HVP/GL/002-01/EN

2014-12-18

WG01

GDSDBAC

HVP GUIDELINE

DISCLAIMER STATEMENTS FOR GENE/DISEASE SPECIFIC DATABASES

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Published by:
Human Variome Project International Limited
Level 5, 234 Queensberry Street, The University of Melbourne VIC 3010, AUSTRALIA

Published 2014-12-18. Printed in Australia.

PDF: ISBN 978-0-9942022-3-9
Print: ISBN 978-0-9942022-1-5

Contents

Foreword **5**
This Document 5
Important Notice **6**
Introduction **7**
1 Scope **7**
2 Terms and Definitions **7**
3 Disclaimer text for Gene-Disease Specific Databases **8**
3.1 The Disclaimer 8
3.2 Usage 8

Foreword

The Human Variome Project is an international consortium of researchers, policy makers and healthcare professionals committed to the free and open collection, curation, interpretation and sharing of genomic knowledge.

The Human Variome Project Consortium envisions a world where the availability of and access to genetic variation information is not an impediment to diagnosis and treatment; where the burden of genetic disease on the human population is significantly decreased; and where the sharing of genetic variation information is standard clinical practice.

To facilitate worldwide and interoperable sharing of genomic knowledge, the Human Variome Project Consortium produces Standards and Guidelines. HVP Standards are those systems, procedures and technologies that the Human Variome Project Consortium has determined shall be used by the community. These carry more weight than the less prescriptive HVP Guidelines, which cover those systems, procedures and technologies that the Human Variome Project Consortium has determined would be beneficial for the community to adopt.

HVP Standards and Guidelines are central to supporting the work of the Human Variome Project Consortium and cover a wide range of fields and disciplines, from ethics to nomenclature, data transfer protocols to collection protocols for clinical data. They can be thought of as both technical manuals and scientific documents, and while the impact of HVP Standards and Guidelines differ, they are both generated in a similar fashion.

HVP Standards and Guidelines make the collection, curation and sharing of information more efficient and reliable by establishing consistent protocols that can be universally understood. They facilitate interconnection of and interoperability between different systems.

HVP Standards and Guidelines represent a consensus of the Human Variome Project Consortium, each member of which has had the opportunity to participate in the development and review of each standard and guideline. In addition, as every effort is made to include all interests in the activity, HVP Standards and Guidelines can be considered to be representative of all interests concerned within the scope of each Standard or Guideline.

The Human Variome Project defines consensus as significant agreement between all affected parties covered by the scope of the standard or guideline. Consensus requires that all views and objections be considered, and that a concerted effort be made toward their resolution.

More information on the Human Variome Project is available at the Project's website (http://www.humanvariomeproject.org/). Procedures for the development of HVP Standards and Guidelines can be found in *PD06-2011: Standards Development Process*, available at http://short.variome.org/PD06-2011.

This Document

This document has been prepared the HVP Working Group: WG01: Disclaimer Statements on G/DSDB websites. The Gene/Disease Specific Database Advisory Council acted as Sponsoring Council.

An Exposure Draft (HVP/ED/002-01/EN) of this Document was released to the Human Variome Project Consortium on 2014-05-29. The consultation period ended on 2014-07-28.

A Draft for Approval (HVP/DA/002-01/EN) was submitted to the Sponsoring Council: 201-11-06.

The Gene/Disease Specific Database Advisory Council recommended that the International Scientific Advisory Council publish the Draft for Approval as an HVP Guideline after minor formatting and readability changes (HVP/DA/002-02/EN): 2014-07-29.

The International Scientific Advisory Committee approved publication as an HVP Guideline 2014-12-18.

Important Notice

HVP Standards and Guidelines are not intended to replace or substitute for any applicable legislation or regulation in any jurisdiction, or any institutional policy or funding agreement that a genetic variation information resource is operating under. Implementers of HVP Standards and Guidelines are responsible for determining and complying with all appropriate ethical and cultural protection practices and all applicable laws, regulations, policies and agreements.

Introduction

The Human Variome Project has established a common text for website or database disclaimers. Elements of disclaimers that are commonly seen on gene and disease specific databases have been analysed to produce a general disclaimer which can be applied to any G/DSDB which adhere to the vision and mission of the Human Variome Project.

1 Scope

This document contains text for a website disclaimer that should be used on gene/disease specific databases (G/DSDBs) that are members of the Human Variome Project. The disclaimer is designed to simplify the process of establishing a gene or disease specific database by providing a common disclaimer statement for inclusion on website pages. As a standard statement, it covers issues of particular concern for the creators and maintainers of G/DSDBs, as well as typical limitations of liability and copyright notice.

The purpose of the disclaimer is to limit legal liability for submitters, curators, and managers of G/DSDBs. By placing a disclaimer notice on a website or database system in a prominent position, users of the site will be notified of the appropriate use of the database and the information contained therein.

Disclaimers are required to notify users of the intended use of a G/DSDB. The Human Variome Project common disclaimer accomplishes several goals:

1. Informs users of the purpose of the database and certain responsibilities of submitters and curators.
2. Limits liability for database managers/curators and submitters.
3. Protect the rights of copyright holders of the database content
4. Facilitates establishment of databases which are in line with HVP vision.

The database disclaimer is not a ‘terms of use’, ‘terms and conditions’ or ‘database policy’. The disclaimer applies to databases that are in keeping with the statements made in the disclaimer.

2 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

User
A person who accesses the gene/disease specific database. This includes submitters and curators, as well as other visitors to the database.

Submitter
A user of the database who also submits data that is publicly accessible.

Curator
A user of the database who has the ability to edit and approve of submitted information. A curator is expected to notify submitters when their information is edited in a substantial way.

3 Disclaimer text for Gene-Disease Specific Databases

3.1 The Disclaimer

All contents of this database are protected by local and international copyright laws. The information is submitted for the purpose of sharing genetic and clinical information. Genetic variants listed may or may not have a causal association with disease phenotypes, irrespective of stated classifications or other information presented in the database. All information in this database, including variant classifications, is subject to change and there is no warranty, express or implied, as to its accuracy, completeness, or fitness for a particular purpose. Use of this database and information is subject to User responsibility and discretion. Clinical decisions regarding individual patient care should be carried out in conjunction with a healthcare professional with expertise in the relevant genes and diseases. We do not accept any liability for any injury, loss or damage incurred by use of or reliance on the information provided by this database.

Database submitters are required to adhere to their institution's rules for data sharing, and local and national laws. Personal identifiers should not be submitted. Submitters retain the rights to use and edit their data. Database curators may curate data to ensure that database formatting and quality standards are met. They may also share submitted data with external parties for research purposes or for sharing with other databases.

3.2 Usage

Anyone is free to use the disclaimer by placing it on the front page, and/or subsequent pages of the webpages which display the contents of a gene/disease specific database. The disclaimer text is suitable for any database that shares information about gene variants and/or associated diseases, and which adheres to the vision and standards set by the Human Variome Project.

The disclaimer text may be copied, edited and distributed under the terms of the Creative Commons Attribution-ShareAlike 4.0 International License.