Briefing Paper: Legal Issues on Phenotype Data Accessibility

A paper prepared following internal discussions of the International Mouse Phenotyping Consortium, Interphenome and CASIMIR

La Jolla, November 3rd 2009

Background and Objectives:

Mouse phenotype data is currently scattered through several large public databases. Whilst much data originates from large scale "community projects" such as EUMODIC, EUCOMM and the other members of the International Knockout Mouse Project, other databases, such as the Mouse Genome Database (MGD), Mouse Tumor Biology Database (MTB) and Pathbase collect information from a variety of sources, including the private sector and the scientific literature. These latter databases provide a mechanism for individual investigators to put their published or occasionally unpublished data into the public domain.

In July 2009, representatives of the RIKEN Bioresource Centre, EuroPhenome, Mouse Genome Informatics (MGI) and the Toronto Phenogenomics Centre met in Kyoto. An agreement was made to share and integrate data from each others' databases and phenotyping programmes. The advantages of integrating these disparate data sources are considerable. Such integration will allow for computational analysis of phenotypes across datasets and for the ready identification of the location and availability of mutant lines with desired phenotypes wherever located. However, the seamless integration of these global resources provides two main challenges. The first, syntactic and semantic standardisation together with agreed protocols for data transfer or migration, has already been largely addressed and a range of strategies is now widely agreed upon. The second challenge is that of harmonizing the legal basis on which this data is shared and integrated. With few exceptions the public databases are committed to open and free access to the data they present and curate, in accordance with the principles of the Rome Agenda for post publication data sharing and with the Toronto and Fort Lauderdale principles for pre-publication data.

However the licensing and attribution requirements of different institutions vary and institutions are required to consider warranty and liability, including consideration of any data that may infringe the intellectual property rights of third parties. Since most public databases currently have conditions of use or disclaimers, the variability of practice becomes an issue when large-scale integration is undertaken. There is consequently great advantage to be gained from developing a more uniform licensing strategy that addresses the national and institutional variation in practice while facilitating the main goal of these resources: free and unfettered access and use that reflects and reinforces the sharing norms of the research community. That community includes individual researchers who contribute and use data, their respective institutions, the contributing data centres, and the large-scale community resource projects.

What follows is the summary of a discussion of the terms under which phenotype data should be licensed by representatives of the community convened by Interphenome and CASIMIR and held at the 23rd International Mammalian Genome Conference in La Jolla, California, in November 2009. We compare two simple options of making data available to the public domain with three licensing options from Creative Commons (See Appendix B for the Legal Code that underlies each of these options), namely, cc0 or a waiver of copyright and database rights, cc-By (attribution), and cc-By-SA (attribution and share-alike). Creative Commons is a nonprofit corporation that facilitates sharing through standard-form free licenses and other legal tools (creativecommons.org).

Legal Issues:

We begin by emphasizing that experience and legal opinion suggest that the risk of litigation caused by inadequate, incomplete or ambiguous licensing terms for the use of data from databases of this type is diminishingly small (see below). The advantage of establishing objectively the value of different licensing strategies lies with transparency in the first instance and secondly in assisting data providers to make the case to their institutions and funders for access to their data to be as open as possible in conformity with the Community norm.

1. Developing a Data Sharing Strategy Among Participating Data Centres

There are two levels of legal issues. The first arises at the level of agreement between the contributing data centres, or depending on underlying legal structures, their constituent centres. For example, EuroPhenome is based at MRC Harwell and development is in collaboration with Helmholtz Zentrum Munchen, the Wellcome Trust Sanger Institute, and the Institut Clinique de la Souris. These institutions are parties to a formal agreement, typically for EC projects contained within the Consortium Agreement.

We will work on the assumption that the data centres will provide the data in four ways:

1. The data centres will host their own data and enable access through their own website;
2. The data centres will host their own data and may integrate it with the data received from the other data centres and enable access through their own websites.
3. The data centres will contribute their data to a central resource which will have its own portal or access point for users; and/or
4. The integrated data set from multiple data centres will be hosted at individual data centres but will be accessible to users through a central portal or access point.

