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Governance Principles

(V5. Adopted August 2018)

Purpose

ICE-HBV aims to fast-track the discovery of a safe, effective, affordable and scalable cure to benefit all people living with CHB, including children and people living with HCV, HDV and HIV co-infection. ICE-HBV intends to contribute to the elimination of CHB as a global public health challenge.

Governing Structure

The Governing Board (GB) is responsible for the strategic direction and general governance of ICE-HBV

Role

The GB possesses the highest and most extensive authority concerning decision-making and administration for ICE-HBV. The GB decides on strategic priorities for ICE-HBV. It supports the Honorary President, Chair and Deputy Chair in their representation roles. It gives guidance to the secretariat to design and run the initiative. The GB appoints its own members and plays an active role in the establishment of scientific working groups. The GB ensures the development of sustainable resources for ICE-HBV. The GB approves yearly budgets and defines ICE-HBV policies (confidentiality policy, industry engagement rules, etc).

Composition

The Board shall consist of up to fifteen voting members and up to three non-voting members. Ideally, board members shall be representatives from key partner institutions and stakeholders but the Board may appoint unaffiliated individuals in their personal capacity based on their skills and networks.

Board members must have recognized international/regional experience. The Board should seek regional representation and gender balance among its members.

The initial composition of the Board shall be nine voting members and two non-voting members according to the following breakdown:

Voting:

- two seats for representatives of the Doherty Institute (DI);
- two seats for representatives of the ANRS;
- two seats for representatives of the International HBV Meeting;
- one seat for a representative of a global advocacy/patient organization;
- one seat for a representative of each region most-affected by HBV (Africa and Asia)

Non-Voting:

- The Honorary President (hereafter the “HP”);
- The Executive Secretary (Program Manager, hereafter the “PM”) shall be an ex -officio non-voting Board member.

Nomination

Board members shall be appointed by the existing Board members. Each organisation or constituency that is entitled to have one or more voting Board members will determine a process for selecting its Board member(s), provided that such Board Member(s) shall possess skills relevant to ICE-HBV and provided that the process with respect to any constituency shall be acceptable to the Board. Each organisation or constituency shall be entitled to replace any of its representatives, and any such replacement shall be approved by the Board.

Unaffiliated individuals can be selected if the GB decides to do so.

Resignation

Board members can resign at any time by writing to the GB and the Secretariat.

Organisation of the Board

Current GB members terms are 4-year, starting at adoption date (10 April 2018).

Once the first term is complete and every two years after this, no more than half of the GB members will be replaced. At the end of the first term (9 April 2022), one seat per each founding member (DI, ANRS, and International HBV Meeting) will be open for replacement with priority given to including new organizations that the Board chooses. Founding members will keep minimum one seat each on the GB at all times.

GB members can be reappointed for another term of 4 years and then should rotate off. The departing GB members can be reappointed after a one-term hiatus.

Board members will select the Chair and a Deputy Chair of the Board from among their own voting members. The Chair and the Deputy Chair shall be selected for a two-year period. The Deputy-chair at the end of the Chair term (9 April 2020) is promoted to Chair and a new Deputy elected from the GB. The Chair and Deputy-Chair are responsible for running the Governing Board and representing ICE-HBV, together with the immediate past-Chair.

Decision-Making

A quorum shall be a majority of all voting Board members (or their permitted alternates). The Board will use all reasonable efforts to make decisions by consensus. If no consensus can be reached, any decision of the Board shall require a two-thirds majority of members present and voting. Unanimity is needed regarding new members of the GB. The Board may also act by means of teleconference, e-mail, proxy, or other method of communication, subject to procedures determined by the Board from time to time.

No decision taken by the Board is binding on any organisation providing members to serve on the Board.

Honorary President

The HP represents the initiative and promotes research for an HBV cure in diverse fora, within and beyond the HBV research community. The HP primarily acts as spokesperson for ICE-HBV and as advocate for HBV cure research. The honorary president takes part in the GB.

The GB and the Secretariat identifies opportunities for public speaking and supports the HP's participation to these events by providing logistic and content assistance (slides, speaking notes).

The HP is an open-ended position at the discretion of the GB.

