



Policy of **impartiality**

Policy of **impartiality** and procedures concerning **impartiality declaration** for external advisors/consultants, including members of committees/working groups set up by the Danish National Genome Center and employees in the Danish National Genome Center.

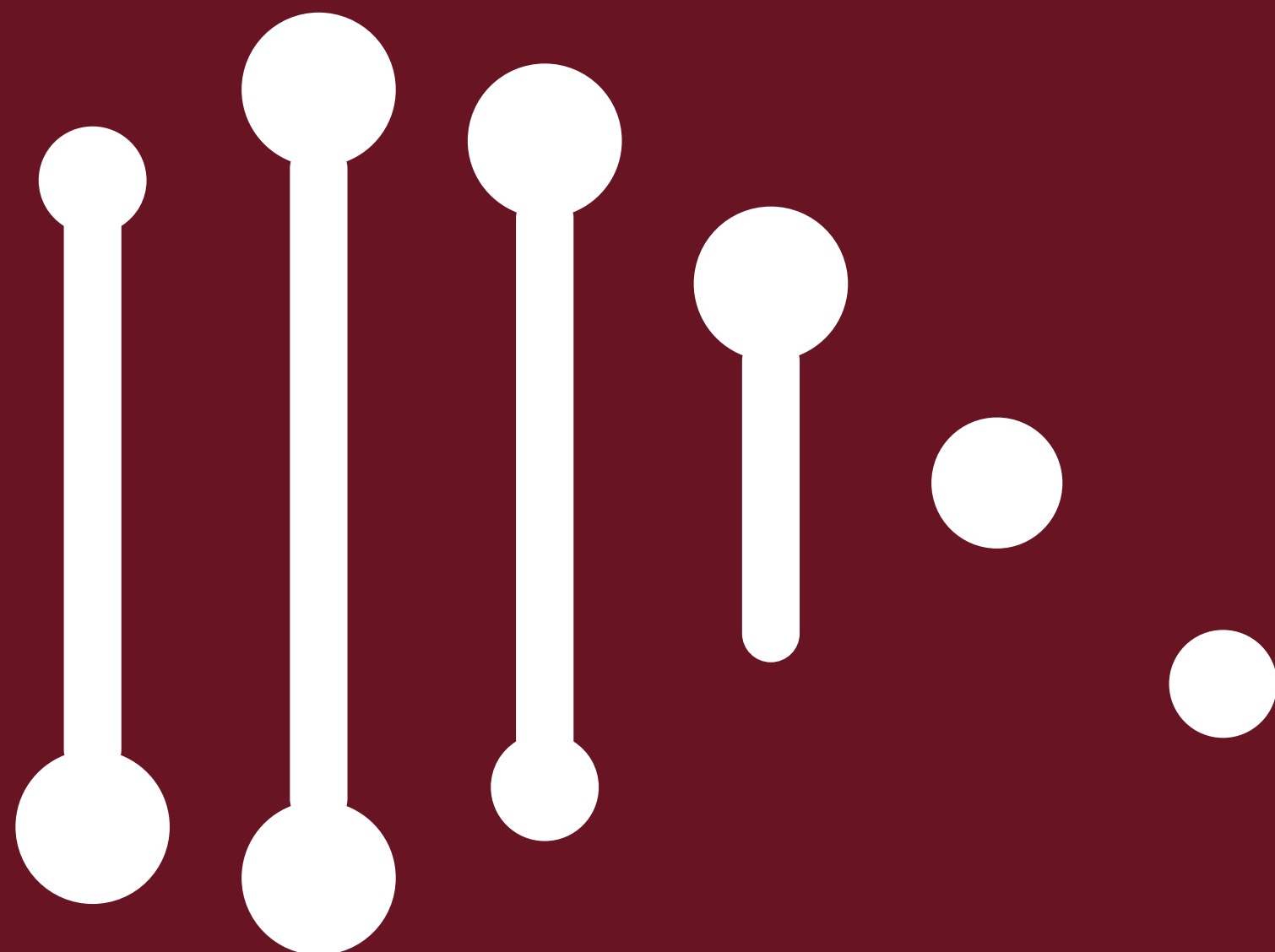


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1. Purpose

The policy of impartiality sets the frame for the application of the Danish Public Access to Information Act's impartiality rules in the Danish National Genome Center, but has, at the same time, a wider aim than the law in terms of securing that, the agency's external advisors/consultants, including members of committees/working groups set up by the Danish National Genome Center and employees in the Danish National Genome Center, both are and appear capable.