Option 1 enables centres to provide data access to users in accordance with their own institutional requirements or preferences. However, to avoid confusion in the user community, there are still benefits to developing a uniform licensing strategy among data centres, especially if identical data are made available via multiple options.

Option 2, if the data is not integrated and its original source can be identified, enables a data centre to provide access to users in accordance with the licensing requirements of each data centre. This is administratively more complex and may lead to confusion for the user community. It would require significant resources to be devoted to managing the data to ensure that separate packets of data are licensed under the specific licensing terms of the donor. Again, there are significant benefits to developing a uniform licensing strategy among data centres, especially if identical data are made available via multiple options.

Option 3 with fully integrated data from multiple sources would require a uniform licensing strategy among data centres for administrative efficiency and ease of use. This would avoid the significant costs involved in managing the data to ensure that separate packets of data are licensed under the specific licensing terms of the donor.

Option 4 raises the same concerns as Option 2, and again, a uniform licensing strategy is the least administratively complex option.

2. The Distinction Between a Contract and a Waiver

The three over-arching legal forms discussed below are (1) no legally enforceable agreement; (2) a license; and (3) a waiver of rights. The distinction between these is important and has implications for the ability to enforce various data sharing options. Here, we will distinguish between a contract and a waiver. A contract is an agreement between parties that is enforceable in a court of law. Only the actual parties to the contract can enforce its terms and conditions. This is known as privity of contract.

A license is a type of contract that allows use of different types of subject matter. In the context of proprietary data, a license allows a user to do what would otherwise constitute infringing (copyright, patent, database rights etc.) activities.

In common law jurisdictions (e.g., United Kingdom, Canada, United States, Australia) a contract is made when three conditions are met. First there needs to be an intention to create legal relations. In commercial matters, there is a presumption of an intention to create legal relations. Second there needs to be a meeting of the minds through acceptance of the terms on offer, and third there needs to be consideration. Consideration may be anything of legal value and need not be money, it may be goods or services. Of most relevance here, the giving up of legal rights to sue (e.g., through accepting the terms of a waiver) is considered to be consideration. Note that consideration does not mean "market value". In civil law jurisdictions (France, Germany, Japan), all that is required for a legally enforceable contract is a meeting of the minds through offer and acceptance. Consideration is not required.

A waiver, in this context also known as an exclusion of liability clause or a disclaimer, limits or denies liability or gives up other legal rights. It is normally included as a term in a contract, and is common in insurance contracts. The enforceability of exclusion clauses hinges, in the common law, on the extent to which they were brought to the attention of the affected party.

The cc0 waiver, discussed below is a statement whereby PROVIDERS of data disclaim all rights that arise from copyright and database rights but not patent or trademark. It is not a contract because it is a one-sided statement of the giving up of rights made by the PROVIDER. There is no "acceptance" of the terms by the USER of the database. The issue that arises, though, is that the cc0 waiver contains terms beyond the giving up of legal rights in copyright and database protection. It also makes disclaimer statements on warranty and third party IP issues. The extent to which these would ensure legal protection for claims against a database are an open question, as discussed below, and will vary between jurisdictions. However, the realistic likelihood of such claims needs to be kept in mind and is likely extremely small.

3. Costs and Benefits of Different Data Sharing Strategies

Assumptions

Our analysis is based on the following assumptions:

1. acknowledgement of contribution and effort in developing and providing phenotype data to a centralized data centre is essential;
2. that the community norm for such acknowledgement comes in the form of scientific citations that may be tracked;
3. identification of the source of data is necessary for quality control purposes;
4. institutions likely require consideration of warranty and liability, including consideration of any data that may infringe the intellectual property rights of third parties;

5. resources for enforcement of any licensing provisions are severely limited, and in fact, to our knowledge, there has never been any litigation of licensing provisions for individual and institutional use of public domain genomics data. Therefore legal risk arising from the use of phenotype data is almost non-existent; and
6. setting a citation format that implicitly acknowledges the contributions of all participating data centres would increase the overall citation for all participating centres because they would be acknowledged in use of all the data, not just the data which they contributed.

