



EDCTP

European & Developing Countries
Clinical Trials Partnership

EDCTP Code of Conduct and Declaration of Interests Policy



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1 Introduction

The integrity of EDCTP and the activities it supports depend on decisions made in a bias-free environment and the avoidance of conflicts and potential conflicts of interest, as well as the appearance of such conflicts. EDCTP expects all individuals who are involved in EDCTP activities, in particular individuals serving in governance and advisory positions, to comply with high standards of professional conduct.

EDCTP's procedures and principles for managing potential conflicts of interest and for ensuring confidentiality within its governance and decision-making bodies and processes are described in this policy. Any individual involved in EDCTP activities should understand fully the terms of his/her appointment, duties and responsibilities, and act accordingly. It is recognised that there are varying degrees of conflict. EDCTP expects that all potential conflicts should be disclosed so that the relevance of a potential conflict can be evaluated.

Breaches of the Code and Policy will be investigated and EDCTP has the right to take action in cases where individuals have exhibited biased behaviour or action. These actions may include:

- Requiring an individual to choose between the competing activities
- Prohibiting an individual from playing a decision-making role in EDCTP relevant to the conflict
- Exclusion from participating in EDCTP review processes, committees and governance bodies

2 Scope and definitions

This Code and Policy applies to the following persons:

- Members of the EDCTP General Assembly (GA)
- Members of the EDCTP Strategic Advisory Committee (SAC), including the interim SAC
- Members of EDCTP Scientific Review Committees (SRCs)
- External Reviewers (ERs)
- Observers of any GA, SAC and/or SRC meetings
- EDCTP Grantees present and/or participating in EDCTP meetings subject to the Code and Policy
- Consultants, contractors and freelancers performing work on behalf of EDCTP
- EDCTP Executive Director (ED) and other EDCTP Secretariat staff members
- Staff members of European Union Institutions, bodies and agencies present and/or participating in EDCTP meetings
- Any other individuals involved in EDCTP activities, particularly those participating in ad hoc advisory committees, panels or working groups formed by EDCTP.

The following terms apply:

- **Interest** meaning the relation of being objectively concerned in something (having a right or title thereto, a claim thereupon, or a share therein). Declarable interests shall be interests falling within the fields of operation of EDCTP
- **Conflict of Interest (CoI)** meaning a situation where an individual is in a position to exploit his/her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his/her cooperation with EDCTP
- **Annual Declaration of Interest (ADoI)** meaning the written declaration to be submitted annually
- **Specific Declaration of Interest (SDoI)** meaning the written declaration to be submitted before each meeting or activity, such as conducting a review of an application or report
- **Oral Declaration of Interest (ODoI)** meaning the verbal declaration to be made at the beginning of each meeting

Persons subject to this Code and Policy shall declare all interests corresponding to the following definitions:

1. **Scientific** meaning situations where an individual has a professional scientific interest. This includes situations where the individual has:
A **direct (disqualifying) interest** in an application, including where the individual is an applicant, co-applicant or sponsor of a fellow within the same evaluation round and/or has been involved in the preparation of an application
An **indirect (non-disqualifying) interest** in an application, including where the individual holds or is currently seeking funding for research on the subject matter; is a direct competitor of the applicant(s); is a current collaborator or has collaborated with any of the applicants in the past three years as evidenced by joint publications or joint grants or is planning to do so; is supervising or has supervised the doctoral work of any of the applicants; has provided a personal recommendation or letter of support to an applicant or has provided advice or input to an application or proposal.
2. **Financial interest:** economic stake or share in a body with an interest in the subject matter. This includes stocks, equities or bonds; intellectual property rights (royalties, patents, copyright) and any other situation that may result in financial benefit, direct or indirect, from a decision made by EDCTP.
3. **Member of a managing body or equivalent structure:** participation in the internal decision-making (board member, trustee or director) of a public or private entity with an interest in the subject matter.
4. **Member of a scientific advisory body:** participation in the activities of a scientific advisory body (permanent or ad hoc) managed by a body with an interest in the subject matter.
5. **Employment:** any form of regular occupation or business, part-time or full-time, paid or unpaid, including self-employment (consultancy), in any body with an interest in the subject matter.
6. **Ad hoc or occasional consultancy** meaning any ad hoc or occasional activity in which the concerned person provides advice or services to a body with an interest in the subject matter. This includes services provided on an honorary basis (for free or without payment of fees).
7. **Interests of family members and other personal involvement** meaning interests in the subject matter held by partners or persons dependent on the individual submitting the DoI, as well as close personal ties that may result in bias.
8. **Other memberships or affiliations:** any membership or affiliation not falling under the definitions provided above that is relevant for the purpose of this policy, to any organisation or body with an interest in the subject matter, including professional organisations.
9. **Other relevant interests** meaning any interest not falling under the definitions above and relevant for the purposes of this policy.

