

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

**A CODE OF PRACTICE FOR DECLARING AND DEALING WITH
CONFLICTS OF INTERESTS**

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1 Scope

- 1.1 This code of practice is written for the chair and other non-executive and executive directors of the board of the National Institute for Health and Clinical Excellence (NICE or the Institute), the members of its advisory bodies, the experts who assist advisory bodies, the Institute's employees and the employees of those organisations that provide NICE with the evidence on which it forms its recommendations. It describes the circumstances in which they should declare an interest that might conflict, or be perceived to conflict, with their duties and responsibilities to the Institute.
- 1.2 The chair of the board, other non-executive directors, the chairs and members of the Institute's advisory bodies, and the employees of NICE are concerned with matters that are connected with industries and organisations whose activities have an impact on the health of individuals and/or on the population. These include not only the healthcare industries but also professional bodies such as the Royal Colleges, professional associations, universities, the NHS, and advocacy groups with a primary focus on health or public health, and private healthcare organisations. It is desirable that members of the Institute's board, its advisory bodies and its employees should have good understanding of the work of these enterprises. It is also desirable that some should have practical experience of the scientific problems of intervention development, health research, and the delivery of healthcare. To avoid any public concern that pecuniary or other interests might prejudice the advice of NICE, the arrangements that govern relationships between the board, its advisory body members, and its employees on the one hand, and both the healthcare industries and professional organisations on the other, should be on the public record.
- 1.3 Because the Institute places such reliance on the work undertaken by the external bodies that it commissions to produce clinical guidelines (the national collaborating centres) as well as those it asks to provide syntheses of evidence, it is essential that the same discipline in declaring and assessing the importance of potential conflicts of interest be applied to their employees. This code therefore encompasses the employees of the national collaborating centres and the employees of organisations (referred to as 'evidence contractors') that work with NICE to provide evidence statements which will be used by standing advisory committees and guideline development groups.
- 1.4 In this Code, the definition of terms set out below will apply:
- 'Healthcare industry' encompasses:
- companies, partnerships or individuals who are involved with the development, manufacture, promotion, sale or supply of health technologies that are, or may be, used by the NHS including

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medicinal products subject to the licensing provisions of the Medicines Act (1968) and relevant EU legislation; and medical devices subject to relevant EU legislation

- companies, partnerships and individuals who are involved in the development, manufacture, promotion, sale or supply of products or services which are advertised, promoted or marketed as contributing to the promotion or maintenance of good health
- trade associations, both in the UK and elsewhere, representing companies involved with such interventions.

‘Professional Organisations’ refers to: the medical, nursing, and midwifery Royal Colleges and Faculties; health and public health professional associations, bodies and societies; universities; NHS organisations; or any other bodies with whom NICE has a contractual relationship or with whom NICE is considering entering a contractual relationship.

‘Advocacy Group’ refers to organisations whose functions include speaking for and on behalf of individuals and groups with an interest in health or health-related matters of the kind on which NICE issues guidance.

‘Members’ includes all advisory body members for the committees and groups described in 2.2 below.

‘Employees’ refers to full and part-time employees of NICE and the staff of the organisations listed in 2.3 below.

‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

‘Expert advisor’ refers to clinical, patient or other experts invited to attend and take part in a NICE advisory body meeting.

‘Evidence contractor’ refers to organisations that NICE contracts, directly or indirectly, to supply evidence used by the guidance-producing advisory bodies.

1.5 This Code is consistent with the Institute’s Standards of Business Conduct Policy.

1.6 If members or employees or expert advisors have interests not specified in this Code but which they believe could be regarded as either influencing their advice or role or be perceived to influence their advice or role, they should declare them.

2 Who is covered?

2.1 At NICE itself:

- the chairman and other non-executive members of the board
- all employees.

2.2 Chairs and members of the following advisory bodies to the Institute:

- Partners Council
- Citizens Council
- Appraisal Committees
- Interventional Procedures Advisory Committee
- Public Health Interventions Advisory Committee
- Clinical Guideline Development Groups and Guideline Review Panels
- Public Health Programme development groups
- Technology Appraisal Appeal Committee
- Topic Selection Consideration Panels
- Research and Development Committee
- any ad hoc group established to produce NICE guidance and any such standing or project-specific advisory groups that may, from time to time, be established.

2.3 The employees of those organisations ('evidence contractors') with which NICE contracts, directly or indirectly, to supply evidence used by the guidance-producing advisory bodies referred to in 2.2 above, including:

- the clinical guideline National Collaborating Centres
- those employees working wholly or partly on work for NICE commissioned from the public health collaborating centres and other public health evidence contractors
- those employees working wholly or partly on work for NICE commissioned from the technology assessment review groups
- those employees in the Decision Support Unit working wholly or partly on work commissioned by NICE

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- those employees at the Interventional Procedures Advisory Committee (IPAC) Review Body working wholly or partly on work commissioned for NICE
- the employees of other groups from which NICE may, from time to time, commission evidence reports.

2.4 Clinical, patient or other experts ('expert advisors') invited to attend and take part in a NICE advisory body meeting.

