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RECOMMENDED SYSTEM STATUS

PD08.1-2013

WHAT IS RECOMMENDED SYSTEM STATUS?

The Human Variome Project facilitates the integration of free and open collection, curation, interpretation and sharing of human genetic variation information into routine clinical practice. To achieve this, the Human Variome Project Consortium works collaboratively to define international standards and guidelines that describe best-practice methodology in each of these areas, which can then be utilised in the implementation of specific systems and processes.

Recommended System Status is an accreditation process designed to encourage the adoption of Human Variome Project Standards and Guidelines and to provide clear guidance to data providers and consumers as to which systems, procedures and tools are known to be in compliance with these standards. It is awarded in a non-exclusive manner to specific systems, processes and tools that have been assessed under the process described below as complying with relevant Human Variome Project Standards, Guidelines, Policies and Position Statements, and that are made available free of charge for non-commercial use.

BENEFITS OF RECOMMENDED SYSTEM STATUS

Recommended systems, processes and tools will be listed publicly on the Human Variome Project website and included in appropriate sections of the *Human Variome Project Solution Blueprint*; the Project's compendium of information on how to effectively collect, curate, interpret and share genetic variation information freely and openly. Recommended systems may also publicly display their status by using the phrase "a recommended system of the Human Variome Project" alongside the Human Variome Project logo (subject to the Human Variome Project Style Guidelines¹).

WHO GRANTS RECOMMENDED SYSTEM STATUS?

Recommended System Status is granted by the Human Variome Project International Scientific Advisory Committee after consideration of the comments and recommendations of at least three peer reviewers.

PROCESS OVERVIEW

1. Applicant prepares application following the requirements stated in this document

¹ See PD05-2011: Human Variome Project Style Guidelines – available from <http://short.variome.org/PD05-2011>

2. Application sent to activity_proposal_submission@variome.org
3. Application received by International Coordinating Office
4. Liaison Officer appointed
5. Initial review conducted to ensure the application meets the requirements stated in this document
6. International Coordinating Office prepares advice for the committee on the system's level of compliance with published HVP Standards and Guidelines
7. Application and ICO advice forwarded to International Scientific Advisory Committee
8. International Scientific Advisory Committee asks at least three individual to provide comments and a recommendation to the committee concerning the system's usability, reliability and uptake under an open peer review process
9. ISAC votes to approve the application based on the system's level of compliance and the comments and recommendations of the reviewers

APPLICATION STAGE

Applications for Recommended System Status can be made at any time to the Human Variome Project International Coordinating Office. Applications should consist of a concise summary of:

- the system and its features;
- the extent to which the system is currently being utilised;
- the HVP Standards and Guidelines the system is compliant with; and
- the access and license terms and conditions under which the system is made available.

All applications should consist of no more than two pages and must be emailed to activity_proposal_submission@variome.org. Applicants are encouraged to suggest up to three potential reviewers for their application.

As well as accepting applications from system and process developers, the International Scientific Advisory Committee may also invite specific applications for consideration or consider systems and processes without application.

INITIAL REVIEW STAGE

Upon receiving an application, the International Coordinating Office appoints a staff member as liaison officer for the remainder of the review and decision and publication stages and to act as the primary point of contact for all parties involved. Following appointment, the liaison officer conducts a preliminary review to ensure that the application is complete and meets the guidelines stated in this document. During this preliminary review, the liaison officer may request that the applicant redraft their application and resubmit.

Once an application has passed its initial review, the liaison officer prepares advice for the International Scientific Advisory Committee on the system's level of compliance with existing HVP Standards and Guidelines. The advice may also contain information on similar systems in existence and provide context to the proposal that the ICO believes will be useful in assessing the system's suitability for Recommended System Status. A copy of this advice will be made available to the applicant.

The liaison officer then forwards the application and the ICO advice to the International Scientific Advisory Committee for their consideration at the next scheduled meeting. At this meeting, the International Scientific Advisory Committee may decide to:

- reject the application outright;
- request further information from the submitter and reconsider the application; or
- put the application out for peer review.

PEER REVIEW STAGE

As well as an indication of compliance with Human Variome Project Standards and Guidelines, Recommended System Status is an indication of the system's usability, reliability and uptake. In order to gain as wide as possible perspective on these issues, the Human Variome Project places a strong weight on the views of the human genomics and genetics community. These views are captured and incorporated into the decision making process for awarding Recommended System Status during the peer review stage.

The Human Variome Project uses an open peer review process. Reviewers must sign their reports, include basic information on where they are employed and declare any competing interests or conflicts of interest they may possess or be perceived to possess.

A pool of potential reviewers is identified by the International Scientific Advisory Committee once an application has progressed to the peer review stage, taking into account any suggested reviewers included in the application. The ICO liaison officer randomly selects potential reviewers from this pool and invites them to participate in the peer review process. Each application is reviewed by at least three individuals.

The reviewers, in preparing their comments, are asked to consider:

- the compatibility of the system with other Recommended Systems;
- the usability and relevance of the system;
- the reliability and robustness of the system;
- the availability of system documentation and training materials; and
- the extent to which the system is currently being utilised.

To ensure the timely progression of the review process, reviewers are asked to complete their reviews within one month. If additional time is required to complete a thorough review, reviewers should contact the ICO liaison officer for the application.

The referees may make the following recommendations to the International Scientific Advisory Committee:

- Approve the application
- Ask the applicant to reapply if the issues raised in your comments are addressed; or
- Decline the application

DECISION AND PUBLICATION STAGE

Once comments and recommendations are received from three reviewers, the application is put before the International Scientific Advisory Committee for a final decision on the acceptability of the system, procedure or tool for Recommended System Status.

In making their decision, the International Scientific Advisory Committee will consider both the comments and recommendations of the reviewers, and the level of compliance of the system with HVP Standards and Guidelines. The final decision of the International Scientific Advisory Committee can be:

- Approve the application
- Resubmit for review if issues raised by the referee are addressed
- Decline the application