its [website](#). Main activities include, but are not limited to, funding research projects, organising scientific meetings and providing support to users of the family of EQ-5D instruments.

The EQ-5D can be obtained as a 3-level (3L) or 5-level (5L) version for adults and / or as a 3-level version (Y-3L) and a 5-level version (Y-5L) for the youth. Please see the recommended age range for each version below:

0–3 years	No EQ-5D-Y version is available for this age range
4–7 years	For children aged 4–7, the EQ-5D-Y Proxy version should be used No self-reported EQ-5D-Y is available for this age range at present
8–11 years	EQ-5D-Y should be used The EQ-5D-Y is more understandable for children in this age range than an adult version of the EQ-5D
12–15 years	Both the EQ-5D-Y and adult EQ-5D versions can be used Generally, EQ-5D-Y is recommended. However, depending on study design, it might also be appropriate to use one of the EQ-5D adult versions. For example, if a study includes both adult respondents and respondents between the ages of 12 and 15, the study team might prefer to use just one version of EQ-5D across the whole study population
16 years and adults	Use an adult version (EQ-5D-3L or EQ-5D-5L) A possible exception would be a study that only includes children up to age 18. In this case, it may be preferable to use EQ-5D-Y in all study participants, to avoid using two different versions of EQ-5D

EQ-5D is primarily designed for self-completion. Self-completion means that respondents will complete the questionnaire themselves, without assistance. If respondents cannot manage this, EQ-5D versions are available for completion by interviewers or caregivers, see below:

Situation	Who completes EQ-5D	Whose health status is reported	EQ-5D version
Respondents are physically and mentally able to complete the questionnaire themselves	Respondent	Respondent	• Self-complete
The respondents are physically unable to complete the questionnaire themselves, but can communicate the answers to an interviewer	Interviewer	Respondent	• Interviewer administered (IA) • Telephone (will be superseded by IA) • Face-to-face interview (will be superseded by IA)
The respondents are mentally unable to complete the questionnaire themselves. Instead, a caregiver who knows the person well will assess the health of the respondent, who is unable to communicate the answers	Caregiver	Respondent, as reported by Caregiver.	• Proxy 1^a
The respondents are mentally unable to complete the questionnaire themselves. An interviewer asks the caregiver who knows the person well to assess the health of the respondent, who is unable to communicate the answers	Interviewer	Respondent, as reported by Caregiver	• IA Proxy 1

- a. Proxy version 1: The proxy (parent, other caregiver or informant) is asked to respond to the questionnaire by providing their own impression of the child or adolescent's health status on the day of administration. Note that Proxy 2 versions have been discontinued. Please contact EuroQol Support if you need a Proxy 2 version.

Further information on the EQ-5D versions and available modes of administration can be found in the User Guides, which can be found [here](#) on the EuroQol website.

EQ-5D data can be entered on paper and on digital devices such as PDA/smartphones, tablets or laptop/desktop computers. A digital version of EQ-5D is available which can be used on any kind of digital device.