Analysis

The following will discuss five options for sharing data:

1. Public Domain: meaning providing free and unrestricted access and use of phenotype data to the public . A more formal definition might be: *"Data in the public domain refers to data that may be eligible for copyright or other proprietary protection but instead has been donated to the public and as such is available for anyone to use for any purpose."* This is the simplest option that accords with research community norms, especially in functional genomics. Such an option has the fewest transaction costs.

   Non-legally binding terms may be located on the user interface, such as those currently on the EuroPhenome site. These indicate an appropriate citation (in the case of EuroPhenome to a scientific publication) and a disclaimer: "EuroPhenome provides this data and software in good faith, but make no warranty, express or implied, nor assume any legal liability or responsibility for any purpose for which they are used." Such terms may not be legally enforceable but draw the attention of users to expected community norms of behavior. A simple statement could be drafted to disclaim all warranties, including those involving any intellectual property rights of third parties. In addition, there could be a statement that use of the software and data is deemed acceptance of the terms and that usage is by a person having authority to do so on behalf of his employer/institution. Such a statement will address the warranty/liability concerns of institutions, while establishing a citation norm, and enabling the freest access possible for users commensurate with the creation of a mouse commons discussed in the Rome Agenda.

   The problem with this option, though, is the same as its main benefit - that it is in no way legally binding. It is therefore necessary to properly consider the pros and cons of legally enforceable alternatives as we have done. However, one point to keep in mind while reading the following discussion is the actual likelihood of (1) risk and (2) resources for enforcement against both direct users and users that obtain data from secondary sources (e.g., from direct users). These need to be considered strongly while weighing the legal options that will have the effect of complicating the sharing process and increasing transaction costs. The cumulative effect of even small increases in complexity and transaction costs may be significant and needs to be weighed carefully against any potentially realizable benefits of legal agreements.

2. A Simple Click Wrap License: This option would formalize and make more legally enforceable the minimal terms under which data is to be made available for users. Clicking through the terms is more likely to bring these to the attention of users, thereby emphasizing community norms. This option would likely satisfy any institutional requirements for a formal license for use. For example, the very simple terms on the Europhenome website or the suggested alternatives in (1) above.

   There are a number of problems with this option:

a) to make a legal agreement enforceable, the parties need to have capacity and authority to enter into the agreement.
b) if there is unlikely to be any enforcement of the terms because of policing and resource constraints, there is little point in complicating the process. Using a Click Wrap License, because of the capacity issues, could discourage use and unnecessarily complicate acceptance by all the players.
c) Click Wrap License would not apply to recipients who obtain the data from a secondary source. The license would only apply to primary users (direct down loaders) of the data (i.e., those that had actually agreed to the terms of the click wrap license) and not to recipients of the data from secondary sources. Adding any conditions to the click wrap license to capture secondary users would add to transaction costs and if not done properly (e.g., through a CC Attribution-Share Alike License discussed below) would not be enforceable. "License chain breaking" is a common problem. When the subject matter is copyrightable, this can be solved in a straight-forward way, because copyright gives the provider the ability to demand license compliance or sue for infringement. For non-copyrightable subject matter, "License chain breaking" leads to the unenforceability of Click-Wrap terms as against downstream users.
d) The entities waiving their rights (i.e., the data centres) may not be the copyright or database rights holders. It is true that these rights arise automatically, but they may vest in employers or government or in the donors who contributed data to the centres in the first place; and
e) This is a legal agreement meaning that THE PARTIES to the agreement must have the legal capacity (status) and authority to enter into the agreement in order for it to be enforceable. Most users will not have the authority to bind their institutions. Involving institutional legal counsel and individuals who have the authority to make contractual terms binding for data use binding on institutions will increase transaction costs and lead to the same issues and delays currently present with Material Transfer Agreements, which need to be negotiated and authorized by institutional representatives

The Creative Commons Options (See Appendix B for Legal Code)

3. Creative Commons – cc0: This is not a license but a waiver of copyright, database and unfair competition rights to the extent that these exist. It does not waive patent rights or trade mark.