The Danish National Genome Center aims to have a culture with transparency in the work and case management securing that decisions and settlements are objective. The National Strategy for Personalized Medicine, 2021-2022, states in conjunction the need to collaborate and coordinate the rising activity within personalized medicine. The transparency and objectivity in relation to the collaboration of multiple parties requires a clear and applicable policy of impartiality, securing that all employees as well as external partners are not just capable, but appear capable at the same time, which help building trust in the work of the Danish National Genome Center. That is why the policy of impartiality and the impartiality declarations are disclosed on the Danish National Genome Center's website.

This policy of impartiality is inspired by the Danish Health Authority's policy of impartiality that was released in February 2020¹.

2. Background

A person, who is working in the public sector and has a personal or financial interest in the outcome of a concrete case, cannot take part in the management of that particular case. That is the core requirement of impartiality – and the rules concerning incapacity. If a person is incapable, there is a risk that he or she is impartial in the judgement of a case. In other words, the person's own interests can influence the settlement in the case, which is, of course, unacceptable. The impartiality rules should not just work against concrete subjective regards in the Danish National Genome Center's management, but they should also create trust in a broader sense to the Danish National Genome Center and the agency's case management, decisions and general work. That is why the rules implies to a number of situations, that entails the risk of subjective decisions or that the public perceives as risky.

3. Responsibility

The Chief Executive Officer of the Danish National Genome Center is responsible for the continuous updates of the policy of impartiality and for the impartiality declarations being handled in the same procedures.

In terms of the committee and working groups, it is the responsibility of the executive secretariat and the health professional team to inform about the policy of impartiality and the impartiality declaration along with gathering, assessing, journalizing and publishing the declarations. If a person has a potential conflict of interest or if there are any other concerns about whether the person has an impartiality challenge, the respective committee/the respective working group or the chairperson in collaboration with the executive secretariat decides whether the conflict of interest leads to incapacity.

In terms of the employees in the Danish National Genome Center, the personnel manager has the responsibility for informing about the policy of impartiality. In that regard, impartiality declarations from employees

with managerial responsibilities are collected, and the associated personnel manager has the responsibility

¹ <https://www.sst.dk/da/om-os/strategi-og-grundlag/habilitet>

to assess, journalize and publish the declarations in question. For other employees, their impartiality is reviewed and assessed in connection with their employment and the annual employee evaluation. The personnel manager has the responsibility for the examination and assessment.

In terms of the external advisors/consultants, who are loosely connected to the Danish National Genome Center (i.e. they are not members of a committee, a network, a work group or related), it is their contact leader in the Danish National Genome Center who is responsible for informing about the policy of impartiality and the impartiality declaration along with gathering, assessing, journalizing and publishing the declarations.

The executive secretariat in the Danish National Genome Center administratively supports the Chief Executive Officer, the personnel managers and chairpersons for the working groups etc.

4. Impartiality Rules

Chapter 2 of the Danish Public Access to Information Act concerns incapacity². Generally, the Danish Public Access to Information Act is only applicable in cases where settlements are decided. However, the impartiality rules apply to cases about contractual relationships and similar private law provisions as well. With regard to the agency's additional management activities, such as making settings, preparation of guidelines, statements and reviews, the corresponding impartiality considerations applies. A person, who is incapable, should therefore not take part in any decision-making, if the decision has crucial importance in accordance to the Danish Public Access to Information Act.

4.1 About doctors', nurses', dentists', and pharmacists' connection to the industry

The Danish Medicines Agency's rules concerning doctors', nurses', dentists', and pharmacists' connection to the industry applies to employees in the Danish National Genome Center and external advisors/consultants as well, including members of committees/working groups set up by the Danish National Genome Center belonging to the mentioned groups. Therefore, these people should be aware about the Danish National Genome Center's own impartiality policy and the statutory rules about Industry Corporation³.