1.2. Requesting permission

Registration

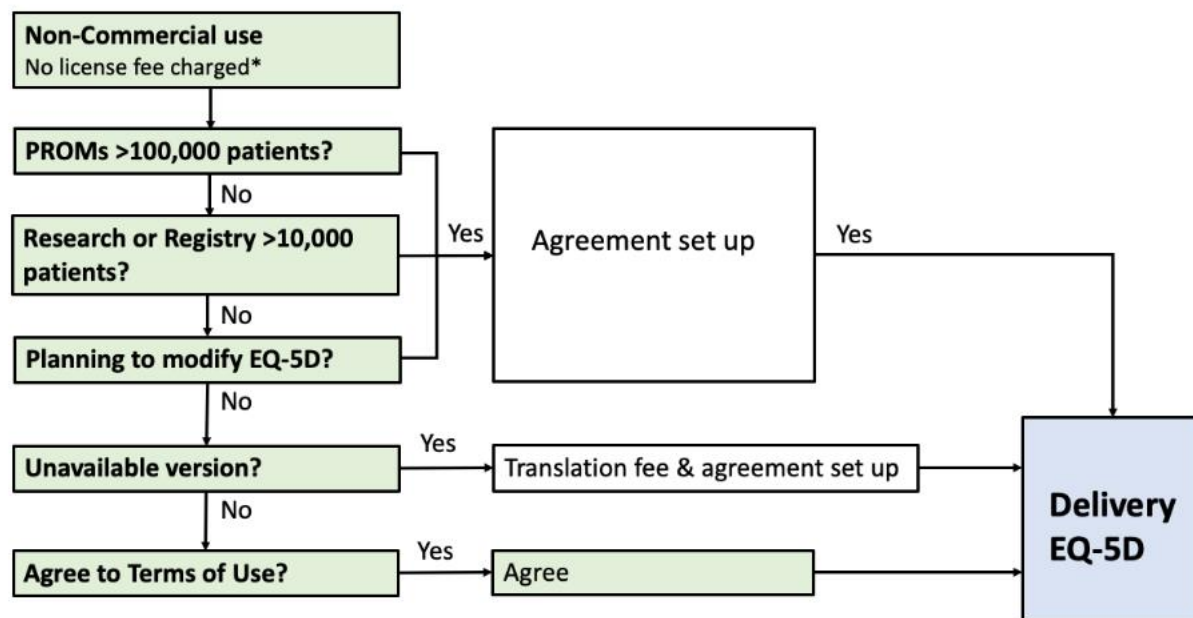
A request to use the EQ-5D is initiated by filling out the registration form on the EuroQol website. After receipt of the registration, the EuroQol Office Team will determine the applicable policy and respond with more information on how the EQ-5D can be obtained.

License process

The EuroQol Research Foundation prefers to license EQ-5D to end-users of the instrument. Third parties, such as consultancies, CROs and vendors, are required to disclose the name of the sponsor during or after the registration in order to check available active license agreements.

Depending on the outcome of the EuroQol Office Team's review (the request might be considered as commercial or non-commercial), a license agreement will be drawn up or acceptance of our Terms of Use for non-commercial users will be required. This User License Policy will be the basis for such review. For a flowchart of the User License Policy, see Diagram 1.

Diagram 1: Flowchart User License Policy



*: Except when EQ-5D data is collected with the intention to charge a fee for access;

Delivery

Once the appropriate agreements are in place, delivery of requested EQ-5D versions will take place via the EQ-5D User Portal, a custom internet portal that users can access during the agreed period (typically 3 years). EQ-5D Paper versions are made available as Microsoft Word files. EQ-5D Digital versions are made available either as modules for Supported Platforms (REDCap, LimeSurvey and Qualtrics) or as Microsoft Excel sheets for any other digital platform, together with the Digital Representation Design Guidelines and example Representations for each requested country and language. Note that modules for Supported Platforms are made available only to non-commercial users due to restrictions imposed by these platforms.

Use

The EQ-5D Paper versions and the Supported Platforms Modules are ready for use and should be used as-is. The wording of these Modular EQ-5D versions has been checked by the EuroQol Office Team and the correct screen layout is integrated in every modular version.

For regular EQ-5D Digital versions the user will be responsible for implementing the EQ-5D on a digital platform of choice. To assist with the correct digital implementation of EQ-5D, the Digital Representation Guidelines and example Representations are provided via the EQ-5D User Portal. The Digital Representation Design Guidelines are detailed instructions on how to build the digital implementation on a digital platform. The Representations are example screenshots of digital reproductions for each requested language adhering to the Digital Representation Guidelines, and the language specifics as shown in the delivered Microsoft Excel translation sheets. These Representations will allow users and vendors to check their digital EQ-5D implementation themselves for adherence to EuroQol's standards and for the correct implementation of all EQ-5D elements, as provided in the Microsoft Excel sheet.

Note that users of EQ-5D Digital versions are solely responsible for the correct implementation of EQ-5D. The EuroQol Research Foundation does not accept any liability due to incorrect digital implementation of EQ-5D by a user or vendor. Any deviation of the Representation is at the own risk of the user. Therefore, users are strongly encouraged to set up a quality process for checking the correctness of all digital EQ-5D implementations prior to the start of data collection. Screenshot review by the EuroQol Office team is no longer mandatory. However, the EuroQol Office Team is available to help with screenshot review or digital implementation issues.

