Complete on screen

Form for disclosing relationships[1]

- Background -

The Institute for Quality and Efficiency in Health Care (IQWiG) has the task of developing scientific recommendations on medical issues. In accordance with the law (§139a [para. 1] Social Code Book V [SGB V] – statutory health insurance https://www.gesetze-im-internet.de/sgb_5/__139a.html), it operates with professional independence. It therefore also expects unbiased fair judgement from all those involved in the preparation of its products. To this end, you as a person involved by IQWiG are asked to disclose relationships that may influence this goal – so-called conflicts of interest. This concerns all relationships with health care institutions, in particular **pharmaceutical companies, medical device manufacturers and industrial interest groups**, but also other relationships that may give rise to conflicts of interest, such as involvement in guideline development.

The disclosure of such relationships is made on the basis of the questions in this form. Answering 'yes' to a question and then disclosing relationships does not automatically constitute a conflict of interest, as relationships are considered in relation to the underlying project question and the nature and extent of participation.

Details on what relevance the information provided has for IQWiG, and how this information is dealt with, are explained at https://www.iqwig.de/en/: 'Frequently asked questions about the form for disclosing relationships' (see https://www.iqwig.de/en/participation/disclosing-relationships/faq-form-for-disclosing-relationships/).

- Data protection -

The details of your disclosure will be treated confidentially. Only IQWiG staff involved in processing and evaluating the information are given access. If a contract is concluded (this only applies to reviewers and external experts), all persons who are allowed to view the contract also have access. If you are involved in the preparation of an IQWiG product, e.g. as an external expert or reviewer, or assist in the identification of patient-relevant outcomes, your information will be summarised and made publicly available in IQWiG's products on IQWiG's website www.iqwig.de or www.gesundheitsinformation.de. For the criteria listed in questions 1 to 7, it is only summarised whether this type of relationship exists or not. Concrete partners or amounts of payments are not mentioned.

If you participate as an external expert or reviewer, your name will also be mentioned in the product. If you help to identify patient-relevant outcomes, your name will only be mentioned if you consent to this on a separate consent form. Your consent to be named is voluntary. If you do not consent, the information about your relationships will be anonymous.

[1] Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

SAMPLE

- Instructions for completing this form -

This form asks 7 questions about different types of relationships. If you do not have a relationship of this type, please tick 'no'. Otherwise, for each question, please provide a complete list of your relationships and – if requested in the respective question – the amount of any remuneration. So please fill in all columns of the table to describe a relationship, or give reasons if you cannot fill in a field. If additional space is required, you may attach additional pages. If you fill out the form electronically as a PDF file, you can add as many rows as you like to each table.

Please indicate ALL relationships in response to the questions, even if you think that a relationship does not constitute a conflict of interest (exception question 7, see there).

Project (number and title):

Project number: _____

Project title: _____

Task:

- ☐ Collaboration as an external expert on an IQWiG product
- ☐ Collaboration as a medical-scientific advisor (e.g. for an early benefit assessment, assessment of potential, or a new examination and treatment method with high-risk medical devices)
- ☐ Production of a ThemenCheck (Topic check) report according to §139b (para. 5) SGB V
- ☐ Information on patient-relevant outcomes
- ☐ Other: _____

Contact information:

Title (if any), first name, last name: _____

For queries, email address: _____

or telephone number: _____

SAMPLE

Question 1: Employment / self-employed activities / voluntary activities

Are you, or have you been, within this year and the last three calendar years employed by

- an organisation in the health care system (e.g. a hospital, an organisation in the self-government, a professional association, a contract research organisation)
- a pharmaceutical company
- a medical device manufacturer
- an industrial interest group

or have you worked for them on a self-employed or voluntary basis, or are you, or have you been, self-employed in your own practice?

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please add the following details

Company etc.	From (month/year)	To (month/year)	Position	Employed / self-employed / voluntary

>> Add a further entry for question 1 <<

SAMPLE

Question 2: Consulting relationships

Are you, or have you been, within this year and the last three calendar years advising

- an organisation in the health care system (e.g. a hospital, an organisation in the self-government, a professional association, a contract research organisation)
- a pharmaceutical company
- a medical device manufacturer
- an industrial interest group

(e.g. as a reviewer or expert, in connection with clinical trials as a member of an advisory board / Data Safety Monitoring Board [DSMB] or a steering committee)?

