



National Review of Clinical Services

Conflict of Interest Policy

Background

The Irish health system faces on-going challenges in allocating limited public resources to provide for growing population health needs, while still striving to meet individual patients' expectations and demands. Policy decisions which underpin the strategic delivery of healthcare need to strike an appropriate balance between providing population-level access to established screening and prevention programmes, diagnostics, and treatment modalities, while also facilitating access to new and emerging innovations in care.

The health system is required to both anticipate, and respond to, evolving patient needs, new technological advances, and changes in organisational structures. The health system must continually adapt and change in order to maximise health outcomes for the population, and to deliver equitable, high quality services for all.

A vital part of this are National Reviews of Clinical Services (NRCS) which are the responsibility of the Clinical Effectiveness Unit (CEU) and which support policy-makers in making evidence-informed decisions about delivery of clinical services. The CEU, as part of the Department of Health, is expected to maintain high standards of probity in the way it conducts its activities. The CEU is committed to operating in an open and transparent manner and includes the management of all real and potential conflicts of interest of any members of Review Steering Groups etc. Similarly, our staff are bound by the *Civil Service Code of Standards and Behaviour* (2004) in the discharge of their duties and includes avoiding conflicts of interest.

Aim of this policy

The aim of this policy is to protect the integrity of professional judgement and to preserve public trust for all activities of the CEU/NRCS. To achieve this, the policy will set down principles supported by procedures which will ensure robust mechanisms are adhered to, while providing support and direction to participants in CEU/NRCS activities. The procedures will set out how to declare interests, how to manage managing conflicts of interest (COIs) and will allow for the disclosure by publication of descriptions of COIs (this final item is work in progress).

The scope of this policy

The policy can be applied to a range of persons/participants in CEU/NRCS activities, but is specifically aimed at members of Steering Groups. We are committed to effective implementation of the COI policy and will:

- Ensure wide publication and understanding of the policy
- Develop an open and transparent culture where dealing with COI matters can be freely raised and discussed
- Ensure that matters under discussion are clearly defined and communicated in advance to all stakeholders
- Identify preventative measures that deal with emergent conflict situations
- Decide on individual cases as they arise and review at-risk areas

- Enforce the policy including proportional consequences for non-compliance when detected
- Evaluate the effectiveness of the policy

What are conflicts of interest?

The Institute of Medicine (2009, p. 46) define COI as ‘a set of circumstance that creates a risk that professional judgement or actions regarding a primary interest will be unduly influenced by a secondary interest’

Other descriptions include:

- ‘A divergence between an individual’s private interests and his or her professional obligations such that an independent observer might reasonably question whether the individual’s professional actions or decisions are motivated by personal gain, such as financial, academic advancement, clinical revenue streams, or community standing’ (Schünemann et al 2009).
- ‘A financial or intellectual relationship that may impact an individual’s ability to approach a scientific question with an open mind’ (Schünemann et al., 2009, p. 565).
- ‘Intellectual COIs are academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual’s judgment about a specific recommendation’ (Guyatt et al., 2010, p.739). This is referred to as a personal interest here.

Types of interests

In the context of the work of the CEU/NRCS, a COI is any interest that could potentially influence or be perceived to influence the direction or content of a review, and any interest that could result in bias in the other work or decision making processes.

For the avoidance of doubt, the policy identifies and organises interests as: *specific* or *non-specific* as a precursor of the following: *Personal financial*, *Personal non-financial* and *Non-personal financial* and are explained below.

A. Specific interest relates to an item under consideration. This will be clearly defined and communicated in advance e.g. an item on the meeting’s agenda.

B. Non-specific interest relates to an interest that is not under discussion.

1. **Personal financial** interest is when there is or may be opportunity for personal financial gain or financial gain to an immediate family member. Examples include: being a recipient of payment, fees or shareholdings.

When this interest is **A. specific** it must be declared and the person will normally absent themselves from discussion and decision making processes on that specific topic. When this interest is **B. non-specific**, the person should declare and may participate unless the Chair decides otherwise.

2. Personal non-financial interest is when a person has published an opinion or an academic paper on matters under consideration by the CEU/NRCS. It also refers to holding office in any organisation with a direct interest in the matter under consideration e.g. the HSE, Clinical Programmes, HIQA, medical and nursing schools and universities.

When this interest is **A. specific** it must be declared and the action is then decided by the Chair/CEU. Due to the nature of Steering Group membership in NRCS i.e. members are nominated by interested organisations to participate in the Steering Group; the interests to be declared under this section relate to additional interests members might hold as an individual.

When this interest is **B. non-specific**, the person should declare and may participate unless the Chair/CEU decides otherwise

3. Non-personal financial interest relates to the organisation in which the person is employed being in receipt of payment or benefit including commissioned research contracts from CEU/NRCS.

When this interest is **A. specific** or **B. non-specific** it must be declared and the person may participate unless the Chair/CEU decides otherwise.

Rules for managing declared interests/conflicts of interest

1. Every person participating in activities of the NRCS or on a Steering Group is required to make a declaration of interests at regular intervals as defined by this policy.
2. At the start of every Steering Group meeting, the Chair will invite all present to consider the agenda and to make a renewed verbal declaration if any potential of conflict could arise. When a verbal declaration is made the person will be asked to complete a renewed declaration using the NRCS Conflict of Interest form. The minutes of the meeting will reflect this occurrence and will include the person's name, interest declared and the action(s) taken if any.
3. Every declaration form will be reviewed by the Chair who will co-sign the form to note the declaration and to record any actions/control taken.
4. Every signed declaration of interest form is retained as a record by the CEU. Every such record is subject to disclosure under the Freedom of Information Act 2014. All information provided will be processed in accordance with the Data Protection Acts 1988 and 2003.
5. Records will be published by way of summary minutes of meetings on the Clinical Effectiveness section of the Department of Health website.

6. The period of relevance for the declaration of interest is 12 months before joining and at any time during membership of a Steering Group and/or other groups/panel/team acting on behalf of the NRCS.
7. Failure to make a full declaration of all relevant interests may lead to the person's membership being withdrawn.
8. In managing a declared conflict of interest, the reference person must first determine the type of conflict and relevance to the item/matter under consideration.
9. A range of actions/controls can be considered by the Chair/CEU and they are:
 - a. advice regarding confidentiality of documents under consideration
 - b. on-going monitoring for any potential conflict
 - c. denying access to relevant documents
 - d. exclusion from specific discussions
 - e. permission to participate in discussion when appropriate balance of opinion is available but exclusion from decision making.