The benefits of this option include:

a) If the data does contain copyrightable elements, and it is released into the Public Domain without a clear statement of waiver, like CC0, the door remains open to the data provider or someone who later acquires rights in the copyrighted elements to sue for infringement against subsequent users. In other words, the price for being wrong about copyrightable subject matter is that the "public domain" status could be later "revoked" retroactively. This is what CC0 is intended to prevent.
b) This option addresses warranty, liability, and third party intellectual property claims;
c) Some institutions may require a legal agreement before releasing data and this CC0 may satisfy this requirement in a manner that most resembles simply making data available in the public domain; and
d) There is legal certainty that rights, to the extent they exist, are waived (but see the issues below surrounding the uncertainty of the extent of those rights). However, that legal uncertainty may make it even more imperative that there is a clear statement of intent to place in the public domain that is binding and can be relied upon. Otherwise, anyone using the data faces the risk that should any part of the data be discovered later to be copyrightable (or the provider changes its position with respect to copyrightable subject

matter), then rights to use the data can be retroactively revoked. The resulting situation can be perilous for data projects that have already embedded the data and cannot easily remove it without serious disruption. So the question addressed by CC0 is "can this PD status be relied upon"? In the absence of CC0 (or something like it), that reliance must be on the basis of a legal judgment, which is subject to the "uncertainty of the extent of those rights". CC0 removes that uncertainty, to the maximum extent legally possible to do so.

The problems with this option include:

a) The underlying legal code could be perceived by users as complex and will increase transaction costs as institutions or individuals attempt to interpret it;
b) There is no need to waive rights to place data in the public domain. Data can simply be made available as per the Public Domain option 1 above, especially when data and materials sharing are already community norms;
c) There will generally be legal uncertainty as to the extent of the rights that have been waived regardless of whether the simple Public Domain option (1) is used or whether cc0 is used. For example, it will be uncertain whether the data is in fact copyrightable subject matter in different jurisdictions where the definition of copyrightable subject matter varies. In addition, database laws vary between European countries and other countries. This is a problem only to the extent that cc0 has the same effect as option (1) but increases transaction costs by being more complicated;
d) The entities waiving their rights (i.e., the data centres) may not be the copyright or database rights holders. It is true that these rights arise automatically, but they may vest in employers or government or in the donors who contributed data to the centres in the first place. To the extent, there are third party rights, the third party right owner can always sue for infringement at any time, regardless of whether CC0 is used;
e) CC0 may not waive the right to attribution, which is a moral right. In some jurisdictions, moral rights rest with the creator and may not be assigned, for example, to an employer even though many employment contracts where the copyright vests with the employer require employees to waive their moral rights. However, whether moral rights have been waived by the creator will remain uncertain in any specific case of data generation (same issue as d above). However, moral rights do not apply to data in the United States, and among other countries, are subject to varying scopes and limitations; and
f) The issue of whether the limitations and disclaimer section ("4. Limitations and Disclaimers." In the Legal Code for cc0 in Appendix B below) section would be enforceable by a Data Centre in the absence of a contract (cc0 is not a contract) is an open question. The answer likely varies between jurisdictions, and, in some jurisdictions, this legal question is likely not settled. For example, in the United States, disclaimers of warranties are enforceable without a contract because specific statutory laws (commercial codes) allow for disclaimers as "conditions of sale" where "sale" is interpreted very broadly. However, in other jurisdictions this may not be the case. There, the "limitations and disclaimers" section is likely no more enforceable by the Data Centre than a disclaimer on a web site where there is no click wrap license. In this regard, cc0 would be no more enforceable with respect to limitations and disclaimers (especially about warranty and 3rd party IP issues) than simply placing the data in the public domain as per Option 1.