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please add the following details (separately for each company and consulting topic)

Company etc.	Consulting topic	Period	Total sum of payments

>> Add a further entry for question 2 <<

SAMPLE

Question 3: Fees

Have you, within this year and the last three calendar years, directly or indirectly received fees from

- an organisation in the health care system (e.g. a hospital, an organisation in the self-government, a professional association, a contract research organisation)
- a pharmaceutical company
- a medical device manufacturer
- an industrial interest group

(e.g. for talks, trainings, comments or articles)?

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please add the following details (separately for each company)

Company etc.	Type of work	Topic	Date/period	Total sum of payments

>> Add a further entry for question 3 <<

SAMPLE

Question 4: Third-party funds

Have you or your employer or your practice or the institution for which you do voluntary work, within this year and the last three calendar years, received third-party funds, i.e. financial support (e.g. for research activities, the conduct of clinical studies, other scientific services, or patent applications) from

- an organisation in the health care system (e.g. a hospital, an organisation in the self-government, a professional association, a contract research organisation)
- a pharmaceutical company
- a medical device manufacturer
- an industrial interest group?

(If you work in a large institution, it is sufficient to relate the required information to your working unit, e.g. hospital department, research group.)

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please add the following details (separately for each company and project topic)

Company etc.	Project type	Project topic	Period	Total sum of third-party funds	Recipient: personal/ institution

>> Add a further entry for question 4 <<

SAMPLE

Question 5: Other support

Have you or your employer or your practice or the institution for which you do voluntary work, within this year and the last three calendar years, received any other financial remuneration or payment in kind (e.g. equipment, staff, support with organising an event, reimbursement of travel expenses or registration fees for trainings/conferences) from

- an organisation in the health care system (e.g. a hospital, an organisation in the self-government, a professional association, a contract research organisation)
- a pharmaceutical company
- a medical device manufacturer
- an industrial interest group?

(If you work in a large institution, it is sufficient to relate the required information to your working unit, e.g. hospital department, research group.)

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please add the following details (separately for each company etc.)

Company etc.	Type of support	Period	Sum	Recipient: personal/ institution

>> Add a further entry for question 5 <<

SAMPLE

Question 6: Stocks, shares, patents, utility models

Do you possess stocks, options or other shares from

- an organisation in the health care system (e.g. a hospital, a contract research organisation)
- a pharmaceutical company
- a medical device manufacturer
- an industrial interest group?

Do you possess shares in a so-called 'sector-specific fund' that is targeted towards pharmaceutical companies or medical device manufacturers?

Do you possess patents for a pharmaceutical product, a medical device or a medical method, or a utility model for a pharmaceutical product or a medical device?

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please add the following details (separately for each type of stock/share/fund/patent/utility model etc.)

Stock/share/fund/patent/utility model	**Current value**

>> Add a further entry for question 6 <<

SAMPLE

Question 7: Other

Are you or have you ever been involved in the production of a

- clinical guideline or
- clinical study

with a topic similar to this project?

Are there any other circumstances that, from the point of view of an impartial observer, may be assessed as conflict of interest (e.g. activities in health-related interest groups or self-help groups, political, academic, scientific or personal interests)?

☐ No
☐ Yes (if yes, please provide details in the table below)

If yes, please list them

>> Add a further entry for question 7 <<

SAMPLE

I hereby confirm with my signature that I have truthfully and completely provided these details.

I am aware that the above-mentioned details will be published in the corresponding product, which is accessible on the IQWiG website and forwarded to the Bonn University and State Library and to the German National Library, in a summarised form together with my name. **'Summarised form' means that the answers to the questions of this form will be published as 'yes' or 'no', but without stating the specific details (including the amount of remuneration/fees).**

Note: If I participate in a consultation on patient-relevant outcomes as a person affected, my name will only be published with my explicit consent (separate form).

Beyond this, the details provided will not be published.

_____ _____

(Place, date) (Signature)

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