Executive Committee

An Executive Committee (hereafter "EC") composed of HP, Chair, Deputy Chair, Immediate Past Chair and PM as ex-officio/non-voting is responsible for the day to day direction of ICE-HBV between GB meetings. The EC is in charge of implementing GB decisions with support from GB members when required.

Secretariat

The Doherty Institute, with support from ANRS, oversees ICE-HBV secretariat.

Financial Principles

Non-Profit Purpose

All of the purposes of ICE-HBV shall be exercised exclusively for charitable, scientific or educational purposes. ICE-HBV has no profit motive.

Per-Diem & Support

ICE-HBV does not provide per diem to GB members. Members participate pro-bono. If budget allows, the secretariat may provide travel assistance to GB members attending meetings on behalf of ICE-HBV.

Funding Sources

ICE-HBV may be funded by donations, contributions and commitments from certain constituencies represented on the Board and third parties, including without limitation nations, governmental and non-governmental organisations, private foundations, and such other sources as the Board determines are consistent with the purpose of ICE-HBV. Industry engagement rules are specified in Annex 6. Where Board members represent organisations, these organisations should contribute financially and/or in-kind to ensure the sustainability of ICE-HBV.

Funds Management

The University of Melbourne holds and manages ICE-HBV resources on behalf of the Doherty Institute (as Secretariat). Exceptions can be made for ICE-HBV to access geographically restricted grants.

ANNEX 1 - 2016/2020 Governing Board Members

Peter Revill, Australia (Chair)

Fabien Zoulim, France (Deputy Chair)

Christian Bréchet, USA (Honorary President)

Anna Kramvis, South Africa

Joan Block, USA

Massimo Levrero, Italy

Sharon Lewin, Australia

Wenhui Li, China

T. Jake Liang, United States

John Tavis, USA

Capucine Penicaud, Ex-Officio, France

ANNEX 2 – Senior Advisors Group

Senior Advisors are appointed by the GB and serve as ICE-HBV champions, ensuring visibility and credibility, giving guidance on strategic questions and supporting fundraising efforts. They also provide direct scientific advice to working groups when necessary.

Senior Advisors will be gathered at least yearly by teleconference and in person. The Senior Advisors Group will be chaired by the Honorary President.

Frank Chisari, USA

Marion Peters, USA

Raymond F. Schinazi, USA

Stephen Locarnini, Australia

ANNEX 3 – Working Groups Terms of Reference

(Immunology Example – Adopted April 2017)

The Working Group on Immunology (WGI) is responsible for producing immunology research recommendations in order to develop a global HBV cure scientific roadmap in collaboration with the other working groups.

Role & Responsibilities

WGI members review current immunology research in the HBV cure field, identify research gaps and provide research recommendations to address these gaps. They focus on the review of immunological biomarkers of HBV natural history, treatment response and disease progression.

They contribute to the writing and submission of joint position papers and in particular the publication of a global HBV cure scientific roadmap every four years, starting in 2018. To do so, they collaborate with ICE-HBV working groups on virology, innovative tools and clinical studies.

WGI members provide advice to ICE-HBV secretariat regarding key local and regional stakeholders to involve in the initiative and they share their networks to support the building of the Coalition. They participate in resources development efforts made by the secretariat by providing input and documents when appropriate.

Composition

The WGI is composed of 8 to 12 researchers representing excellence in HBV immunology worldwide.

WGI members are invited by the Secretariat based on recommendations from the WGI Co-Chairs in consultation with ICE-HBV provisional governing board (the Board). Whenever possible the WGI seeks to ensure diversity, geographical and gender balance, as well as promote mid-career investigators.

The Board nominates two WGI Co-Chairs who are responsible for running the WGI and ultimately for providing research recommendations discussed by the group in written format to ICE-HBV secretariat.

Members and Chairs are nominated for an initial 2-year period. The membership will be reviewed in January 2019. Shall one member step-down, WGI Co-Chairs will nominate replacement with advice from the Board and support from the Secretariat.

Decision-Making

The WGI takes decisions by consensus. Co-Chairs work together to resolve any disagreement that may arise.

Confidentiality

Unless indicated otherwise, discussions within the working group are confidential and documents should not be shared outside of ICE-HBV members.

