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HVP COUNTRY NODES

November 2014

PREAMBLE

The Human Variome Project exists to facilitate and support the collection, curation, interpretation and sharing of information on variation in the human genome in a responsible, free and open manner so that this information can be effectively integrated into routine clinical practice and research. The Human Variome Project is a network of professional people, institutes, and data sharing infrastructure, linked through a series of formal governance structures that each participate in some way to the collection, curation, interpretation and sharing of this information for improving health outcomes around the world.

Recognising that data collection and sharing is almost always subject to laws, regulations and best practice guidelines operating at national and subnational levels, the Human Variome Project Global Collection Architecture proposes that much of the routine data collection will be done through HVP Country Nodes. Country Nodes are a vital component for achieving improved health outcomes for people both within the country and around the world.

HVP COUNTRY NODES: A DEFINITION

An HVP Country Node is defined as having three components:

1. A repository, or linked network of databases, that collect and store information on variation in the human genome that has been generated within each country and that enables the sharing of that information both nationally and internationally;
2. A governance structure that ensures that the work of the Node is both sustainable in the long term and is consistent with all relevant national and international ethical, legal and social requirements; and
3. A set of policies and procedures that ensures that the repository is operated and maintained in a responsible and accountable manner that is consistent with both national and HVP Standards.

HVP COUNTRY NODES: WHAT DO THEY DO?

The three components above enable HVP Country Nodes to carry out specific roles both within their country and internationally:

1. Taking an active role in ensuring that data on variation is easily shared among research institutes, projects, diagnostic laboratories and clinics;
2. Contributing to building the capacity for storing and sharing data responsibly within the field of medical genetics and genomics;

3. Monitoring and reporting on activities that will contribute to better targeting of healthcare planning and policy development; and
4. Sharing data between other HVP Country Nodes and international Gene/Disease Specific Databases in the Human Variome Project Consortium.

Exactly how each HVP Country Node fulfils these roles is determined by each country and will be based on their unique mix of needs and capabilities. All HVP Country Nodes should progressively increase their activities by seeking to expand and improve the quality of their data collection activities within the country and their networks with other researchers, clinicians, diagnosticians, counsellors, patient groups, and relevant government officials both at the national level and in other countries. Ultimately, the data that is collected, stored and shared should be of a quality appropriate for use in clinical settings.

Because HVP Country Node repositories contain information on patients and subjects, every care must be taken to ensure that the data is collected and stored in a responsible manner. Countries vary in their cultural, religious and ethnic backgrounds; they also have different legislative and regulatory environments. HVP Country Nodes must conduct all their activities openly and transparently, and within all the relevant national requirements.

HVP Country Nodes must have an appropriate form of governance and decision making capacity to develop the policies and procedures for sustainable activities. Policies determining how data is collected, stored and shared must be developed and implemented. These practices should be reviewed and updated on a regular basis. The quality of the data that is collected, stored and shared must be transparently assessed and reported.

HVP Country Nodes do not operate in isolation. As part of an international consortium, they are active in Human Variome Project activities, participating in the development of HVP Standards and Guidelines and sharing their knowledge and experience with other HVP Country Nodes. Continuing membership of the Human Variome Project Consortium and recognition as an HVP Country Node is at all times subject to the Human Variome Project Code of Conduct.

BECOMING AN HVP COUNTRY NODE

TYPES OF HVP COUNTRY NODES

Interim status is offered to those who are able to meet two requirements -

1. agree to work towards meeting the requirements of the core definition above in sections 2 and 3 by signing a letter to that effect—a sample letter is in **Attachment A**; and
2. are able to provide satisfactory evidence that they in fact represent their country. In most cases this evidence would be a letter with appropriate letterhead addressed either to the individual or group making the application or to the current Chairperson of the ICCAC of the Human Variome Project indicating the level of recognition/endorsement from one or more of the following: the national Human Genetics society; an officer of the national Ministry of Health, or Science and Technology or similar; the national college of pathologists or similar professional society. A suggested draft letter is in **Attachment B**.

Interim status is only available for one organisation in each country.

To commence the process of obtaining interim status, please contact Liaison Officer at the Human Variome Project International Coordinating Office (ICO).

Interim members can progress to **full status** after undergoing an accreditation process that assesses the level of compliance of the interim Node with published HVP Standards and Guidelines and in accordance with their agreement to move towards meeting the full status requirements defined above in sections 2 and 3. The process for an interim Node becoming a full Node is set out in the document – **Moving to Full Status – a Guide for Interim HVP Country Nodes** (forthcoming).

Observer status is offered to national organisations and individuals who intend to establish an HVP Country Node but do not yet meet the requirements of interim status, or who feel that they are not yet ready to make an application. Observer Status can be offered to a maximum of four organisations or individuals per country. To apply for Observer Status, an application needs to be made using the form in **Attachment C**. The completed form should be sent to at the Human Variome Project ICO.