Each individual covered by the Code and Policy is responsible for considering and disclosing actual or potential conflicting interests.

3 General principles

The following general principles shall apply:

- The identification and handling of conflicts of interest shall be based on the evaluation of the ADoIs, SDoIs and ODoIs
- The responsibility for a complete and truthful declaration shall lie exclusively with the person completing the declaration
- Only activities having taken place in the last three years preceding the submission of the declaration shall be declared

In the category of Scientific Interests, EDCTP makes a distinction between Direct (Disqualifying) and Indirect (non-disqualifying) interests.

With regard to the review of applications, an individual who has a Direct (Disqualifying) interest (as defined above) may not

- Act as a reviewer in relation to any application within the evaluation round

- Be a member of any advisory body or decision-making body within the evaluation round or decision-making process.

All other declared interests will be considered in the context of the EDCTP activity to be undertaken, the role of the individual in the decision-making process and the extent of involvement/potential conflict of interest (CoI). In general, a current interest falling under the following categories:

- Financial
- Membership of a management body
- Membership of a scientific advisory body
- Employment
- Ad hoc or occasional consultancy
- Interests of family member and other personal involvement
- Scientific interests classified as Indirect (Potential) conflicts
- Other memberships or affiliations
- Other relevant interests

That relates to an application or item on the agenda shall normally be considered in conflict with any participation of the expert in the item at issue. The concerned person shall not be present when that item is discussed, voted or anyway processed by that group and shall not receive the paperwork relating to that item.

In exceptional circumstances and to ensure the integrity of the scientific review process, a waiver may be granted to an external expert, who has declared an indirect (non-disqualifying) interest), where his/her expertise is considered essential for the task and no suitable alternative expert is found. For example:

- Under category 4 Employment, when an expert is working in a different department, laboratory or institute to the one where the work is to be carried out and where the constituent bodies operate with a high degree of autonomy
- Under category 6 Scientific, when an expert who declares interests in the form of collaborations or publications (current or in the past three years) that are unrelated to the application under review

The expert may be allowed to participate in the evaluation, if duly justified by the limited size of the pool of qualified experts. The decision to grant a waiver must be taken by one of the EDCTP Directors and the reasons for the waiver must be documented, as well as the measures taken to limit the potential conflict. This information will be made available to the relevant advisory or decision-making body and will be specified in the report of the evaluation round.

4 Procedure for making declarations

4.1 Annual Declaration of Interest (ADoI)

Members of the EDCTP Constituencies, the GA and SAC, as well as Observer members of these Constituencies shall declare annually in writing any interest falling within EDCTP's remit. These persons shall also confirm whether they consider themselves to be in a potential CoI with respect to any EDCTP activity in which they are, or may become, involved.

Only persons with an approved ADoI may be appointed and serve as a member of the General Assembly or Scientific Advisory Committee, or be invited as an Observer to a meeting which is subject to the Code of Conduct and Policy on Declaration of Interests.

Members of the EDCTP Constituencies, the GA and SAC, as well as Observer members of these Constituencies shall also make a declaration concerning confidentiality and commitment in accordance with the form.

Individuals who are required to submit an ADoI shall declare any interest belonging to the categories defined above with respect to all activities in which they are involved or have been involved during the five years preceding the submission of the declaration and which fall within EDCTP's remit.