3 What interests are involved?

3.1 The following is intended as a guide to the kinds of interest that should be declared. If a person covered by this code (as defined in section 2) is uncertain whether an interest should be declared, he or she should seek guidance as follows:

- Non-executive directors: from the chair of the board
- Chairs of advisory bodies and employees of the Institute: from the Institute's centre directors
- Members of advisory bodies: from the chair of the relevant advisory body
- Evidence contractors' employees: from his or her head of department
- Expert advisors: from the chair of the advisory body
- Neither an individual covered by this Code, nor the Institute, are under an obligation to search out links of which they could not reasonably be expected to be aware between a company or organisation in which they have a connection or interest and another company or organisation.

3.2 Although particular attention is given to members' or employees' pecuniary interests, the Institute is also conscious that risks to an individual's reputation could also be (or be perceived to be) prejudicial to his or her advice. Arrangements covering 'reputational risk' are therefore also considered in this document (see below).

3.3 **A personal pecuniary interest** involves a current personal payment, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**' or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

- Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind, both those which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.

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- Any fee-paid work commissioned by a healthcare industry for which the individual is paid in cash or in kind, both those which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.
- Any shareholdings, or other beneficial interests, in shares of a healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual)
- Expenses and hospitality provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences, both which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.
- Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

No personal interest exists in the case of:

- assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- accrued pension rights from earlier employment in the healthcare industry.

3.4 **A non-personal pecuniary interest** involves payment or other benefit that benefits a department or organisation for which an individual has managerial responsibility, but which is not received personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific**,' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples include the following.

- The holding of a fellowship endowed by the healthcare industry.
- Any payment or other support by the health industry, or by NICE, that does not convey any pecuniary or material benefit to an individual personally but that might benefit him or her. Examples include:

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- i) a grant from a company for the running of a unit or department for which a member is responsible
- ii) a grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member is responsible
- iii) the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible;
- iv) one or more contracts with, or grants from, NICE.

An individual covered by this Code is under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within the departments for which they are responsible if they would not normally expect to be informed.

3.5 **A personal non-pecuniary interest** in a topic under consideration might include, but is not limited to:

- i) a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review
- ii) a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence
- iii) holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- iv) other reputational risks in relation to an intervention under review.

3.6 **A personal family interest** relates to the personal interests of a family member and involves a current payment to the family member of the employee or member. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

- Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.
- Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

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- Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).
- Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)
- Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

No personal family interest exists in the case of:

- assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- accrued pension rights from earlier employment in the healthcare industry.

3.7 It is inappropriate for the chair or non-executive directors of the Institute, the chairs of its advisory bodies, or the executive directors, the centre directors or other employees, or the employees of the Institute's clinical guidelines national collaborating centres, to have any current personal interests, as defined in paragraph 3.3 (in the case of a guideline or programme development group, the interests concerned are those relevant to the matters being considered by the group). Nor should they accept expenses or hospitality from the healthcare industries, other than to seek reimbursement for the reasonable and proportionate costs involved in travel, accommodation and associated subsistence, for attending conferences at which they have been asked to speak or otherwise play a formal role. Such expenditure should be in accordance with the Institute's speaking engagements policy.

4 When should interests be declared and what action is required?

Appendix A sets out, for each group, when a declaration of interest should be made and Appendix B summarises the action which should be taken when interests are declared at advisory body meetings.

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On appointment

- 4.1 The chair, the other non-executive board members, and employees of the Institute must declare all categories of interests on appointment, and then annually. This also applies to the chairs and members of the Institute's advisory bodies and the staff of the clinical guidelines national collaborating centres. Only the name of the company and the nature of the interest are required; the amount of any salary, fees shareholding, grant etc need not be disclosed. An interest is current if the member or employee has an ongoing financial involvement with the healthcare industry; or if the member or the department or organisation for which he or she has managerial responsibility is in the process of carrying out work for the healthcare industry; or if the member holds office in a professional body that is contracted to NICE. Non-personal interests involving less than £1000 from all sources in the previous year need not be declared.
- 4.2 The chair of the Institute, the other non-executive directors, the chairs of advisory bodies, the employees of NICE and the employees of the clinical guidelines national collaborating centres should divest themselves of their personal pecuniary interests (as defined in paragraph 3.3) on appointment, or as soon as is practical thereafter. If this is likely to take more than 3 months the following action should be taken.
- The chair of the Institute should discuss his or her position with both the vice chair of the Institute and the chair of the audit committee.
 - Any other non-executive board members should discuss his or her position with the chair of the board.
 - The chief executive should discuss his or her position both with the chair of the board and the chair of the audit committee.
 - Any other executive director or a centre director should discuss his or her position with the chief executive.
 - A chair of an advisory committee or an employee of NICE or the clinical guidelines national collaborating centres should discuss his or her position with the chief executive or deputy chief executive.
- 4.3 The declaration of personal family interests by a member or employee will not be a bar to his or her employment or appointment to the Board or advisory body. When this personal family interest may have a bearing on specific aspects of the work of the employee at NICE or the clinical guidelines national collaborating centres, then the employee should discuss this with his or her line manager who will set up appropriate arrangements to ensure that the interest does not conflict with the employee's duties.
- 4.4 Any uncertainty about potential conflicts of members of advisory bodies on appointment should be resolved at the discretion of the relevant chair

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and recorded in the letter of appointment. Members with conflicts that could be regarded as prejudicing their contribution to the discussion should be excluded from the group or committee. It is recognised that individuals may have some interaction with the healthcare industry and, while this should be declared, it does not necessarily preclude membership of an advisory body.