MEMBERSHIP OF THE INTERNATIONAL CONFEDERATION OF COUNTRIES ADVISORY COUNCIL (ICACC)

Both interim and full HVP Country Nodes are entitled to appoint a representative to the International Confederation of Countries Advisory Council (ICACC). These representatives are also the formal point of contact between the Human Variome Project ICO and the HVP Country Node. Individuals and organizations with Observer Status may participate in the ICACC, but may not vote on matters raised in ICACC meetings.

As a formal representative body of the Human Variome Project Consortium, the ICACC plays an important role in the operation of the Project. Specifically, the role of the ICACC is to:

1. Promote and develop the work of HVP Country Nodes – both their own and others within the network – through active participation in meetings and relevant official working groups; by representing the Human Variome Project at various national and international fora
2. Contribute to the development of HVP official documentation including *Activity Proposals*, *Human Variome Project Solution Blueprint* and the *Project Roadmap*;
3. Provide information on their Node's activities for HVP reports and publications;
4. Take an active role in the expansion of the network of HVP Country Nodes around the world by providing guidance for other Consortium Members in initiating, developing, financing and operating their Nodes and by contributing to creating regional networks and developing/developed country partnerships for knowledge sharing and capacity building;
5. Provide guidance and advice to the International Scientific Advisory Committee and Human Variome Project Board on matters concerning national and regional collection and sharing of genetic variation information.

ATTACHMENT A - Suggested letter from applicant to the Human Variome Project when making a formal application to become an Interim HVP Country Node

Chair of the Human Variome Project ICCAC
c/o- Human Variome Project ICO
Level 5
234 Queensberry Street
University of Melbourne VIC 3010
AUSTRALIA

[Date]

Dear

On behalf of (INSERT country name) we wish to apply for Interim Status as an HVP Country Node.

In making our application we wish to indicate that we will fully understand that an HVP Country Node is defined as having three components as listed below:

- A repository, or network of interrelated data repositories, that collects and stores information on variation in the human genome that has been generated within each country and that enables the sharing of that information both nationally and internationally;
- A governance structure that ensures that the work of the Node is both sustainable in the long term and is consistent with all relevant national and international ethical, legal and social requirements; and
- A set of policies and procedures that ensures that the repository is operated and maintained in a responsible and accountable manner that is consistent with both national and HVP standards.

We will work together to establish a functioning Node that meets this definition. We also agree to carry out specific roles on an Interim HVP Country Node both within our country and internationally, more specifically to:

- Take an active role in ensuring that data on variation is easily shared among research institutes, projects, diagnostic laboratories and clinics;
- Contribute to building the capacity for storing and sharing data responsibly within the field of medical genetics and genomics;
- Monitoring and reporting on activities that will contribute to better targeting of healthcare planning and policy development; and
- Sharing data between other HVP Country Nodes and international Gene/Disease Specific Databases in the Human Variome Project Consortium.

In fulfilling the requirements of becoming an interim HVP Country Node please find attached a letter(s) from the (INSERT NAME/S) indicating their support for our group to become the HVP Country Node for (insert country).

We would like to propose that (INSERT NAME and TITLE) will be our representative on the Human Variome Project International Confederation of Countries Advisory Council (ICCAC). We understand the role of the ICCAC and agree to participate. A second for this position is: (INSERT NAME and TITLE)

We have also read and understood the document Membership Requirements for HVP Consortium Members and agree to follow it.

Yours sincerely,

ATTACHMENT B – Suggested letter from National Human Genetics/Genomics Society or similar supporting the application

On official letterhead of organization

Chair of the Human Variome Project ICCAC
c/o- Human Variome Project ICO
Level 5
234 Queensberry Street
University of Melbourne VIC 3010
AUSTRALIA

[Date]

Dear

I wish to inform you that our Society/Organization (INSERT full name) fully endorses the application of (INSERT name and title) to represent (COUNTRY) to apply for interim status of HVP Country Node.

We are aware of the work of the Human Variome Project and are happy to support the work on HVP through the establishment of an Interim Country Node in our country.

Yours sincerely,

OBSERVER STATUS FOR THE HUMAN VARIOME PROJECT INTERNATIONAL CONFEDERATION OF COUNTRIES ADVISORY COUNCIL APPLICATION FORM	
Applicant Information	
Register as an organisation	
Organisation Name:	
Country:	
Representative/Key Contact:	
Address:	
Phone:	Fax:
Email:	
OR REGISTER AS AN INDIVIDUAL	
Name:	
Title/Position	
Institution:	
Country:	
Address:	
Phone	Fax:
Email:	
<i>I hereby apply for Observer Status in the Human Variome Project International Confederation of Countries Advisory Council. I agree to work toward establishing a Human Variome Project Country Node.</i>	
Signature of applicant	Date
Signature of Head of Organization	Date