Secretariat

The Doherty Institute, with support from ANRS staff, is in charge of the WGI secretariat. The secretariat support co-chairs in running the WGI and provides project management services, publications coordination and logistic assistance to members. The secretariat is not responsible for drafting of scientific recommendations and reporting back on WGI scientific discussions.

Per-Diem & Support

ICE-HBV does not provide per diem to WGI members. It is a non-profit organization, members participate pro-bono. If budget allows, the secretariat may provide travel support to WGI members attending ICE-HBV meetings.

ANNEX 4 – Stakeholder’s Consulting Group Terms of Reference

Adopted April 2018

The Stakeholders’ Consulting Group (SCG) is responsible for providing input on the development of the ICE-HBV global research roadmap. It provides advice to researchers working towards the discovery of a safe, affordable, scalable and effective hepatitis B cure, accessible to all including children. SCG members work together to ensure appropriate HBV cure preparedness and the timely and effective translation of scientific discovery into health outcomes.

Role & Responsibilities

SCG members review scientific recommendations developed by ICE-HBV scientific working groups and provide advice on the overall initiative. SCG members offer suggestions to ICE-HBV secretariat regarding other key stakeholders to involve in the initiative.

SCG discussions are articulated around three pillars:

- Better clinical care
- Community engagement (scientific literacy, clinical trials liaison, etc)
- Policy changes

The SCG can lead specific projects relevant to these three pillars. These projects must be endorsed by ICE-HBV Governing Board to be considered ICE-HBV activities.

Composition

The SCG is composed of key stakeholders in the field of HBV cure research. This includes, but is not limited to, representatives from research and regulatory agencies, foundations, NGOs, community-based organizations, research institutes and international organizations. Diverse regional representation is key.

SCG members are invited by the Secretariat based on recommendations from SCG Co-Chairs and ICE-HBV governing board (the Board).

The Board nominates 3 Co-Chairs who are responsible for running the SCG with support from ICE-HBV secretariat. Co-Chairs are invited for an initial 2-year period, renewable once.

Decision-Making

The SCG is a consulting body. No decision-making process is required.

Secretariat

The Peter Doherty Institute for Infection and Immunity, with support from ANRS staff, acts as SCG secretariat. The secretariat supports co-chairs in their role by providing project management services.

Per-Diem & Support

ICE-HBV does not provide per diem to SCG members. ICE-HBV is a non-profit organization; all members participate pro-bono. If budget allows, the secretariat may provide travel support to community members attending SCG meetings.

Activities

The SCG will meet at least yearly in conjunction with relevant international meetings. Other SCG meetings will be organized:

- For each pillar, to progress specific projects endorsed by the SCG.
- At regional conferences, to ensure regional engagement.

2017-2019 Co-Chairs:

Timothy Block (Hepatitis B Foundation)

Veronica Miller (HBV Frum)

Ulrike Protzer (DZIF)

2018 Projects Endorsed by Governing Board and SCG Co-Chairs

- Pillar 1. Develop an HBV Cure cost effectiveness model, led by Mehlika Toy and Benjamin Cowie.

-Pillar 2. Organise a community scientific literacy workshop for community leaders at the next World Hepatitis Summit (or even before at the Toronto Summit), in partnership with WHA, led by Michael Ninburg and Margaret Littlejohn.

- Pillar 3: Develop a policy/implementation commentary on HBV elimination for publication in Lancet or similar journal underlining the importance of HBV cure, gaps in the response and the lack of funding for HBV, under the leadership of Jeffrey Lazarus. The second step will be to build an investment case based on the cost-benefit analysis.

ANNEX 5 – Confidentiality Policy

(Adopted July 2017)

Objective:

To permit members of the ICE-HBV working groups share data freely without compromising their publications or intellectual property positions.

Policies:

Data: Data generated by the ICE-HBV working groups as part of their collaborative ICE-HBV efforts are the product of the working group as a whole, not the individual investigators. Therefore, their use in publications, presentations, and patent applications needs to equitably address the entire group's contribution.

Confidentiality: Data shared between members of the working group and the ICE-HBV governing board will be confidential and will not be distributed beyond the labs of the individual working group or governing board members without approval from the full working group. Confidential data may be shared with the stakeholders consulting group members only after receiving approval from the responsible working group and the Governing Board, and an explicit agreement from the stakeholders to maintain the data in confidence.

