

Rules on the prevention, avoidance and management of conflicts of interest applicable to the governance bodies and other bodies or groups of the Innovative Health Initiative Joint Undertaking (IHI JU)

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CHAPTER I- SCOPE, GENERAL OBLIGATIONS AND DEFINITION

Article 1 - Subject

The Innovative Health Initiative Joint Undertaking (hereafter 'IHI JU') is dedicated to maintaining high ethical standards, and to adhering to the principles of integrity, objectivity, honesty, in compliance with the relevant rules and regulations at all time.

Ethics, integrity and transparency are key drivers of IHI JU actions in performing its mission and achieving its objectives. The members of all IHI JU governance bodies and other advisory groups, staff, scientific experts, and all external contractors must pursue the highest standards of ethics and integrity in the exercise of their duties.

Regardless of the impeccable behaviour of members of IHI JU bodies and groups, certain situations can be reasonably considered by others (citizens, journalists, politicians, etc.) as raising an ethical question. This can have serious financial, political, legal or reputational repercussions on the IHI JU, the European Commission and IHI JU governance bodies.

The present document lays down rules for the prevention, avoidance and management of conflicts of interest applicable to the members and alternates of the Governing Board, States' Representatives Group, Science and Innovation Panel (the "Governance Bodies" or, individually considered, the "Governance Body") and other bodies or groups of the IHI JU, in order to ensure, in a transparent and consistent manner, the prevention and the handling of situations where potential, perceived or actual conflicts of interest may arise. This includes protection of the financial interests of the IHI JU against fraud.

Article 2 - Legal background

According to the Regulation establishing the Joint Undertakings (Single Basic Act¹), 'the Governing Board shall adopt rules for the prevention, avoidance and management of conflicts of interest in respect of the members and other persons serving the governing board and in the other bodies or groups of the joint undertaking'².

Prevention and management of conflict of interest situations across the Joint Undertakings are governed by:

- a) The Single Basic Act, and in particular Article 42(2);
- b) IHI JU Financial Rules³, in particular Article 14 and Article 27;

¹ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, OJ L 427, 30.11.2021, p. 17–119, ELI: <http://data.europa.eu/eli/reg/2021/2085/oj>.

² Single Basic Act, Article 42(2).

³ Decision IMI2-GB-DEC-2020-16, adopted by the Governing Board by means of Decision IHI-GB-DEC-2023-14 of 23 June 2023, concerning the list of decisions adopted by the Governing Board of the Innovative Medicines Initiative 2 Joint Undertaking that shall continue to apply for the Innovative Health Initiative, amended by Decision No IHI-GB-2023-14 of 23 June 2023 (Ares(2023)4372184)

- c) IHI JU Anti-Fraud Strategy⁴;
- d) Rules and procedures of each Governance Body of the IHI JU⁵;
- e) IHI JU Privacy Statements.

These rules on the prevention, avoidance and management of conflicts of interest applicable to the governance bodies and other bodies or groups of IHI JU do not replace but complement the above-listed rules, and those in the Code of Conduct to be adopted by the Governing Board in line with Article 16(11) of Single Basic Act, and describe the key principles, definitions, rules and procedures applicable in IHI JU in situations of conflicts of interest.

Article 3 - Scope and persons concerned

These rules shall apply to the following categories of persons involved in the work and activities of the IHI JU:

- Members and alternates of the Governing Board,
- Members of the Science and Innovation Panel,
- Members and alternates of the States' Representatives Group,
- Members of other bodies or groups of the IHI JU,
- Persons invited to attend meetings of the Governing Board or of any of the other advisory bodies of the Joint Undertaking, including observers,
- Other persons serving the Governing Board or the other advisory bodies in whichever capacity,

also collectively referred hereinafter as the "Members of the IHI JU bodies or groups".

Furthermore, the general principles included in this decision shall also apply *mutatis mutandis* to any person who will provide any formal advice to the IHI JU where more specific provisions are not established.

Article 4 - General principles on conflict of interest and personal interest

4.1 General principles

The main objective of these rules is to ensure that the Members of the IHI JU bodies or groups have no individual or corporate interest which could affect their independence, as per the requirements of the Council Regulation 2021/2085 setting up the Joint Undertakings under Horizon Europe⁶ (the 'Single Basic Act') and other applicable provisions.

⁴ Decision IHI-ED-DEC-2022-39 of 16 December 2022, adopting the Anti-Fraud Strategy of the Innovative Health Initiative Joint Undertaking (Ares(2022)8755031).