1.3. Non-commercial use

After registration, EQ-5D can be used for free by non-commercial parties. No license fee will be charged for EQ-5D use of any scale, large or small. Please note that it is not allowed to commercialise (e.g., resell or make available for commercial intent) the collected EQ-5D data. Instead, if there is commercial interest in the EQ-5D data, please contact the EuroQol Office and the fee will be determined based on the size and scope of the request. The maximum term for which permission can be arranged is 10 years. Users should re-register after this term to request permission to continue using the EQ-5D.

1.4. Non-commercial use (research)

In case of non-commercial requests to use the EQ-5D for research purposes, such as randomised controlled trials, cohort studies, case-control studies and cross-sectional studies, no license fee is charged to use the EQ-5D. The rationale is that such use is in line with the EuroQol Research Foundation's Mission: This use will result in new publications on EQ-5D, which is of benefit to the EuroQol Group and its members, and to the scientific community as a whole.

For large research studies ($N > 10,000$), additional terms may apply. These terms could involve a statement that the licensee will kindly review future requests from individual EuroQol members for research collaboration and data sharing. Considering that the EQ-5D is provided free of charge for this substantial data collection,

such a request for research collaboration or data sharing should not result in fees being charged to the EuroQol member.

1.5. Non-commercial use (non-research)

In case of non-commercial requests to use the EQ-5D for non-research purposes, such as clinical use, for benchmarking, reporting to authorities, or for Patient-Reported Outcome Measurement (PROM) / Routine Outcome Measurement (ROM), no license fee is charged to use the EQ-5D.

This includes use of EQ-5D by hospitals, clinics and health insurance companies, both publicly and privately funded.

For very substantial projects involving >100,000 patients, a license agreement will be drawn up at no cost. At the discretion of the Board of the EuroQol Research Foundation, special arrangements may be put in place for these very substantial projects, such as research collaboration and/or collaborative research funding.

Granting these requests without charging a license fee is in line with the Vision of the EuroQol Research Foundation, which is to improve decisions about health and health care throughout the world.

1.6. Non-commercial use of digital versions

The EuroQol Research Foundation has developed modular digital EQ-5D versions for use on popular survey platforms such as REDCap, LimeSurvey and Qualtrics. These modular digital versions for supported digital platforms can be used free of charge by non-commercial users. Upon acceptance of the Terms of Use for non-commercial users the requested EQ-5D modules will be provided, as well as a guidance document. Please see section 2 if your requested EQ-5D module is not available.

For the digital use of EQ-5D on currently unsupported digital platforms, for which no modular digital versions are available, the regular digital versions can be used. These digital versions can be used on any kind of digital device.

As outlined in Section 1.2, the user is responsible for the correct implementation of EQ-5D. To assist with the correct digital implementation of EQ-5D, the Digital Representation Guidelines and example Representations are provided via the EQ-5D User Portal, together with the requested versions..

1.7. Commercial use

A commercial company, such as a pharmaceutical company, medical device manufacturer or any other for-profit stakeholder can register on the EuroQol website to use the EQ-5D. After registration, the EuroQol Office Team will check whether the requester already owns an active license agreement for the requested version; if not, a license fee is proposed. If the proposal is acceptable, a new license agreement – or an amendment, in the case of an existing agreement – will be established between the company and the EuroQol Research Foundation.

A license agreement will specify which EQ-5D language versions can be used. The agreement is limited to a single format (paper or digital; see Section 1.2). The effective term of the license is 3 years. The company

receives permission to use the specified EQ-5D language versions for a given format in all (clinical) studies/projects starting during the 3-year period.

Once the license agreement has been fully executed, the EuroQol Research Foundation will deliver the licensed languages via the EQ-5D User Portal that will be accessible for 3 years, see Section 1.2. Finally, the invoice will be delivered according to the instructions in the license agreement.