Individuals shall indicate whether interests declared are **current** (currently on-going activities) or **past** (no longer on-going, but completed during the three years preceding the submission of the declaration).

Details of the body or organisation of relevance for each declared interest shall be given. This includes the full name, location (city and country) and nature (private or public).

Details on the subject matter of each declared interest shall be given, indicating the domain in which the activity is, or was, carried out and clarifying the interest and role of the concerned body or organisation in the matter and the role of the concerned person.

Individuals subject to the Code of and Policy shall update and resubmit to EDCTP their ADoI without delay following any change in their interests.

Individuals are required to confirm that they have complied with the Code and Policy and have made all relevant disclosures on submission of subsequent ADoIs.

4.2 Specific Declaration of Interest (SDoI)

Individuals who are requested to submit an SDoI shall consider the agenda of the specific meeting and/or the proposal, application or report under consideration, and their current ADoI (where an ADoI has been submitted), and declare one of the following:

- All interests to be declared with respect to the agenda of the specific meeting and/or the proposal, application or report under consideration,
- That there are no new interests to be declared
- That there are additional interests that require an update of the ADoI, specifying their particulars.

Declarable interests shall consist of any interest belonging to the categories defined above with reference to the items on the agenda of the meeting or with reference to a specific item (for example a research proposal, application for research funding or grant report), as appropriate.

By declaring interests, it shall be specified whether interests declared are current or past.

Details of the name of the body or organisation as well as the subject matter for each relevant interest shall be provided with reference to the items on the agenda of the meeting and/or the specific item.

An individual, who has declared an interest, shall not be present when that item is discussed, voted or anyway processed and shall not receive the paperwork relating to that item.

4.3 Oral Declaration of Interest (ODoI) at the beginning of the meeting

At the beginning of each meeting subject to the Code and Policy, taking into consideration the meeting agenda, persons required to submit ODoIs shall declare orally any interest not already declared through the ADoI or the SDoI that might be considered prejudicial to their independence in relation to the items on the agenda of that meeting.

Any interest declared orally shall be recorded in the minutes of the meeting.

5 Identification and handling potential conflicts of interest of expert reviewers and SRC members

For all experts requested to perform a specific task, such as providing a scientific evaluation of a grant application or annual report and/or participation in an SRC, the general principles of this policy apply. The expert will be required to make an SDoI and ODoI in order to determine whether the expert should abstain, or be recused from, a specific item on the agenda and/or from reviewing a specific proposal or report.

Interests will be assessed by considering whether the specific interests declared by a person are compatible with the tasks to be assigned by EDCTP to him/her, in relation to the agenda items for the meeting and/or the applications under review, as well as the number and extent of potential CoI. The assessment will be based on the principles outlined in this policy.

6 Procedures for administration of the Code and Policy

6.1 Overview

To ensure the scientific integrity of its programmes through transparency and proper management of conflicts of interest, EDCTP has implemented the following measures:

- New members receive an orientation programme, including a presentation on the EDCTP Code of Conduct and Declaration of Interests Policy
- Each SAC, SRC and GA meeting begins with a review of the Policy and the processes for managing conflicts during meetings
- Members are encouraged to highlight CoI where these have not been declared in advance by themselves or by other members
- Members of the GA, SAC and Secretariat are required to make Annual Declarations of Interest (ADoI)

6.2 Screening of Annual Declarations of Interest (ADoIs)

Upon receipt of an ADoI, the ED and the Director of Finance and Administration shall screen the declaration in order to assess potential conflicts of interest arising in any of the categories described in this policy. The screening of the ADoIs shall be performed according to the following criteria:

- Membership of governance bodies, advisory committees, scientific review committees or working groups shall not be allowed when EDCTP identifies a potential conflict of interest of a general nature when that would regularly lead to the exclusion of the expert from the meeting of that scientific group. As a rule, GA and SAC members may not serve on EDCTP scientific review committees.
- Chairmanship and membership of scientific committees, scientific panels or working groups, interests falling under category 8 (Other memberships and affiliations) and category 9 (Other relevant interests) shall be assessed in light of the mission, scope, funding and nature of the activities of the concerned organisation.