Publications: All publications and public presentations of confidential data produced as part of the collaborative working group projects must be approved by the working group and Governing Board in advance.

Intellectual property: Intellectual property stemming from ICE-HBV collaborative research remains with the individual working group members and is governed by the laws of the countries in which the investigators reside, unless superseded by previous intellectual property claims in the form of patent application. Funding agencies may retain an interest in the intellectual property generated through ICE-HBV collaborative research projects. This interest will be governed by the terms of the grants and contracts which provided funds to conduct the research.

Administrative Procedures:

- Administration of these policies is the responsibility of the working group chairpersons and the Governing Board.
- The working group chairpersons and Governing Board will establish mechanisms to review and approve public release of confidential data generated by the working group. These policies are to be tailored to the needs of the individual working groups and need not be the same for all working groups.
- All data shared between members of the working group that is part of the ICE-HBV collaboration must be labeled as "Confidential" within data files and in any physical or electronic communication containing the data. Failure to do so may endanger patentability of intellectual property.
- Authorship of publications and presentations including confidential ICE-HBV data will comprise the working group members who contribute to the body of work to be presented, following scientific norms. The working group chairpersons and the Governing Board will resolve any conflicts that may arise relative to authorship.
- All working group members will acknowledge in writing that they have received a copy of these policies and agree to abide by them.

ANNEX 6 – Industry Engagement Guidelines

(Adopted August 2017)

Background

The International Coalition to Eliminate Hepatitis B is a global initiative aiming to support the discovery of a safe, affordable, scalable and effective cure, available to all persons living with CHB. To achieve this, our vision is to create an international, independent, research-based and patient-centered forum in order to coordinate, promote and foster collaborative arrangements working towards a cure for HBV. The Coalition is not an incorporated entity. The Doherty Institute act as ICE-HBV secretariat under the legal responsibility of the University of Melbourne. ICE-HBV does not perform research per se, but engages in research coordination and promotion.

ICE-HBV has a real interest for collaboration with private sector entities, specifically from the pharmaceutical and diagnostics industries but also with companies from other sectors. Some pharmaceutical, diagnostics and IT companies have a direct commercial stake in HBV cure as suppliers of medical products and have expressed interest to work with ICE-HBV. Other sectors may be motivated to engage with ICE-HBV because their workforce, their clients or the communities in which they operate are impacted by the epidemic: They seek a platform to demonstrate good corporate citizenship.

ICE-HBV considers the private sector a core participant in search for an HBV cure, in addition to academia, community, governments, and civil society. After the publication date of ICE-HBV first scientific strategy, ICE-HBV will seek to work with private sector entities in three ways: as sponsors, as donors, and as participants in activities (see section 3 below). To ensure mutually beneficial relationships free of conflicts of interest, it is important to provide clarity for all involved on opportunities, limitations and accountabilities. The present guidelines have been developed for this purpose.

1. Guiding principles

1.1 Shared goals

ICE-HBV collaborates with private sector entities whose strategic goals are in good faith aligned with the ICE-HBV vision of discovering a safe, affordable, scalable and effective HBV cure.

1.2 Added benefit

Collaborations with private sector entities are expected to result in additional resources for ICE-HBV activities including financial or in-kind contributions or the provision of technical expertise.

1.3 Avoid conflict of interest

In all collaborations with private sector entities, ICE-HBV will carefully assess the potential for conflicts of interest at both the institutional and individual member level. Any potential conflict of interest will be properly identified, resolved and disclosed.

1.4 No exclusivity

ICE-HBV does not grant exclusive rights to one private sector corporation or industry sector in any project or programme: Every activity for which private sector cooperation is invited is open to multiple organisations,

including to direct competitors in specific market segments. ICE-HBV actively seeks the involvement of multiple organisations.

1.5 Endorsements

In principle, ICE-HBV does not endorse any particular private sector entity, its activities, products or services.

1.6 No corporate influence on strategic direction or scientific recommendations

Private sector collaborators will not have the opportunity to participate in decisions over ICE-HBV strategic direction or scientific recommendations. Private sector collaborators can be invited to provide advice on technical and programmatic matters as per clause 3.2.

