

**Policy and Guidance for managing conflicts of interest related to Data and Biospecimen Access Committee (DBAC) decisions**

**A Introduction and Principles**

Managing conflicts of interest ensures that the process for making decisions relating to data and biospecimen access is fair and free from undue influence. A conflict of interest is any situation in which your personal interests, or loyalties that you owe to another person or body, may (or may appear to) unduly influence or affect a decision. It is inevitable that conflicts of interest will arise, but it is important that they are clearly identified and carefully managed, as in some circumstances even the appearance of a conflict of interest can damage the DBAC’s reputation.

The aim is to balance the need to manage conflicts of interest with the desire to have the best possible quality of decision-making. This policy and guidance describes the processes for disclosing or identifying a potential conflict, how to determine the degree of materiality of the conflict and, based on the materiality, the ways in which that conflict may be managed.

Conflicting interests usually fall into the following categories:

• **Financial interests**: These may apply to you either directly or indirectly through a partner, spouse, close relative, or an entity or institution you are connected to (e.g. being paid to provide a service to the applicant);

• **Non-financial interests**: These cover other kinds of potential gain (e.g. benefitting yourself from gaining access to data or biospecimens through the applicant);

• **Loyalties**: These arise from a personal connection or duty to another person or organisation (e.g. to a past employer, past student, family member, friend, close colleague or frequent collaborator).

Your responsibility is to help identify and manage conflicts of interest by:

• **Disclosing** outside interests that could give rise to potential conflicts so that relevant people are aware of these in advance;

• **Determining** whether you have an actual or perceived conflict before being involved in any decision on behalf of the DBAC;

• **Managing** any conflicts as they arise, in a manner that protects the integrity of DBAC’s decision making while allowing you to give the right level of input to enable the best decisions. The DBAC chair will decide how to manage a conflict, but you also need to make your own personal judgement about it.

1. **Assessing conflicts**

When a potential conflict of interest has been identified, it needs to be decided the degree to which that conflict is material. Could the DBAC member benefit from the success, or failure, of the application? Does the disclosed interest exert an undue influence on the DBAC member? And, if so, is this conflict detrimental to the fairness of the decision-making?

In order to determine whether a conflict is material, the following factors should be taken into consideration (See Annex 1 of this document for examples).

1. **The person’s role in the decision-making process**

A conflict involving a committee member directly involved in the decision making process would normally be regarded as material, but it may be of limited materiality depending on the nature or closeness of the conflict (see below). If somebody is observing a meeting (such as H3Africa investigators and staff members) and does not have a vote, a conflict of interest would normally be deemed to be immaterial.

**(b) The nature of the conflict**

*Personal relationship*

Consider the closeness and duration of the relationship. If you are not sure, ask the DBAC member whether the nature of their relationship would impact on their ability to assess the application impartially.

*Professional relationship*

Consider its closeness, duration and the nature and frequency of the relationship, e.g. how often has collaboration taken place?

**(c) The closeness of the conflict, and (d) The value and nature of the potential benefit**

A large financial gain or conflict involving a current employer is more material than a non-financial benefit or affiliation to a past employer.

A conflict of interest will normally be material if the DBAC member is a shareholder in a company with a financial interest in the application.

1. **Managing material conflicts**

There are a range of restrictions that may be used to manage conflicts in relation to committee members, including:

* Recusing (excluding) the Committee member from the entire meeting
* Not allowing the Chair to chair the meeting
* Recusing the Committee member from consideration of a particular application (no papers, leave the room)
* Allowing the Committee member to contribute to the discussion of an application but not to participate in the decision whether to approve that application

1. **Procedures in dealing with conflicts**

As a general rule the following restrictions would normally apply:

Committee members should be recused\* from applications for material conflicts. These would include:

* direct personal relationships (family member, friend)
* direct professional relationships (such as current collaborators, members of the same institutional Department or Division as principal applicant, business partner)
* if the committee member is an applicant for a an application for access being considered at that meeting
* a sponsor of the applicant

\*recused means does not receive papers and is excluded from discussion of that application).

Conflicts of a more limited materiality can be managed using other options described above. These would include:

* members of different Departments or Divisions within the same institution as the principal applicant
* member of the same department or Division as a co-applicant (depending on level of input to the project and potential gain)

Immaterial conflicts would not normally need to result in a restriction. For example, a co-applicant in a different institutional Department, or with minimal input into the project; observers with no decision making role.

**5. Reporting**

If the decision to manage a potential conflict of interest is to restrict a committee member, this should be recorded in the minutes of the meeting, noting the reason for and the nature of the restriction.

**Annex 1, Examples of conflicts**

Personal relationships

A close family connection between a Committee member and an applicant would represent a material conflict.

Professional relationships

A conflict based on loyalty to a past employer is less material than a conflict that could lead to direct financial gain.

A Committee member working in the same Department as a Principal Applicant would represent a material conflict of interest as they could (directly or indirectly) benefit from the Department receiving access to data or biospecimens, or have a (real or perceived) loyalty to the Department.

If they work in a different Department or Division, or the conflict is with a co-applicant with less input or potential gain from the project, the conflict may be regarded as having limited materiality and a lesser restriction may be more appropriate.

A conflict of interest with a co-applicant working in a different Division within the same institution would not normally be regarded as material.

A collaboration with an applicant would represent a material conflict of interest as the committee member or reviewer could benefit from the award.

A connection between current collaborators would normally be considered to have greater materiality than the connection between co-authors on a paper published several years ago.

As a guide, co-authorship on papers within the past three years would normally indicate close collaboration. However, co-authors on papers with a large number of authors (e.g. genome publications) may not be close collaborators.

Closeness of the conflict

A conflict relating to a co-applicant with insubstantial input to an application is less material than if it relates to a principal or main applicant.

A Sponsor of a Fellow who has submitted an application would have a material conflict with that application, but not with other applications.