



## Coordinating Office Position Paper

### The HVP4 Ethics Panel Session: a starting point

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**Authorisation:**

This Position Paper has been prepared by Timothy D. Smith and represents the official position of the Human Variome Project Coordinating Office only. It does not represent an official position of the Human Variome Project, its Consortium, Advisory Councils or International Scientific Advisory Committee.

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*Heather Howard*

## I Context

In constructing the programme for the upcoming 4th Human Variome Project Biennial Meeting, the International Coordinating Office (ICO) has scheduled two issues to be discussed in the session devoted to Ethics: 1. the plan for development of a Consortium code of conduct; and 2. the potential role of Human Variome Project Ethics Committee.

To assist the panelists in preparing for this session, the ICO has produced this position paper. It exists to serve four functions: 1. to provide some background to both issues programmed for discussion; 2. to suggest some points for each issue that should be debated during the session; 3. to outline the ICO's view on the ideal outcomes from the session; and 4. to stimulate discussion amongst the panelists on additional outcomes.

This is by no means to say that these are the only issues that should be discussed and reported on by the panel. The panel will, as always, need to be guided by the direction articulated from the floor during the session. The panel should also feel free to include any additional topics they feel important to be discussed.

## II Proposed Ethics Committee

### *Background*

A desire for an independent ethics committee for the Human Variome Project has been articulated from two stakeholder groups within the Project.

The International Scientific Advisory Committee, at its October 2011 Meeting in Montreal, Canada, in a discussion about potential mechanisms for assisting databases, proposed that the Project appoint an external Committee that could be consulted for advice, "if any unforeseen situations arise, particularly those arising from individual family situations."<sup>1</sup> During this meeting, it was also suggested that the HUGO Ethics Committee<sup>2</sup> be approached to fulfil this function. This proposal was again raised at the December, 2011 ISAC meeting.<sup>3</sup> and the Committee acknowledged the need to define what function the independent ethics committee would serve.

Simultaneously, the Board of Human Variome Project International Limited (HVPI) recognised the need for an Ethics Committee "to consider and advise the Board on ethical behaviour in the Company and on ethical matters arising in the Company or referred to the Committee by the Board."<sup>4</sup> The Committee, as envisaged by the Board, would exist primarily to assist the Directors and staff of HVPI formulate, monitor and ensure compliance with the Company's Ethics Policy—a policy that would only apply to Directors and employees of HVPI and not the broader Human Variome Project Consortium. However, issues of concern to the various committees and councils established by the board under the Constitution could be referred to the Committee as necessary.

### *Suggested Points for Debate*

The ICO is seeking comment from the Consortium on the role and composition of the proposed Ethics Committee. Areas of particular interest are:

- the purpose of the Committee;
- responsibilities of the Committee; and
- membership of the Committee.

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<sup>1</sup>see Item 7, ISAC01-2011: Minutes 12 October Montreal

<sup>2</sup>now the Committee on Ethics, Law and Society

<sup>3</sup>see Item 3d, ISAC02-2012: Minutes 8 December 2011 Beijing

<sup>4</sup>*Draft Regulations of the Ethics Committee*, Annex B, Governance Framework of Human Variome International Limited

## *Proposed Outcomes*

A report of the outcome of the discussion during the session will be made to the Board of HVPI. The Board will take the Consortium's view into account when developing the Ethics Policy and establishing the Committee.

### **III Development of a Consortium Code of Conduct**

#### *Background*

Becoming a member of the Human Variome Project Consortium implies that an individual or institution has subscribed to a set of shared values that are common to Consortium members. The Human Variome Project has previously published its *Core Values*.<sup>5</sup> These consist of:

- Collaboration - we recognise that success will come by acting together with the widest possible stakeholder group. We will work hard to understand, respect and take account of the differing needs of each.
- Celebration - we will give credit and acknowledge all contributions made, celebrate key milestones, including all diseases that are diagnosed, treated and prevented, as a result of the sharing of data.
- Respect we will work hard to understand and respect the varying needs of all stakeholders. We will have the utmost respect for the privacy and confidentiality of patient information and will be serious about relevant ethical, legal, political and social issues.
- Inclusion - we will include all countries, all peoples and all disciplines without discrimination.
- Service - we exist to serve each other, the Consortium as a whole, its members, the community and in particular, to serve those now and in the future with a disease that can be more easily diagnosed, treated and prevented as a result of the sharing of data.
- Professionalism - we will adopt the highest standards in all we do. Data accuracy and operational excellence will be paramount.

In addition, during the online application process for Consortium membership, applicants agree to a set of Terms and Conditions.<sup>6</sup>

The ICO believes that there is a need to develop a more formal Code of Conduct for Human Variome Project Consortium members.

#### *Suggested Points for Debate*

To ensure that the developed Code is as relevant as possible to Consortium members and to ensure broad acceptance, the Consortium must be involved in the articulation of both the shared values of the Consortium and the Code of Conduct that will be informed by these values.

The ICO is seeking comment from the Consortium on the existing Core Values of the Human Variome Project. Specifically, the ICO would like to know if these existing Values accurately reflect Consortium thinking and are complete. Further, we are seeking from the Consortium a process for any necessary modification to the Values and the development and acceptance of a Code of Conduct for the Human Variome Project Consortium.

The Code of Conduct would need to specify processes for subscribing to the shared value set, monitoring compliance with the Code, demonstrating compliance and procedures to follow in the event of non-compliance.

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<sup>5</sup>see p.12, PD01-2010: Project Roadmap 2010 - 2012

<sup>6</sup>available at [http://www.humanvariomeproject.org/index.php?option=com\\_content&task=view&id=97](http://www.humanvariomeproject.org/index.php?option=com_content&task=view&id=97)

### *Proposed Outcomes*

The ICO suggests that the panel, in the course of the session:

1. introduces the concept for discussion;
2. stimulates discussion on key points amongst the delegates;
3. proposes a process based on that outlined below for the development of the Code of Conduct;
4. gathers feedback on the process and modifies as necessary; and
5. prepares a brief written summary<sup>7</sup> that can be reported to the ISAC for consideration.

### *Proposed Process for Code of Conduct Development*

1. Concept introduced and discussed amongst delegates at HVP4
2. ISAC produces a position paper based on outcomes of the discussion and ISAC meeting
3. Period of public consultation on ISAC position paper
4. Draft Code of Conduct prepared by ICO
5. ISAC approves draft Code
6. Period of public consultation on Draft Code
7. ICO produces final draft
8. ISAC makes recommendation to the Board

We envisage that this process would take between 8–12 months to complete.

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<sup>7</sup>The ICO will provide staff to assist in the preparation of the written summary