1.7.1. License fee structure for commercial use

License agreements are provided per EQ-5D version (i.e. EQ-5D-3L, EQ-5D-5L, EQ-5D-Y-3L or EQ-5D-Y-5L), format (i.e. paper or digital) and language. License fees are calculated accordingly.

Example license agreement structure:

- *A license agreement can be provided to a commercial company for the use of EQ-5D-5L paper version in English for the USA and Spanish for the USA.*
- *If this commercial company would also like to use the digital format of EQ-5D-5L in the same languages, a separate license agreement is required for the use of the digital format of EQ-5D-5L.*

Note that a license agreement covers not only self-complete versions, but also all available interviewer-administered, telephone, face-to-face interview and proxy versions. Please see the EuroQol website to verify the availability of such versions.

Example version inclusion:

- *A license agreement for the use of EQ-5D-5L on paper in English for the USA covers the use of the self-complete version and the interviewer-administered, proxy 1 versions, if available.*

The fee for a 3-year license agreement for use of the EQ-5D-3L, EQ-5D-5L, EQ-5D-Y-3L or EQ-5D-Y-5L is as follows:

1. Paper format, per language	€4,600
2. Paper format exception: Same language, <i>but different country</i>	€2,300
3. Digital format, per language	€7,000
4. Digital format exception: same language, <i>but different country</i>	€3,500
5. Paper format, all available languages (Fixed Price Agreement)	€92,000
6. Digital format, all available languages (Fixed Price Agreement)	€139,000

As the use of a language differs per country, EQ-5D language versions are validated for use in a specific country and are quoted as such.

EQ-5D data can be collected on paper, or digitally on any kind of digital device (PDA/smartphone, tablet or laptop/desktop computer).

If a commercial company intends to use more than 20 EQ-5D language versions on paper or digitally in 3 years, a **Fixed Price Agreement** is recommended. A paper format Fixed Price Agreement costs €92,000 and will give access to all available paper language versions. A Fixed Price Agreement for the digital format costs €139,000 and will give access to all available language versions.

Note that a Fixed Price Agreement (paper, or digital) will include access to all new language versions becoming available for that format within the 3-year license period.

Example license fee structure:

- *The license fee for using the EQ-5D-5L on paper in English for the UK version is €4,600. Also licensing the EQ-5D-5L paper version in English for the USA would cost an additional €2,300.*
- *The license fee for using the regular digital format of EQ-5D-5L in English for the UK version is €7,000.*
- *The license fee for using the regular digital format of EQ-5D-3L in all available languages is €139,000.*

Note for companies interested in collecting EQ-5D data with the intention to commercialise (e.g., resell) this data, the fee structure noted above will not be followed. Instead, the fee will be determined by the EuroQol Office Team, based on the size and scope of the request.

1.8. Third-party agreements

Third parties, such as consultancies, CROs or vendors, are entitled to administer the EQ-5D on behalf of a commercial company after signing a free-of-charge third-party agreement. Such an agreement enables the third party to facilitate the use of EQ-5D languages in a specific study, trial or project. The requested EQ-5D languages will be provided to the third party via the EQ-5D User Portal only once the EuroQol Office Team receives the signed third-party agreement. Please note that clinical study sites are exempted from this requirement.

The license agreement will always be between the end-user concerned and the EuroQol Research Foundation. Negotiations regarding the license agreement can proceed via the third party, if preferred.

2. Translation process

2.1. EQ-5D translations

The EuroQol Research Foundation will explore the feasibility of translating EQ-5D into currently unavailable languages upon request. Assuming that our partner LSP's (Language Service Providers) indicate the resources are available, the EuroQol Office Team will lead the translation project. All translations/adaptations of EQ-5D are produced according to EuroQol's standardised translation protocol, which complies with internationally recognised guidelines. These guidelines aim to ensure equivalence to the 'source' version and consists of, *inter alia*, a forward/backward translation process and cognitive debriefing.

The value of EQ-5D to users is that the multitude of versions and languages allows for multi-country and within-country trials. This will only be possible if there is congruence between the versions in terms of the content and layout, and if the results obtained using the same version in different languages will be interchangeable.