Filling out the Danish National Genome Center's declarations of impartiality does not replace the need to report a connection to the industry to the Danish Medicines Agency or apply for the Danish Medicine Agency's approval of a connection or approval to receive support from a medical business, likewise a report or approval does not replace a declaration of impartiality. The connection rules applies to doctors etc, who execute clinical work in Denmark and are involved in patient treatment. Additionally, the rules also applies if a person takes a leading role with significant impact on other doctors', nurses' or dentists' decisions in terms of patient treatment.

5. Declarations of impartiality

Generally, the incapable person is obligated to announce it. This is also the case if the person is in doubt about his/her own incapacity.

Both the personnel managers and the chairpersons for the working groups in the Danish National Genome Center are responsible for the information about the impartiality policy. Thus, employees in the Danish

² www.retsinformation.dk/forms/r0710.aspx?id=161411

³ www.laegemiddelstyrelsen.dk/da/godkendelse/sundhedspersoners-tilknytning-til-virksomheder/

National Genome Center and external advisors/consultants, including members of committees/working groups set up by the Danish National Genome Center, are informed about the policy no later than in connection with the advisory work or the commencement of the position.

The policy of impartiality is referred to in commissions of working groups etc and the policy of impartiality will be mentioned at the first meeting in the working groups. The members of working groups also have to complete a declaration of impartiality in advance of the first meeting. If a member of a committee or a working group from the Danish National Genome Center has yet to complete a declaration of impartiality, he/she will be considered incapable until the declaration is completed.

Employees, including the external consultants of the Danish National Genome Center, have to inform their personnel manager if there is doubt about impartiality. External consultants/advisors, including members of working groups etc from the Danish National Genome Center, that performs tasks, including counselling for the Danish National Genome Center, have to make sure that available information about possible challenges regarding incapacity is passed on to the relevant leader in the Danish National Genome Center.

To ensure transparency regarding possible challenges with impartiality, the Danish National Genome Center uses a declaration of impartiality in most cases. In the declaration of impartiality, the employee or external consultant/advisor, including members of committees/working groups of the Danish National Genome Center, informs the employer about circumstances, which may be relevant in the evaluation of incapacity.

The demand of completing a declaration of impartiality does not exempt employees from bringing attention to circumstances, which can cause incapacity, irrespective of these circumstances appearing in the declaration of impartiality or not. Employees must immediately inform about new essential circumstances, that has relevance to the impartiality. Employees are also obligated to update their declaration of impartiality.

If it can be proved that a person has acted in conflict with the Danish National Genome Center's policy of impartiality, it will be reported to the manager/presidency of the working group, who will evaluate whether or not the investigation of the case shall be amended without the participation of the incapable member.

5.1 What does a declaration of impartiality consist of?

As a starting point, the person of concern has to confirm their presence or absence of possible relevant impartiality information within the following categories:

- Stocks, shares or any other form of current co-ownership in companies, which operates within the field of the Danish National Genome Center's operating range.
- Current membership of management board, executive committee or other similar positions in such companies.
- Employment or other paid performance of duties (Including membership of advisory board or the like) in such companies within the last 5 years.
- Spouse, companion, member of household or close family⁴ is currently co-owner, employed or in any other way associated with such companies.
- Ownership of patents in areas, which are a subject to the counseling of the Danish National Genome Center.
- Other affiliations or circumstances, which can be relevant to the impartiality.

⁴ This regards nephews and nieces but not siblings of parents or their children (Cousins), jf. Forvaltningsloven with comments by John Vogter, 3rd edition 2001, p. 17.

Extern counselors/advisors, including members of committees/working groups set up by the Danish National Genome Center, have to inform about it, if the persons main working space receives financial contributions from the above mentioned companies, for example grants to, or payment of research projects.

