



Coordinating Office Position Paper

AP01-2012: Disclaimer Statements on LSDB Websites ICO Comments

PP-ICO-06-2012

30 MAY, 2012

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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.

-s-

Heather Howard

I Context

The ICO received the attached Activity Proposal (AP) on the 25th of May, 2012. Pursuant to the Project's *Standards Development Process* (PD06-2011) we are forwarding it to the International Scientific Advisory Committee (ISAC) for referral to a Sponsoring Council (SC). Further pursuant to the *Standards Development Process* we have prepared the following comments on the AP for the ISAC and SC.

II Comments

Background

The presence of a *disclaimer statement* on the website of a gene/disease specific database (G/DSDB) is a relatively common practice. As the AP states, they can be used to:

- protect the rights of curators and data submitters and to control the use of their work; and
- limit the liability of curators and operators when and if the data contained in the database are used for clinical purposes.

Our understanding is that most disclaimers in use by existing gene/disease specific databases focus predominantly on the first use, *i.e.* rights protection and controlling use, and the second use is often not evident in these disclaimers. We believe this is due to a combination of two factors: 1. lack of knowledge on the part of curators that limitation of liability is an issue that should be considered when operating a database; and 2. insufficient resources on-hand to curators to engage the necessary legal expertise to craft such a statement.

There is an opportunity for the Human Variome Project to provide guidance and assistance to database curators and operators on the benefits, uses and recommended content of disclaimer statements.

Scope of Work

We recommend that an HVP Working Group (WG) be convened under the auspices of the Gene/Disease Specific Database Advisory Council as SC to:

1. review the content of existing disclaimer statements on gene/disease specific databases; and
2. prepare "boilerplate" disclaimers that can be freely and easily adapted by curators for their specific application.

The AP outlines the five areas that should serve as a starting point for these boilerplate statements. It should be noted that the WG may wish to expand or contract this list of areas after their review of existing statements is complete.

Contrary to the AP, we do not believe that this work should result in an HVP Standard. If this were to become an HVP Standard, infrastructure operating under the banner of the Project would be required to use the statements specified by the Standard. As it may not be possible for every G/DSDB to use the boilerplate statements that will be developed, we feel that it would be more appropriate for this work to result in an HVP Guideline.

Possible Working Group Members

We recommend that the SC ensure broad representation of skills in the WG. We further recommend that members of the Project's Ethics Interest Group be invited to participate, as well as the members of the Project's Ethics Committee, in the event that such a committee is established.

Available Assistance from the ICO

The ICO is able to provide the following assistance to the WG:

- secretarial assistance;
- face-to-face meeting organisation;
- phone and video conferencing facilities;
- collaborative authoring tools.

The ICO is not in a position to assist the WG financially.

III Summary of Recommendations

We recommend:

- The ISAC refer this AP for action to the Gene/Disease Specific Database Advisory Council
- The G/DSDBAC charter a WG to develop an HVP Guideline
- The HVP Guideline should contain a set of boilerplate disclaimer statements that can be freely and easily adapted by G/DSDB curators

Activity Proposal

Disclaimer statements on LSDB websites

Need

Disclaimers are required to notify users of the intended use of a G/DSDB and to protect the rights of copyright holders of the database content.

A standard disclaimer would also have the sufficient legal, ethical and technical basis for use with G/DSDBs and would provide database managers and curators with an appropriate limitation of liabilities.

Disclaimers with the imprimatur of the HVP may also serve to encourage database creation.

Scope

The areas covered by a standard disclaimer could include:

- Intended use of the database in the context of clinical diagnostic/research fields – to determine the extent that a variant has occurred previously, if at all; to determine if a variant has been associated with a phenotype or disease previously, if at all; to contact submitters/curators for more information relating to a variant.
- Ensure the rights of copyright holders by notifying users of the allowed use of the data, including:
 - Any limitations on the use of data for research, either in summary or for individual variants.
 - Downloading/publishing of data obtained from the database.
- Limitation of liabilities for database managers and curators from the use of data resulting in injury, death, malpractice, etc.
- Warning that inaccuracies may exist in the data, so is not to be relied on for any purpose.
- Rights and responsibilities of submitters to ensure appropriate consent has been obtained, and the privacy of patients/individuals are respected.

Plan of action

HVP to assemble appropriate legal, ethical and technical advice for the contents of a disclaimer (or set of disclaimers) to be used in various types of G/DSDBs. Different types of database usage should be considered (clinical and/or research) when devising the disclaimer contents. The rights of copyright holders should also be considered (database curators or submitters may hold the copyright, depending on the particular database). A review of existing G/DSDB disclaimers would be a good starting point.

Resources Required

Expertise in medical, legal and ethics.

Expected Deliverables

A disclaimer or set of disclaimers relevant to particular types and uses of G/DSDBs.

Recommendation

The disclaimer(s) should be a HVP standard.