2.2. Managing the translation process

The Version Management Committee (VMC) and the Version Management Team (VMT) in the EuroQol Office are responsible for the quality of the translation process of all EQ-5D language versions.

The VMC and VMT do not undertake translations: their role is to ensure that every translation of a version is as consistent as possible with all the other versions and uses phrasing appropriate to the specific country, language and age group.

2.3. Requesting new language versions

Please complete the [registration form](#) on the EuroQol website if you would like to obtain an EQ-5D version that is not available according to the overviews on our website.

Once the translation request has been validated, the VMT Project Management Team will consult EuroQol's partner LSP's to determine:

- whether the requested translation(s) can be delivered
- if the requested translation(s) can be delivered within your deadline
- what the associated costs will be.

If you agree with the translation costs and the estimated delivery date(s), you will have to sign an Approval Letter to initiate the translation process for the new language version(s). Once the Approval Letter is signed and the EuroQol Office confirms receipt, the translation process will start. Hereafter, cancellation costs may apply if you decide to terminate the translation project.

2.4. Translation Policy

Please be advised that only translations of official languages of countries will be initiated by our VMT. At the discretion of the team exceptions can be made if the language is widely used, is a native language or if the language is of scientific interest.

Use of non-official languages

The use of non-official languages in a country is only allowed after written permission of the EuroQol Office (by example the English (UK) version in Belgium). Additionally, once permission is obtained from the Office, the cover page of the questionnaire should reflect the country the version is used in.

Example Cover Page text:

**English version for the UK
for use in Belgium**

→ official text
→ added for non-official use by user

It is allowed to choose any available non-official language version to use in a country. For example, for the use of an English version in Belgium, it is allowed to use any available English version (English (USA), English (UK), English (India), etc). However, for the most accurate results the language version must be understood well by the patient, therefore we advise to choose the language version based on the background of the patient (the country the patient is originally from or if such a version does not exist, we advise to use a language from a country nearby). Please find all available language versions on our website.

2.5. Translation costs

In principle, translation costs for a new language version and an admin fee are covered by the user requesting it. In exceptional cases, at the discretion of the EuroQol Research Foundation, non-commercial users will be offered a waiver for (part of) the translation costs. Please contact the EuroQol Office for more information.

2.6 Alternative translation options

The EuroQol standardised translation protocol to produce official EQ-5D translations follows a strict quality assurance process. EuroQol acknowledges that linguistic resources may be limited or unavailable for certain less commonly translated languages. Additionally, it is recognized users' timelines might not align with the time required to complete the quality assurance process. Therefore, alternative options deviating from the standardized EuroQol translation protocol are available at the user's own risk. Please contact the EuroQol Office to discuss the options.

2.7 Best available version

In the event that an independent translator is contracted to initiate the translation process, the final required step of the translation protocol is to verify the translations with a LSP (for certification and liability purposes). If there are insufficient linguistic resources at EuroQol's partner LSP's, and EuroQol is not able to complete the quality assurance process, the translation cannot be added to the official EQ-5D product library. However, these languages can be made available on request as a '*best available version*', to be used at the own risk of the user. Please find the list of '*best available versions*' on our website. The versions can be requested via the Registration Form or via the Support Form.

3. Intellectual property rights

All intellectual property rights in the EQ-5D, its (digital) representations, and its translations exclusively vest in the EuroQol Research Foundation. Without the prior written consent of the EuroQol Research Foundation, it is not permitted to use, reproduce, alter, amend, convert, translate, publish or make available in any way (digital, hard-copy etc.) the EQ-5D, or parts thereof, and related proprietary materials. When permission is obtained to reproduce or publish the EQ-5D, please use the following copyright and trademark statement:

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4. Contact information

For any questions regarding the EQ-5D User License Policy, please contact the EuroQol Office at the following address and contact details:

EuroQol Research Foundation
Marten Meesweg 107
3068 AV Rotterdam
The Netherlands

T: +31 88 202 6890
<https://user.euroqol.org/support>

Bernhard Slaap
Executive Director
T: +31 88 202 6890
E: slaap@euroqol.org

Gita Varma
Operations Director
T: +31 88 202 6880
E: varma@euroqol.org