4. Creative Commons –Attribution (CC-By): This license requires attribution. However, this is the enforcement of a legal requirement of attribution in a specified form. It is not the establishment of a community norm for citation. As such, it has a number of problems. This option:
    a. Increases transaction costs by requiring a formal license that will require interpretation and consideration by institutional legal counsel;

b. will require enforcement with attendant resources to be effective;
c. may lead to attribution stacking such as occurred with Wikipedia where there are 10,985,857 registered users, including 1,695 administrators;
d. will lead to complexity in managing an integrated database where some data might require attribution while other data would not; and
e. This is a legal agreement meaning that THE PARTIES to the agreement must have the legal capacity (status) and authority to enter into the agreement. Most users will not have the authority to bind their institutions. Involving institutional legal counsel and individuals who have the authority to make contractual terms binding for data use binding on institutions will increase transaction costs and lead to the same issues and delays currently present with Material Transfer Agreements, which need to be negotiated and authorized by institutional representatives.

The benefits include
a. This option addresses warranty, liability, and third party intellectual property claims;
b. Some institutions may require a legal agreement; and
c. It makes attribution of the source of the data in a specific format legally enforceable, but if there is no copyright or other proprietary interest, then it may not be enforceable after all.

5. Creative Commons – Attribution-Share Alike: This is the most restrictive and problematic of the potential options. It has the same benefits as discussed for CC-By above. However, the problems of attribution stacking and legal complexity of sharing of data from an integrated user interface or portal are amplified.

This option:
a. will increases transaction costs by requiring a formal license that will require interpretation and consideration by institutional legal counsel;
b. will increase transaction costs by requiring an integrated data centre to make data available to users on the same terms that it was deposited. This will mean monitoring terms specific to individual components of the data and ensuring those are transferred to users of the integrated data portal. This will lead to a great degree of complexity in terms of data management and make that degree of management mandatory and legally enforceable;
c. will require enforcement with attendant resources to be effective;
d. will require users to enforce the provisions of the license if they share the data with third parties;
e. leads to attribution stacking; and
f. This is a legal agreement meaning that THE PARTIES to the agreement must have the legal capacity (status) and authority to enter into the agreement. Most users will not have the authority to bind their institutions. Involving institutional legal counsel and individuals who have the authority to make contractual terms binding for data use binding on institutions will increase transaction costs and lead to the same issues and delays currently present with Material Transfer Agreements, which need to be negotiated and authorized by institutional representatives.
g. Can severely limit the universe of data that can be combined: share-alike are the least interoperable licenses available. The risk here is to create a legally-enforced “silo” of data that does not operate well with other silos.

CONCLUSIONS

1. There are unlikely to be resources available for enforcement, especially when there is virtually no claim for damages. Since this is the case, the legal terms with respect to data sharing should be kept as simple as possible.
2. A legally enforceable agreement increases transactions costs and causes delays for users, especially if institutional counsel become involved. To avoid the problems apparent in the use of Material Transfer Agreements, the first option of placing data in the Public Domain is the simplest and most efficient.
3. A statement including liability and warranty, including third party IP issues should be considered, however the response should be proportionate to the realistic risk of legal action against or including the data centre.
4. In addition a statement requiring citation in a specific format compliant with the community norms is the best way forward. For data integrated from large public databases this is relatively straightforward, a form of words can be produced which says : "these integrated datasets include data from X, Y, Z" and where possible a literature citation. Where more complex integration, for example from curated literature is used then the database should in line with good practice allow attribution to be transparent so that the reliability of the data can be easily assessed.
5. The added benefit of integrated phenotype data available through a single user interface or portal would be to set a citation format that implicitly acknowledges the contributions of all participating data centres. In this way, the overall citation for all participating centres would be increased because they would be acknowledged in use of all the data, not just the data which they contributed.
6. Creative commons licensing creates potential confusion and in its more restrictive aspects higher transaction costs, particularly for the CC-BY-SA option with its requirement for stacking of attribution in integrated datasets for which there is currently no automatic strategy. In practical terms, the management of such a license would not be feasible for a large, integrated dataset.
7. An explicit statement of what is meant by "public domain" is required, at least for our institutional policy developers if not for inclusion on the websites.