If in doubt whether or not a circumstance shall be listed on a declaration of impartiality, one should as a starting point write it on the declaration

5.2 Who is supposed to fill out a declaration of impartiality?

Declarations of impartiality shall be obtained from the managers, bosses or leaders in the Danish National Genome Center and from external counselors/consultants, including all members of committees and working groups etc who are set up by the Danish National Genome Center.

The use of declarations of impartiality can be omitted for persons who – without being employed in the Danish National Genome Center – contributes with counselling to the Danish National Genome Center if all of the following conditions are met:

- Counselling is happening within a delimited, shorter period and has a modest extent.
- The person is chosen by somebody else than the Danish National Genome Center, for example an academic organization, a patient association or a public institution.
- The person is informed about the rules of impartiality in the Danish Public Access to Information Act and is explicitly being encouraged to inform the Danish National Genome Center about possible problems regarding impartiality, for example in the letter of appointment or during the (first) meeting, if the person is a part of a working group or so.
- Where it is evaluated necessary and relevant, the clarification of possible problems regarding impartiality should continuously be put on the agenda in meetings of the concerned committee, working group etc

On the other hand, it will be necessary to gather declarations of impartiality from members of committees and working groups etc – despite a limited activity of meetings and regardless if the mandate of the group is time limited or not – if the group makes decisions or makes out committing guidelines etc of impactful character regarding the affected part or parties.

As a starting point, an extern consultant or counsellor must fill out a declaration of impartiality. Although it is possible to exclude an external consultant or counsellor from filling out a declaration of impartiality, depending on the character and duration of the tasks of the counseling. This does not count, if the person of concern has to practice counselling as a part of a working group. The question regarding whether or not a declaration of impartiality has to be filled out, depends on a specific assessment made by a manager/leader who makes the deal with the consultant or counsellor. At this assessment one of the main focuses will be the character of the task and the extent of the attachment of the consultant, including whether or not this attachment is comprehensive and long-lasting or just a more loose and delimited task.

It is the content of the task as well as the duration of the task solving that will be included in the assessment of whether or not it is a necessity to fill out declarations of impartiality.

5.3 Publication of declarations of impartiality for members of committees etc and leaders in the Danish National Genome Center

The valid declarations of impartiality for members of committees and work groups etc including managers, bosses and leaders in the Danish National Genome Center will be published on the official website of the Danish National Genome Center.

The declarations of impartiality will be removed a month after the cooperation with the Danish National Genome Center ceases, for example if the work group is discontinued or the employment ends. The publication can be extended if it, as an example, is assessed that it is a necessity due to the results of the functioning of the work group.

6 Guiding criteria of the assessment of impartiality

The assessment of the impartiality regards if the employee of the Danish National Genome Center, the extern counsellor/consultant, or the member of a committee/working group in the Danish National Genome Center, principally or specifically could have a personal, financial or in any other way a subjectively interest in the outcome of a given case, or if any other circumstances are existing which could lead to doubt about impartiality of the person in question.

Representatives in committees, who are chosen by regions, communes, public or private hospitals, academic associations and other stakeholder organizations, will normally be responsible for these aspects and will therefore typically not be incapable during the discussion of topics related to this representation. A single representative can be incapable regarding a specific case, if the person of concern has a personal and individual interest in the specific case, for example by counselling the Danish National Genome Center in a case that can affect the position or employment of the representative.

Membership of drug or medico industry funded advisory boards etc in a company, which contains activities in the specific field that the person of concern counsels the Danish National Genome Center about, can mean that this person is incapable of counselling in the Danish National Genome Center in the specific field. This also counts for co-ownership or comprehensive investor holdings in a company, ownership of patents etc

Examples:

Lars is the leading chief physician in the clinical genetically department in Aalborg and is chosen by the region of Northern Jutland to be in a working group which involves selecting patients to Whole Genome Sequencing. Lars is impartial despite his place of employment because it is expected of him to handle the interests of the region.

Gitte is chosen by "Danske Patienter" (Danish Patients' Association) to be included in The National Network of Specialists in Rare Diseases in Adults. She has previously gone through a treatment for a rare disease herself and she is the chairman of The Union of Rare Diagnoses. Gitte is impartial because it is expected of her to handle the interests of patients.