⁵ Rules and procedures of the IHI JU Governing Board (IHI-GB-DEC-2021-01 of 16 December 2021, Ares(2021)7794628, repealed by decision IHI-GB-DEC-2023-21 of 14 August 2023, Ares(2023)5639029), Rules and procedures of the IHI JU Science and Innovation Panel (adopted on 31 March 2022, Ares(2022)1810439), and Rules and procedures of the IHI JU States' Representatives Group (adopted on 11 March 2022, Ares(2022)2421479)

⁶ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014, OJ 30.11.2021 L 427/17.

Other objectives are:

- Achieving a robust process based on the assessment of the interests of Members of IHI JU bodies or groups reported in declarations of conflict of interest they are requested to sign;
- Implement an effective system which provides adequate monitoring and enforcement;
- Improve the transparency and accountability of the IHI JU's policy.

In the assessment of the declarations of conflict of interest, the following principles apply:

- the identification and handling of conflict of interest shall be based on the evaluation of the declarations of conflict of interest submitted by the concerned Member of the IHI JU bodies as specified below;
- the responsibility for a complete and truthful declaration shall lie exclusively with the Member of the IHI JU bodies or groups completing the declaration.

Furthermore, as an EU body managing EU funds, the IHI JU is responsible for the management of the operational and administrative resources allocated to its programme in the context of the EU research programmes⁷.

According to the Single Basic Act, the IHI JU has a specific obligation to protect the financial interests of its members (see Article 30⁸) and shall reduce the risk of fraud and irregularities by building relevant preventive and protective measures in the Internal Control systems (Article 14 on Internal control of budget implementation and Article 19 on the principle of sound financial management of the IHI JU Financial Rules⁹).

The IHI JU has zero tolerance for fraud and is committed to full transparency and accountability to its partners and stakeholders. The IHI JU continues to pursue the policy of "zero tolerance" against fraud implemented by its preceding initiatives in the past research programmes and reports, without delay, any instance of suspected fraud to the European Anti-Fraud Office (OLAF) and the European Public Prosecutor's Office (EPPO) (where relevant) to investigate these cases¹⁰.

⁷ The operational management of the IHI JU currently includes a few remaining long-lasting projects signed under FP7, the projects funded under Horizon 2020 and the upcoming projects under Horizon Europe.

⁸ Single Basic Act, Art 30.5: "Each joint undertaking shall ensure that the financial interests of its members are adequately protected by carrying out or commissioning appropriate internal and external controls."

⁹ Financial Rules of the IHI JU adopted by the Governing Board by means of Decision No. IHI-GB-2021-03 of 16 December 2021 concerning the list of decisions adopted by the Governing Board of the Innovative Medicines Initiative 2 Joint Undertaking that shall continue to apply for the Innovative Health Initiative, amended by Decision No IHI-GB-2023-14 of 23 June 2023, Ares(2023)4372184

¹⁰ See Commission Decision of 28 April 1999 establishing the European Anti-Fraud office (OLAF), OJ No L 136 of 31.5.1999, p. 20: The investigations are conducted in accordance with Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999, OJ L 248, 18.9.2013, p. 1

4.2 Definitions

The following definitions apply to these rules:

- **Personal Interest** means the fact of being concerned in something, e.g. by having a right, a title, a claim or a share therein. A relevant personal interest may notably be of a financial or non-financial nature and it may also concern a personal or family relationship, any representation of any other interests of third parties or a community of interests with any third parties, any professional or economic affiliation, as well as any other outside activities leading to the situation described.
- **Interest of family member or similar** means interests in the subject matter held by spouses, partners or persons dependent on a member of an IHI JU body or group submitting a declaration of conflict of interest.
- **Declaration of conflict of interest** means a self-declaration, containing information capable of identifying potential independence risks including a potential perceived or actual conflict of interest.
- **Conflict of Interest** is defined under Article 2(14) of the Single Basic Act as a situation involving a member of an IHI JU body or group, where the impartial and objective exercise of his/her functions is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect personal interest in the context of his or her activities in the IHI JU, as referred to in Article 61 of Regulation (EU, Euratom) 2018/1046¹¹.
- **Potential Conflict of Interest** means a situation when a Member of the IHI JU bodies or groups is involved in interests that may appear to be in conflict.
- **Perceived Conflict of Interest** includes situations where it could be perceived to a reasonable person, that the personal interest of a Member of the IHI JU bodies or groups could improperly or unduly influence the performance of their duties and responsibilities.
- **Disqualifying Conflict of Interests** means a situation when a Member of the IHI JU bodies or groups is involved in multiple interests that make him/her unsuitable to participate in a given IHI JU task or activity.
- **Employment** means any form of regular paid occupation or business, part-time or full-time, including self-employment;
- **Consultancy** means an activity where the individual concerned provides advice or services (including training on a one-to-one basis and one-off tasks or assignments) regardless of contractual arrangements or any form of remuneration;

