MDTA User Check list for Human Material

Dear MDTA user,

we kindly ask you to tick all check boxes that applies. It helps und guides us to approve and legally regulate your request faster.

Kind regards
Your Technology Transfer Team

General background to the samples and donors

Does the material come from deceased patients?
☐ Yes ☐ No

Are the samples microbiological samples from humans without human genetic material and without personal reference?
☐ Yes ☐ No

General legal issues

Are samples also obtained from legally incapable donors or donors with limited legal capacity?
☐ Yes ☐ No

In the case of legally incapable donors or donors with limited legal capacity: Is the consent of the legal representatives available?
☐ Yes ☐ No

In the case of deceased donors: Is the consent of close relatives available?
☐ Yes ☐ No

Specific data protection issues

Are health-related data provided? (please specify):
☐ Yes ☐ No

Health data are data that relate to the physical or mental health of a natural person, including the provision of healthcare services, and from which information about their state of health is derived.

Are the data and samples transmitted pseudonymised, coded?
☐ Yes ☐ No

In the case of both anonymisation and pseudonymisation, identifying characteristics must be deleted (in the case of anonymisation) or separated from other personal data (in the case of pseudonymisation) in such a way that it is significantly more difficult to draw conclusions about the person or their data worthy of protection.

Study and patient consent - was there an advisory by the CTO? Please provide references
☐ Yes ☐ No

Is the material recipient/partner mentioned by name in the patient consent and does the patient consent form include the desired purpose?
☐ Yes ☐ No

Does the patient consent still cover the onward transfer of the material to the material recipient / partner for the desired purpose? (E.g. permission for onward transmission to all research institutions within the EU for the specific purpose)
☐ Yes ☐ No

Data protection – are technical or operational measures (TOMs) or opinion from IT available? If yes, please attach.

☐ Yes ☐ No

Locations

Is a shared responsibility of the data planned according to Art. 26 GDPR?[1]
☐ Yes ☐ No

Is there a processing according to Art. 28 GDPR?[2]

☐ Yes ☐ No

Should the recipient's data / results generated with / from the material be shared between contracting partners?
☐ Yes ☐ No

Scope, purpose and recipient of the transfer

Is a transfer of data / results generated with / from the material planned from the material recipient to a regulatory authority?
☐ Yes ☐ No

In the case that there is non academic research, i.e. any commercial use, please provide information

☐ I confirm, that the material / data will not be transferred to a third party.	☐ I confirm that the result / data generated with / from the material will not be shared with a commercially operating third party.
Date and signature:	*Date and signature:*
Name in block letters:	*Name in block letters:*

[1] Art. 26 GPDR refers to Joint Controller for data: two or more controllers jointly determine the purposes of and means for processing (mostly the case, such as between research group working in cooperation or collaboration)
[2] Art. 28 GPDR refers to Processor: processing on behalf of a controller on the basis of a contract (such as a sequencing service provider)