Appendix A. A selection of current attribution and disclaimer statements.

1. Ensembl: Legal Notices

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2. Europhenome

Citing EuroPhenome
Please cite the following publication when referring to EuroPhenome in you papers.
Mallon A-M, Blake A, Hancock JM (2008) EuroPhenome and EMPReSS: online mouse phenotyping resource. Nucleic Acids Res 36: D715-D718.

Disclaimer
EuroPhenome provides this data and software in good faith, but make no warranty, express or implied, nor assume any legal liability or responsibility for any purpose for which they are used.

3. IKMC – Knockoutmouse.org

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Citing MGI Resources

Publications to cite in your manuscripts

Please use the following citation formats when referring to resources available from the Mouse Genome Informatics Web Site in your publications.

MGD:

Bult CJ, Eppig JT, Kadin JA, Richardson JE, Blake JA; and the members of the Mouse Genome Database Group. 2008. The Mouse Genome Database (MGD): mouse biology and model systems. Nucleic Acids Res 36(Database issue):D724-8.

GXD:

Smith CM, Finger JH, Hayamizu TF, McCright IJ, Eppig JT, Kadin JA, Richardson JE, Ringwald, M. 2007. The mouse Gene Expression Database (GXD): 2007 update. Nucleic Acids Res 2007 35(Database issue):D618-D623.

MTB:

Begley DA, Krupke DM, Vincent MJ, Sundberg JP, Bult CJ, Eppig JT. 2007. Mouse Tumor Biology Database (MTB): status update and future directions. Nucleic Acids Res 35(Database issue):D638-D642.

See Mouse Genome Informatics Publications for an expanded list of resources available at the Mouse Genome Informatics website.

To cite specific database projects, use a format similar to that shown in the following examples:

Mouse Genome Database (MGD) at the Mouse Genome Informatics website, The Jackson Laboratory, Bar Harbor, Maine. World Wide Web (URL: http://www.informatics.jax.org). [Type in date (month, yr) when you retrieve data cited].

Gene Expression Database (GXD), Mouse Genome Informatics Web Site. World Wide Web (URL: http://www.informatics.jax.org). [Type in date (month, yr) when you retrieve data cited.

Mouse Tumor Biology Database (MTB), Mouse Genome Informatics Web Site, The Jackson Laboratory, Bar Harbor, Maine. World Wide Web (URL: http://tumor.informatics.jax.org/mtbwi/index.do). [Type in date (month, yr) when you retrieved data cited].

To cite a specific data area or display, use a format similar to that shown in the following examples:

Some homology data for this paper were retrieved from the Mouse Genome Database (MGD), Mouse Genome Informatics, The Jackson Laboratory, Bar Harbor, Maine. World Wide Web (URL: http://www.informatics.jax.org). (June, 2003 [i.e., the date you retrieved the data cited]).
Davisson MT, Cook SA, Eicher EM. The first spontaneous mutation in the mouse Herc2 gene, MGI Direct Data Submission to Mouse Genome Database (MGD), MGI:1349786, (URL: http://www.informatics.jax.org). (1999).

5. TCP- CMMR

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Last Revised: August 20th, 2004

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6. Riken mouse phenome database

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