In the process, EDCTP may seek clarifications from the individual with regard to the information that was declared in the ADoI. EDCTP shall summarise any potential CoIs, along with the preventative measures proposed in that respect. Preventative measures taken to address potential CoIs shall be recorded.

6.3 Screening of Specific Declarations of Interest (SDoIs)

The EDCTP manager supporting the meeting subject to the Code and Policy shall perform screening of the SDoI in advance of the meeting. This shall be done in consultation with the ED or one of the EDCTP Directors,

taking into account the information previously submitted in the ADoI. The EDCTP manager shall report any potential CoIs along with the preventative measures taken in that respect. Any preventive measures taken to address potential CoIs shall be recorded in the minutes of the meeting and/or the report of the evaluation round.

6.4 Screening of Oral Declarations of Interest (ODOIs)

The EDCTP manager supporting the committee meeting subject to the Code and Policy shall perform the screening of the ODoI before starting discussion of any of the items on the agenda. This shall be done taking into account the information previously submitted in the ADoI and in the SDoIs. Any preventive measures taken to address potential CoIs shall be recorded in the minutes of the meeting and/or in the report of the evaluation round.

6.5 Review of the decisions

In case a specific complaint is filed by the concerned person or should a reconsideration of a decision be considered appropriate to address a potential factual mistake, the ED and DFA will consult with the GA Chair to obtain his/her advice. On the basis of the advice provided, EDCTP may review the decision in question taking all measures necessary to rectify the deficiencies identified therein.

6.6 Process regarding omissions for members of EDCTP governance, advisory and scientific review committees and for external reviewers

EDCTP shall systematically and regularly check the compliance of a sample of the submitted DoIs. In case EDCTP is, or is made, aware of information that is not consistent with, or that is missing from, the declaration of an expert and a preliminary assessment suggests that it concerns a declarable interest EDCTP shall seek additional information from the expert with regard to the omission. At the same time, the expert shall be requested to update the missing details of the DoI. Upon completion of the update, the DoI shall be processed and screened in accordance with the present decision. EDCTP may take any appropriate preventive action regarding the expert's participation in EDCTP activities.

6.7 Process regarding breaches of rules on declarations of interest

Where the assessment of an updated DoI (as described above) results in the identification of a CoI, the omission shall be considered a breach of the rules laid down in this policy.

If EDCTP finds an individual to be in breach of the present rules, the ED will establish an Internal Audit Team (IAT), comprising two EDCTP management team members and the EDCTP legal advisor to perform a review of the scientific and/or funding recommendations adopted by the body(ies) to which that individual contributed. Upon receipt of such a request, the IAT shall clarify whether, and if appropriate the extent to which, that individual influenced the decisions and outputs adopted by those bodies. The IAT shall report its findings to the ED. The ED shall take all appropriate measures to address these findings.

In case the seriousness is such that it needs to be considered as a breach of trust, the ED shall propose to the GA steering committee the dismissal and barring of the concerned member from membership of EDCTP's governance, advisory and scientific review committees, as well as from acting as an expert reviewer.

7 Granting of waivers

7.1 Invited speakers and meeting delegates

In addition to the cases described in section 3, there are particular circumstances where EDCTP may invite experts to present their views irrespective of whether they hold potential CoIs, including but not limited to:

- Speakers and delegates at EDCTP stakeholder and/or networking meetings
- Invited experts and speakers giving presentations at GA or SAC meetings

Individuals in this category shall not be required to submit a DoI. Individuals shall be allowed in the meeting only for the relevant point(s) in the agenda and shall play no part in the decision-making processes.

7.2 Observers

Observers may be invited to attend meetings and events organised by EDCTP, or parts thereof. Observers are required to submit an ADoI (where appropriate), as well as SDoIs for each meeting they attend. Since observers do not take part in the decision-making process or drafting of scientific outputs at issue, their exclusion from specific agenda items shall be determined by the ED and the Chair taking into consideration the DoIs. The presence/absence of the observers shall be documented in the minutes of the meeting.