Per is chief physician in the hematology department in Copenhagen and is also a member of an advisory board, which is funded by a pharmaceutical business. This advisory board counsels about clinical conditions related to certain types of cancers. Per is chosen to be in The National Network of Specialists of hereditary hematological diseases. Per is impartial despite of his membership of an advisory board because the counselling in this case is general in nature.

6.1 Waiting period, secondary activity and investor holdings etc

By the selection of external chairmen of committees, working groups etc it is evaluated if the person of concern should be declared incapable in cases that relates to previous workplaces or areas of responsibility, for example in a hospital or in a pharmaceutical or medico industry business. One such waiting period will, as a starting point, last at least one year. The assessment is made by the Danish National Genome Center.

Employees with a main occupation at the Danish National Genome Center, who wishes to take on a side em-

ployment in the health, medicine or medico field, always have to inform their leader. After an evaluation, the management can choose to ask the employee to abstain from taking on a side employment if it is evaluated that the side employment will be a nuisance to the main occupation. The assessment of whether or not a possible side employment will lead to incapability depends on a specific evaluation.

Employees' stock items etc, which are a part of the area of the Danish National Genome Center's functional area, are evaluated of possible incapability by the nearest personnel manager, taking into account the task areas, the quantification of the stock items etc A larger stock item in for example a pharmaceutical company will as a starting point declare the employee incapable in a case management in the specific field in which the company is active.

6.2 External advisers'/consultants' lectures and teaching etc

Occasional teaching or single lectures in courses or in relation to arrangements, which are completely or partially sponsored by the pharmaceutical or medico industry, can from a specific evaluation be compatible with counseling of the Danish National Genome Center in the specific area.

However, comprehensive or returning commitments are incompatible with counselling of the Danish National Genome Center.

Example:

Mona is chief physician in the department of genetics in Aarhus and has given a lecture at the yearly meeting of the Danish Union of Medical Genetics. Her bus ticket, hotel stay and conference dinner is paid for but fees are not. It appears from the program that multiple companies sponsor the meeting, and they hold exhibitions at the yearly meeting too. Due to this being an isolated case without fees, Mona is not declared incapable of handling tasks as the expert of genetics at the Danish National Genome Center.

6.3 Employees' participations at arrangements etc

By invitations to conferences, requests to participate in debate arrangements and such, it is necessary to consider conditions of impartiality and the association to commercial interests. An invitation must be discussed the closest manager.

In relation to receiving gifts at arrangements etc the instructions of "Code of conduct in the public sector"⁵ from Medarbejder- og Kompetencestyrelsen from 2017 is referred to.

7 Further information

If there are any questions regarding the policy or the completion of declarations, please consult the jurists of the executive secretariat in the Danish National Genome Center.

8 List of appendices

Appendix 1: Declaration of impartiality to persons that has to assist the Danish National Genome Center by counselling, teaching or processing cases.

Appendix 2: Declaration of impartiality to employees of the Danish National Genome Center.

⁵ <https://www.medst.dk/arbejdsomraader/hr/retningslinjer-for-embedsmaend/god-adfaerd-i-det-offentlige/>

Appendix 1: Declaration of impartiality to persons that has to assist the Danish National Genome Center by counselling, teaching or processing cases.

Personal information

Name: _____

Qualification and title: _____

Company/Institution: _____

Area of expertise: _____

Task type

If there are any questions regarding the completion of this declaration, please contact the jurists in the executive secretariat in the Danish National Genome Center.

What are you doing for the Danish National Genome Center?

By the participation in working groups etc please note group (committee, network) or any other association:

Regarding the participation in working groups etc please note second group (committee, network) or any other association, if you have other affiliations:

Regarding the participation in working groups etc please note the third group (committee, network) or any other association, if you have other affiliations:

Information about personal interests

- I own stocks, shares, parts or any other type of co-ownership in companies, which is included in the functional area of the Danish National Genome Center.

If yes, which?

- I am in the management board, executive committee or the like in one or multiple companies or institutions, which are included in the functional area of the Danish National Genome Center.