¹¹ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193, 30.7.2018, p. 1–222

- **Strategic advisory role** means any participation, with a right to vote on or with other means to influence the outputs, in (scientific) board or committee of a public or private entity with interest in the subject matter e.g. member of a managing body or equivalent structure or scientific advisory body;
- **Financial interests** mean any material economic stake or share, including the stocks, equities or bonds, or one of its subsidiaries;
- **Professional or work association membership:** means any participation in a professional or work association, e.g. member of a managing body or member, with a right to vote on or with other means to influence the outputs or have access to confidential information, in the field of IHI JU activities.
- **Other relevant interest** means any interest not falling under the definitions provided above and relevant for the purposes of the present decision e.g. member of an entity receiving an IHI JU grant or other funding.

CHAPTER II – OBLIGATIONS OF THE MEMBERS AND ALTERNATES OF THE GOVERNANCE BODIES

Article 5 - General obligations

- a) The Members of the IHI JU bodies or groups shall carry out their duties and act, under their statutory function, in the sole interest of the IHI JU. The Members of the IHI JU bodies or groups shall carry out their duties objectively and impartially, keeping their duty of loyalty to the IHI JU, and shall abstain from any action adversely affecting the reputation of the IHI JU.
- b) The Members of the IHI JU bodies or groups shall not seek or act in any way to take undue advantage of, or exercise undue influence on the implementation of the programme and the activities of the IHI JU.
- c) The Members of the IHI JU bodies or groups should not, in the performance of their duties, deal with a matter in which, directly or indirectly, they may have any personal interest such as to impair their independence as this would compromise or reasonably be perceived to compromise the impartiality and objectivity of a decision, opinion or recommendation of the IHI JU.
- d) A conflict of interest can arise even if the person does not actually benefit from the situation, as it is sufficient that circumstances compromise the exercise of their functions in an objective and impartial manner.
- e) Relevant personal interest may be of a financial or non-financial nature, and it may concern a personal or family relationship or representation of any other interest of third parties or professional affiliation and other outside activities.
- f) The perception of a conflict of interest can constitute a reputational risk to the IHI JU. Therefore, taking due consideration of proportionality, specific backgrounds, all relevant facts and mitigating circumstances, a risk of potential or perceived conflict of interest should be treated as if it were an actual conflict of interest.

- g) It is the responsibility of the Members of the IHI JU bodies or groups to ensure that their conduct is in line with the rules regarding the conflict of interest in both letter and spirit. Each Member of the IHI JU bodies or groups shall assume an individual responsibility by declaring in good faith his/her interest and information, in compliance with the applicable provisions.
- h) To prevent conflicts of interest, the Members of the IHI JU bodies or groups should not be involved in applications or projects nor occupy the position of external expert for the evaluation of proposals in the framework of the calls launched by the IHI JU.

Article 6 - Specific obligations in relation to conflict of interest and personal interest

The appointed Members of the IHI JU bodies or groups shall fill in the declarations on confidentiality and conflict of interest, in accordance with the respective rules and procedures of the relevant IHI JU body or group, if they exist, and in any case before attending the first meeting of the relevant IHI JU body or group and before having access to the relevant platform and confidential information. A model declaration is adopted by the IHI JU bodies or groups and annexed to the relevant rules and procedures.

- a) Any actual or potential conflict of interest must be declared by the Members of the IHI JU bodies or groups with regard to the agenda of any official meeting they will attend in such capacity, before attending such meeting.
- b) Members of the IHI JU bodies or groups must promptly disclose all relevant information about a personal interest when circumstances change following their initial disclosure or when new situations arise. If at any time in the course of his/her duties, a Member of the IHI JU bodies or groups becomes aware of any potential conflict of interest or any perception of a conflict of interest, he/she is obliged to inform the chairperson of the relevant body or group of the IHI JU. This must be done spontaneously submitting an updated declaration on conflict of interest or a written notification, as it is most appropriate, unless otherwise established in the applicable rules of procedure or in the decision or act appointing him/her as Member of the IHI JU bodies or groups.
- c) In cases where the declaration referred to above shows a potential or actual conflict of interest, the competent IHI JU body or group shall take the appropriate measures, in collaboration with the IHI JU Programme Office, and taking into account the relevant rules and procedures, if they exist, before the Member of the IHI JU bodies or groups takes up/resumes his/her duties.
- d) Any permission granted in compliance with the applicable rules and procedures pursuant to a declaration submitted by a Member of the IHI JU bodies or groups shall be limited to the specific situation described in the declaration and cannot be extended to any other similar situations.
- e) Any change of the initial situation described in the declaration shall be considered as a new situation and must be brought to the attention of the relevant body or group of the IHI JU and of the IHI JU Programme Office, according to the above-mentioned rules and applicable provisions.