1.7 Transparency

ICE-HBV is committed to the principle of transparency of process and decision-making. With respect to private sector collaborations ICE-HBV will at a minimum disclose:

- The existence of the collaboration
- The identity of the collaborators
- The nature and scope of the collaboration

All active collaborations between ICE-HBV and private sector entities will be listed on ICE-HBV website (www.ice-hbv.org).

2. Eligibility

2.1 Responsible business practices

ICE-HBV aligns to responsible business practices based on universal principles of human rights, labour, environment and anti-corruption. ICE-HBV will only collaborate with organizations that commit to adhering to these principles in their day-to-day business wherever they have a presence, and strive to reflect these principles in their policies and procedures.

ICE-HBV works only with private sector entities who do not actively or implicitly support:

- discriminatory workplace practices that include, but are not limited to, real or perceived HBV status, sexual orientation, gender identity, mental or physical disability, age, race/ethnicity, marital status, family or care giver's responsibilities, pregnancy, religion;
- views that would negatively impact people living with HBV

3. Types of engagement

3.1 Grants & Sponsorship

ICE-HBV will seek Corporate supporters award grants in cash and sponsorship in cash and in-kind based on a request developed by ICE-HBV secretariat. Unrestricted grants are preferred and usually support ICE-HBV core activities. Some grants can be restricted to a specific activity (research project, conference participation, organisation).

The objectives and implementation approach of each grant will be defined by ICE-HBV. Private sector entity representatives will not have decision-making authority with regard to project/programme implementation. Collaborators will be duly acknowledged as a donor/grantee but it will not receive direct benefits.

3.2 Participation in activities

Representatives of private sector entities may participate in ICE-HBV activities to provide technical or programmatic expertise during consultation meeting and specific project meetings (when public-private collaborations are established for specific research projects, such as the cccDNA assay standardization group). They will not be part of decision making process involving general strategy and scientific positions of ICE-HBV. They will not have access to scientific working group meeting proceedings nor will they attend general working group meetings unless they are specifically invited by the working group.

Any intellectual property (IP) arising from the work of ICE-HBV groups will remain the exclusive domain of ICE-HBV investigators and their institution of origin, according to their relative participation to the production of IP.

4. Processes

4.1 Due diligence

ICE-HBV will carry out a due diligence review before a collaboration agreement is signed to ascertain that the partner's values and business practices align with the principles described in this document. The process will consist of a review of publicly available information to assess eligibility and alignment of goals as per sections 1 and 2 above.

Subject to the approval by the ICE-HBV Governing Board, the ICE-HBV secretariat is responsible for implementing the process and providing a recommendation to the authorized signatories to a collaboration agreement on whether or not to enter into the collaboration.

4.2 Agreements

Each donor or sponsor relationship with a private sector corporation will be formalized in an appropriate agreement that describes the roles and responsibilities of both parties, any financial benefits for ICE-HBV, agreed acknowledgment of the collaboration along with specific benefits (in the case of sponsorships), if any, use of each party's name and logo by the other party, intellectual property stipulations, etc.

Collaboration Agreements with private sector entities will require the private sector entity to confirm alignment with the principles of responsible business practice as described in 2.1 above.

For any questions, please contact Capucine Penicaud, Programme Manager (marie-capucine.penicaud@unimelb.edu.au)

ANNEX 7 – Communications Policy

Adopted September 2018

ICE-HBV Governing Board members are authorized spokespeople for the Coalition. Other working group members and stakeholders can exceptionally be allowed by the Executive Committee to speak on behalf of ICE-HBV on specific topics relevant to their area of competency.

ICE-HBV Executive Committee must approve all ICE-HBV written statements (publications, press release, etc). ICE-HBV Governing Board will give general directions for the communications strategy. When unsure about one statement, the EC will consult the Board.

ICE-HBV groups members can propose communications to the Executive Committee for consideration as ICE-HBV endorsed statements. ICE-HBV can co-issue statements in partnership with members of the Coalition, in different languages and for different audiences.

When reporting on projects undertaken under ICE-HBV umbrella, members of ICE-HBV are expected to acknowledge ICE-HBV's contribution.

Board members, staff, and volunteers should be aware of ICE-HBV statements, positions, policies and procedures. The statements and positions should represent the full range of views of the organization's constituencies.