If yes, which?

- Within the last five years, I have been employed or have received payment of tasks done by one or multiple companies or institutions (including hospitals and clinics) which are included in the functional area of the National Genome Center. If yes, which? For advisory boards and other counselling tasks please note the subject you have been counselling about.

- I have a patent on one or multiple products within areas that are included in the functional area of the Danish National Genome Center. If yes, which?

- I have a personal or financial interest in companies, which have the potential of becoming contractors or in any other way take part of a civil-law partnership with the National Genome Center in regards to the task that I am doing for the Danish National Genome Center. If yes, which?

- Is a person in your nearest family employed, co-owner or in any other way associated with companies or institutions, which are included in the functional area of the Danish National Genome Center? If yes, which?

Nearest family:

- *Spouse, companion or roommate*
- *Children, parents or siblings*
- *Nephews and nieces with a special association*

- Is your workplace receiving financial contributions from companies or institutions, which are included in the functional area of the Danish National Genome Center? If yes, which?

- Do you have any other associations, or other circumstances, which can be relevant for your incapability? If yes, which?

Declaration

I have to the best of my knowledge no other irrelevant interests, which potentially can affect my objective work for the Danish National Genome Center. If changes occur, I will immediately complete a new declaration in which the changes appear. The declaration is published on the official website of the Danish National Genome Center.

Date

Signature

Appendix 2: Declaration of impartiality for employees of the Danish National Genome Center

The chief executive officer, managers and leaders in the Danish National Genome Center must complete a declaration of impartiality. This is done to ensure that no one participates in specific decisions or any other work in which personal or financial interests potentially could affect the outcome and therefore create uncertainty regarding the credibility and integrity of the Danish National Genome Center.

The declarations of impartiality creates trust in us making our decisions on a factual basis. It also protects you as an employee by preventing you from working with cases in which there potentially could be a conflict of interests that you might now be aware of yourself.

When you have signed and sent your declaration of impartiality, your nearest leader will decide, if there are any circumstances that can be relevant in regards to your work tasks in the Danish National Genome Center. If your leader decides that there are circumstances, which are problematic in regards to your impartiality, you will be contacted. If you answer "Yes" to any of the questions, it does not necessarily mean that there are problems regarding your impartiality. It depends on a specific evaluation of the circumstances and the task that you will have to handle for the Danish National Genome Center.

Personal information

Name: _____

Title: _____

Information about personal interests

If in doubt about the completion of this, please contact your nearest leader.

- I own stocks, shares, parts or any other type of co-ownership in companies, which are included in the functional area of the Danish National Genome Center.
If yes, which?

- I am in the management board, executive committee or the like in one or multiple companies or institutions, which are included in the functional area of the Danish National Genome Center.
If yes, which?

- Within the last five years, I have been employed or received payment for tasks done by one or multiple companies or institutions (including hospitals and clinics) which are included in the functional area of the Danish National Genome Center. If yes, which? For advisory boards and other counselling tasks please note the subject you have been counselling about.

- I have patent on one or multiple products within areas that are included in the functional area of the Danish National Genome Center.

If yes, which?

- I have a personal or financial interest in companies, which have the potential of becoming contractors or in any other way take part of a civil-law partnership with the Danish National Genome Center in regards to the task that I am doing for the National Genome Center.

If yes, which?

- Is a person in your nearest family employed, co-owner or in any other way associated with companies or institutions, which are included in the functional area of the Danish National Genome Center?

If yes, which?

Nearest family:

- *Spouse, companion or roommate*
- *Children, parents or siblings*
- *Nephews and nieces with a special association*

- Is your workplace receiving financial contributions from companies or institutions, which are included in the functional area of the Danish National Genome Center?

If yes, which?

- Do you have any other associations, or other circumstances, which can be relevant for your incapability?

If yes, which?

Declaration

I have to the best of my knowledge no other irrelevant interests, which potentially can affect my objective work for the Danish National Genome Center. If changes occur, I will immediately complete a new declaration in which the changes appears. The declaration is published on the official website of the Danish National Genome Center.

Date

Signature

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