

We need to remind you that the IPR-Helpdesk project deals with issues related to intellectual property. Therefore, in the following paragraphs we will mainly deal with the intellectual property-related provisions of the agreements that you sent to us, hoping that you will find our comments useful.

Furthermore, we understand that these agreements include references to other procedures and provisions established by the different working groups of your project that we are not aware of. We will thus try to provide you with a general analysis, while commenting specific clauses of your agreements whenever necessary. Should you have any specific questions regarding intellectual property, please do not hesitate to address them again to our Helpline service.

Finally, you may find useful information by browsing the IPR-Helpdesk website. For instance, the document “[Material transfer agreements within the framework of RTD EU funded projects](#)” could prove useful in your case.

It is highly **important** to remember that any commitment at consortium level should comply with the rules as established in your EC contract (the contract you signed with the EC to carry out the project), in particular those related to the access rights, protection, use and dissemination (including publication) of the results obtained in the project.

1. **GenomEUtwin Data Access and Security**

We understand that this is not the final agreement to be signed by the entities participating in your project, but a proposal that would lead to the establishment of such agreement. In any case, please keep in mind that the final document, should (or could) contain the following sections:

Identification of the parties, where you should identify each and everyone of the participating centres, by its official name, headquarters, etc. Furthermore, and since you decided that only a minimum number of individuals will have access to the TWINNET database, it would be perhaps useful to mention the names of these persons in the final agreement, while making

sure that they are completely aware of their rights and obligations by means of e.g. an internal agreement to be signed between the authorised individuals and the relevant centres.

Definitions, where you can provide with the definitions of terms the parties consider it necessary. For instance, the term “approved publication” appears quite often in this document, so it could be defined since the very beginning. Another example, you refer to the “principle of equal sharing” of the data and scientific results between all contributing centres. It would be useful to define what you understand from “equal sharing”. Even though the document refers to “merging”, “sharing” and “loaning”, does this mean that the contributing centres will also share the ownership of the scientific results or just their use? If these or other terms are already defined in other agreements or working papers of your project, you could make reference to these definitions and include the related documents in an Annex.

- Ownership, where you can establish clear rules concerning the ownership of the data to which you refer. (Please bear always in mind the rules on ownership of knowledge as established in Article 8 of Annex II to the EC contract). In your agreement you mention “merging”, “sharing” and “loaning”. However, as mentioned above, the scope of these terms may be a bit vague. Should each participating centre retain the ownership of the information it brings into TWINNET, this should be clearly mentioned in your agreement.

Another issue to take into consideration here is the ownership of scientific results generated by the common scientific work of more than one contributing centre (should there be joint ownership?)

- Use, where you may establish the conditions and limits of using the data in question¹. In your document you mention that “data may only be used according to the intents and research goals outlined in the publication proposal for which the data were accessed”. This may of course prove sufficient (depending on the details included on the “publication proposal”), but you could also define the boundaries that apply to all publication proposals, if any (for instance, you could mention that the commercial use of merged data is not permitted for any of the participating centres).

¹ Please note that the term “use” is utilised here in its common meaning (not according to the FP5 terminology. See Article 1 (27) of Annex II).

- Confidentiality, where you can establish the obligation of all participating centres and scientists authorised to work on these data to respect the confidentiality of all information they obtain in the course of their work. In your document you make reference to a series of technical measures aiming at protecting the confidential character of such data (analysis on a secure site, encryption, etc.). Nevertheless, it would be useful to clearly mention that participating centres and scientists have an obligation of confidentiality, and even to establish a mechanism in order to qualify information as confidential, if necessary.

 - Liability issues, where you may establish the responsibility of a party that does not comply with the obligations provided by the agreement, and eventually provide for sanctions or mechanisms in order to repair the eventual damages caused by a breach of obligations.

 - Governing Law and dispute resolution systems. Here you should define the law applicable to your agreement, and eventually provide for dispute resolution systems, court proceedings or alternative mechanisms (such as mediation or arbitration), as you all consider it more appropriate.
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2. GenomEUtwin Agreement for sharing and access to biological samples and GenomEUtwin data

With regard to this second agreement, we can make the following comments.

- Identifying the parties would be, once again, necessary (see above).

- Definitions. Please consider the possibility of defining certain terms, if you consider it necessary for the correct understanding of the agreement by all parties.

- Confidentiality. We consider that a separate clause providing for the obligation of the participating centres to respect the confidentiality of data would be useful in this case. You mention that “sample materials and data will not be distributed further to any individuals...”

but this might not be sufficient in order to ensure the protection of confidential information. You could clearly mention that no communication of data to any unauthorised party or person is allowed.

- Use. In the first two sections, “Transfer of samples” and “Biological samples”, you provide with an explanation of the exchanges to be done under the agreement and of the way each party (PC, KTL, genotyping laboratories) is meant to use the samples. If this is the only allowed use, i.e. if the parties in question may only use the samples and other elements for the specific purposes mentioned here (processing, quality control, dilution, etc.) you should clearly mention this fact. Remember that in case you need to restrict the use to these purposes, the definition of the relevant terms could be useful for each party to know exactly what can or can not be done.

- Later on the document, you provide that data and sample materials cannot be distributed to third parties “for the duration of the project”. You should maybe provide for the parties’ rights after the end of the project. Normally, the party that owns the data or sample materials will have the right to dispose them as it wishes, always within the limits of FP5 rules (for instance, it should always keep in mind the obligations as to the grant of access rights to participants for use purposes –i.e. for further research or for exploitation activities). But what about the parties that eventually used these data or samples in their work? Do they also have the right to distribute them (or simply communicate them) to third parties after the end of the project? This section could complement confidentiality-related clauses.

- Status of original samples and data generated. The meaning of “data generated” is a bit unclear, much more because of the FP5 rules related to knowledge, according to which mere information generated in the project is deemed as “knowledge” and belongs to the contractor carrying out the work leading to that knowledge.

Therefore, please make sure that the commitments you undertake comply with the ownership regime as established in the EC contract.

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- Publications. Do the parties have the right to publish data related to the scientific work over these data and samples? If yes, you could perhaps establish a procedure or approval of such publications, by the competent committee of your project or by all participating centres. Please note that the Commission shall always be informed of any planned publication in advance (please see Article 9.3 of the Annex II)

 - Liability, governing Law and dispute resolution systems. The comments made under section 1 above could also apply here.