8 The EDCTP Secretariat

8.1 Declarations of interest of members of the EDCTP Senior Management Team

Members of the EDCTP senior management team (ED, DFA and Directors of North-North and South-South Networking) shall undertake to act independently in the public interest. For this purpose, they shall make a declaration of commitment and an ADoI indicating any direct or indirect interests which might be considered prejudicial to their independence. They shall also make their best efforts to refrain from involving themselves in any activity that would result in a CoI. Those declarations are made annually in writing and will be screened by the GA steering committee.

The members shall inform the GA steering committee of any change in their interests by updating their ADoI. When the GA steering committee receives an updated DoI from the EDCTP senior management team, it shall review and reach a conclusion with regard to the DoI assessment and shall recommend a follow-up. If an identified conflict that is substantially affecting the work of the EDCTP management team or EDCTP's reputation is not resolved, the GA steering committee shall consult with the GA. Acting on a two-thirds majority, the GA may ask for the replacement of the concerned person.

8.2 Declarations of interest of other EDCTP staff

The requirement to declare annually their interests applies to all EDCTP staff members, irrespective of whether they are on duty or on leave. In addition to the interests defined in this document, EDCTP staff shall declare also any negotiation with prospective employer(s) having a vested interest in EDCTP or in its activities.

Declarations of members of staff shall be screened by the responsible line manager. When the line manager identifies a potential CoI, he or she shall highlight the finding to the ED and DFA.

Employment by EDCTP shall be considered in conflict with membership of an EDCTP scientific review committee.

Negotiations with a prospective employer may be considered as a CoI when the staff member has received an offer and the tasks assigned to the staff member have an impact on EDCTP's decision-making process.

The ED, after having consulted the GA Steering Committee and having heard the member of staff concerned, may decide to reassign the person in question or take any measure considered appropriate to ensure the potential conflict of interest in question does not occur, or to remedy a CoI. In this situation, the ADoI shall be updated accordingly.

Any change regarding interests already declared shall result in a swift update of the ADoI, which shall be submitted to the responsible line manager without delay.

The procedure laid down in this Article is without prejudice to disciplinary measures that may be taken by the ED in accordance with the Staff Regulations.

9 Declaration by tenderers to procurement procedures

EDCTP shall require legal or natural persons who apply to EDCTP's procurement procedures concerning a scientific or technical project to submit a true, accurate and up to date SDoI using the template provided by EDCTP.

In the context of the paragraph above, legal or natural persons shall declare any interest that may be considered prejudicial to their independence with reference to the subject matter of the concerned procedure and to the operational body that will carry out the project or provide the requested services. The declaration shall be submitted together with the offer.

Tenderers shall update their declarations without delay in case of any change in those interests. In case of amendments submitted during the period of implementation of the contract or grant project to the declaration, EDCTP reserves the right to ask for individual declarations for project team members involved or proposed for involvement in activities under the respective contract or grant project.

9.1 Screening of declarations

The screening of the declarations of interest submitted by tenderers shall be performed by the EDCTP Evaluation Committee designated for each procurement or grant call, with the participation, or under the supervision, of the EDCTP DFA if he/she is not already part of the committee.

Should a potential CoI be identified, the Evaluation Committee shall request the tenderer to put in place within a set time period measures appropriate to prevent the occurrence of that conflict, such as the replacement of the individual(s) with the identified conflict.

The Evaluation Committee shall assess the measures taken by the tenderer and the above sequence shall be repeated until no potential CoI is identified, or until the tenderer is excluded from the procedure for his or her inability to adopt the appropriate measures. In that case, the tenderer shall be excluded and his or her offer shall not be retained for contract/grant award.

10 Publication and protection of personal data

Without prejudice to Regulation (EC) No 178/2002, EDCTP shall process all Declarations of Interest pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

The purpose of the data processing is to safeguard the independence of EDCTP and its constituent bodies.

The EDCTP ED is the controller of handling the declarations of interest.

This policy will be made available on the EDCTP website.