At advisory body meetings

4.5 Advisory body members and other individuals covered by this Code who are attending to take part in the meeting should declare relevant interests at each advisory body meeting and at appeal panels and state into which of the following categories they believe the interest falls.

- A person declaring a **personal specific pecuniary or personal family specific interest** shall take no part in the proceedings as they relate to the intervention or matter and will normally leave the meeting until the matter has been concluded. In exceptional circumstances he or she may, at the discretion of the chair, answer questions from other members but should then leave the meeting until the discussion has been concluded.
- A person declaring a **personal non-specific pecuniary interest** may take part in the proceedings unless, exceptionally, the chair rules otherwise.
- A person declaring a **non-personal specific pecuniary interest or a personal family non-specific interest** may take part in the proceedings unless he or she has personal knowledge of the intervention or matter either through his or her own work, or through direct supervision of other people's work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions.
- A person declaring a **non-personal non-specific pecuniary interest** may take part in the proceedings unless, exceptionally, the chair rules otherwise.
- When someone declares a **personal non-pecuniary interest** the chair of the advisory body shall determine, on a case-by-case basis, whether he or she should take part in the proceedings.

Special note on Competitor interventions

If a member is aware that an intervention or matter under consideration is, or may become, a competitor of an intervention developed, manufactured, sold or supplied by a company in which the member has a current personal pecuniary or personal family interest, he or she should declare an interest in the company marketing the rival intervention. The member

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should seek the Chairman's guidance on whether to take part in the proceedings.

In evidence publications

- 4.6 Where an individual covered by this Code is responsible for authoring, in whole or part, a document that is prepared specifically to inform one of the Institute's advisory bodies, they must declare any interests in accordance with this Code.

5 Record of interests and their publication

- 5.1. A record is kept at the Institute, or the relevant body, of:
- names of individuals who have declared interests on appointment, as the interest first arises or through the annual declaration, and the nature of the interest;
 - names of individuals who have declared interests at meetings giving dates, names of relevant interventions and companies, details of the interest declared and whether the member took part in the proceedings.
- 5.2 Information about any interests declared under this Code will be made publicly available on the Institute's website, in the form of a statement of annual declarations, though the minutes of advisory bodies or in guidance publications.

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A code of practice for declaring and dealing with conflicts of interests

Appendix A: When is it necessary to declare an interest?

| | Declaration on appointment | Annual declaration | Declaration at advisory body meeting | Declaration in evidence publication ⁴ |
|---|----------------------------|----------------------------|--|---|
| NICE board chair and non-executive directors¹ | Yes | Yes | Yes (when acting as a member of an appeal panel) | Yes if relevant (e.g. in appeal panel decision letters) |
| NICE employees¹ | Yes | Yes | Yes | Yes |
| NICE advisory body chair^{1,2} | Yes | Yes | Yes | Does not author evidence publications |
| NICE advisory body member² | Yes (except ad hoc groups) | Yes (except ad hoc groups) | Yes | Yes |
| NCC employee | Yes | Yes | Yes | Yes |
| Evidence contractor³ | Discuss with NICE | Not relevant | Yes | Yes |
| Expert advisor⁴ | Not relevant | Not relevant | Yes | Yes |

1 The chair of the Institute, the other non-executive directors, the chairs of advisory bodies, the employees of NICE and the employees of the clinical guidelines national collaborating centres should divest themselves of their personal pecuniary interests (as defined in paragraph 3.3) on appointment, or as soon as is practical thereafter.

2 See section 2.2 for information about advisory bodies.

3 Employee of body contracted to supply evidence assessment to a NICE advisory body.

4 Clinical, patient or other expert invited to attend a NICE advisory body meeting.

A code of practice for declaring and dealing with conflicts of interests

Appendix B: Declaring interests at an advisory body meeting

| Type of interest | See section | Action |
|--|-------------|---|
| Personal specific pecuniary | 3.3 | Declare and withdraw |
| Personal non-specific pecuniary | 3.3 | Declare and participate (unless, exceptionally, the chair of the advisory body rules otherwise) |
| Personal family specific interest | 3.6 | Declare and withdraw |
| Personal family non-specific | 3.3 | Declare and participate (unless, exceptionally, the chair of the advisory body rules otherwise) |
| Non-personal specific pecuniary interest | 3.4 | Declare and participate, unless the individual has personal knowledge of the intervention or matter either through his or her own work, or through direct supervision of other people's work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions |
| Non-personal non-specific pecuniary | 3.4 | Declare and participate (unless, exceptionally, the chair of the advisory body rules otherwise) |
| Personal specific non-pecuniary | 3.5 | Declare – action is at discretion of the chair of the advisory body |