Article 7 - Procedures

7.1 Procedures to manage a conflict of interest

- a) The Executive Director shall ensure that the IHI JU implements appropriate awareness-raising measures to all the bodies or groups of the IHI JU on rules for the prevention, avoidance, and management of conflicts of interest. These measures must also ensure that the bodies, groups or persons falling within their scope have continued familiarity with those provisions.
- b) Unless otherwise established in the relevant rules and procedures, any Member of the IHI JU bodies or groups who becomes aware of a potential or actual conflict of interest related to its activities shall immediately inform the chairperson of the competent body or group of the IHI JU who will inform without delay the IHI JU Programme Office and the IHI JU Members. If the conflict of interest regards the chairperson, the vice-chairperson of the respective body or group should be informed.
- c) The concerned Member of the IHI JU bodies or groups will be asked to provide further information. Following that, after consulting the IHI JU Programme Office, the relevant IHI JU body or group shall decide on the appropriate measures to be taken in compliance with the applicable rules and procedures of the respective body or group and apply them in collaboration with the IHI JU Programme Office. If such rules do not exist in relation to a non-statutory group, the issue should be referred to the Executive Director of the IHI JU who may decide to refer the decision to the Governing Board.
- d) A conflict of interest should be resolved with appropriate mitigating actions. The following actions may notably be taken in case of a potential, perceived or actual conflict of interest:
 - disclosure to the appropriate people;
 - recusal from decision-making whenever possible;
 - segregation of duties;
 - written mitigating action plan.

7.2 Ex-post treatment of situations of non-compliance with the obligations under the present rules

The chairperson of the relevant body or group of the IHI JU shall immediately inform the IHI JU Programme Office of any conflict of interest related to its Members and the measures taken to prevent and manage the respective conflict of interest.

In case of failure by a Member of the IHI JU bodies or groups to declare an actual or potential conflict of interest or failure to comply with the applicable rules on conflict of interest, the competent body or group shall decide the appropriate measures to be taken after hearing the respective Member of the IHI JU bodies or groups, and after consulting the IHI JU Programme Office.

If the concerned person was involved in a decision-making procedure without having declared an interest, the respective body or group may undertake remedial actions, in particular to review or withdraw the decision if seriously affected by the conflict of interest. This implies carrying out an *ex-post* review of the person's activities and contributions to the deliberation and vote.

CHAPTER III – GENERAL AND FINAL PROVISIONS

Article 8 - Register

- a) The declarations of conflict of interest or statement of interest made by a Member of the IHI JU bodies or groups, shall be adequately recorded by the IHI JU Programme Office for a period of 5 years after the expiration of the mandate of the Member of the IHI JU bodies or groups, in compliance with the rules on documents management established by the European Commission.
- b) The above register shall be maintained in compliance with the applicable provisions of Regulation (EU) 2018/1725¹² on protection of natural persons with regard to processing of personal data.

Article 9 - Transparency

- a) The IHI JU shall publish on its website the present rules for the prevention, avoidance and management of conflict of interest.
- b) Bearing in mind the legal rights of individuals in relation to personal data protection, in particular Regulation (EU) 2018/1725¹³, the name of the Members of the IHI JU bodies or groups of the IHI JU together with the name of their employer¹⁴ may be published on the IHI JU website, where required or relevant.
- c) Where relevant, the declarations of interest by the Members of the IHI JU bodies or groups of the IHI JU shall be available for public scrutiny with due respect to the Single Basic Act, and the applicable EU rules on protection of personal data¹⁵ and access to documents¹⁶. Where deemed relevant, the concerned person's CV (or a summary of his/her professional experience) could also be made available.

¹² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

¹³ See above.

¹⁴ For stakeholders' representatives and members of non-statutory bodies or groups, it would suffice to list the organisation represented.

¹⁵ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

¹⁶ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43–48