The conservation period of Declarations of Interest per category of data subjects shall be:

- For Members of EDCTP constituencies and review committees (GA, SAC and SRCs) as well as expert reviewers, five years after the discharge for the budgetary year to which the DoI relates
- For the ED and senior management team, five years after the discharge for the budgetary year in which the ED and management team member terminates his/her mandate at EDCTP
- For EDCTP staff, five years after the discharge for the last budgetary year in which they worked for EDCTP
- For DoIs submitted in the context of grants and procurement, five years after the discharge for the budgetary year in which the contract or grant was terminated.

Individuals with active EDCTP involvement have a right to access their DoI and to update or correct it at any time. In case EDCTP has knowledge of information that is not consistent with the declared interest, or in case of failure to submit a DoI, the individual concerned will be contacted with the purpose to update the Declaration on the missing information. In the event that an internal procedure is opened to investigate compliance with the policy, the individual will be notified.

11 Confidentiality

The integrity and reputation of the EDCTP programme is dependent on the professional conduct and behaviour of the Secretariat, GA and SAC members and observers, SRC members and ERs. In addition to complying with the policy on Declaration of Interests, individuals must respect the confidentiality of EDCTP discussions and review procedures, and must not disclose confidential information.

GA and SAC members, as well as ERs selected to participate in EDCTP SRCs, who are approached for advice and guidance about EDCTP policies and procedures, may provide publicly available information about EDCTP's policies or procedures however they should ensure that they do not provide details of any non-public EDCTP policies or procedures.

If an individual is approached for specific technical advice on an application to the EDCTP, the individual may provide such advice (subject to the restriction above), but must disclose to the relevant member of the EDCTP Secretariat that he/she has provided advice. The individual will be regarded as having a conflicting interest in that application.

Members of the GA and SAC should facilitate the functioning of the EDCTP Secretariat by forwarding all enquiries of a policy and procedural nature to the relevant member of the Secretariat.

11.1 Confidentiality at meetings and policy development

An SAC, SRC or GA member should not, prior to a meeting of that committee, discuss in private any application which is to be considered at that meeting with any other member responsible for reviewing that application. If an SAC, SRC or GA member does have any such discussion, this must be reported to the Chairperson and the manager of the committee or the EDCTP ED before the start of the meeting.

11.2 Confidentiality of applications and funding decisions

Committee and Assembly discussions, contents of papers and correspondence relating to applications for funds, including the reasons for deciding to fund or not to fund, are all strictly confidential. Committee members and reviewers have a right to expect that their comments will be treated in confidence by the EDCTP Secretariat and other members of the Committees and Assembly. Accordingly, all Committee members, Assembly members and observers:

- Must keep confidential documents secure and not disseminate them to anyone
- Must destroy all hard and electronic copies of documents after an assignment
- Must not discuss applications with anyone else (including colleagues based at the member's host institution, other scientific experts and reviewers) without prior permission from EDCTP
- Must keep the membership of an SRC confidential. The EDCTP Secretariat will release details of the composition of scientific review committees according to the guidelines laid down by the European Commission
- Must keep the identity of applicants and reviewers confidential at all times
- Must not discuss with applicants, either in connection with the applicant's own application or any other application, or anyone else, any aspect of the review discussions or recommendations regarding an application.

Feedback on EDCTP applications will be provided by the EDCTP Secretariat in accordance with its standard operating procedures. Committee and Assembly members should refuse any requests for information or explanation of how a particular funding decision was reached. Any such request must be referred to the EDCTP Secretariat.

Members of the SAC, SRC and GA who are approached by individuals or organisations for information on the status or outcome of their applications must refuse to provide such information and must always refer all such enquiries to the EDCTP Secretariat. SAC, SRC and GA members must not release decisions on applications. It is the responsibility of the EDCTP Secretariat to communicate with individuals regarding the status and outcome of their application.

EDCTP reserves the right to investigate and take action against individuals who breach its policy on confidentiality. In case the seriousness is such that it needs to be considered as a breach of trust, EDCTP shall propose to the GA steering committee the dismissal and barring of the concerned member from membership of EDCTP's governance, advisory and scientific review committees, as well as from acting as an expert reviewer.