

MDTA No [_____] – User Check list

**Dear MDTA user,
we kindly ask you to tick all checkboxes that apply. It helps us to process your request faster.**

Kind regards

Your Charité BIH Innovation Team Patents & Licences

Please consider: the MDTA only applies for human material.

General background to the samples and donors

- Incoming material?
- Outgoing material?
- Does the material come from deceased patients?
- Are samples also obtained from legally incapable donors or donors with limited legal capacity?
- Are the samples microbiological samples from humans without human genetic material and without personal reference?

Specific data protection issues

- In the case of legally incapable donors or donors with limited legal capacity: Is the consent of the legal representatives available?
- Are health-related data provided? Please specify:
- Are the data and samples transmitted pseudonymised, coded?
- Study and patient consent - was there an advisory by the CTO? Please add number here:

- Data protection - is an opinion available from the data protection support? Please add number here:
- Is the material recipient/partner mentioned by name in the patient consent and does the patient consent form include the desired purpose?
- 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)

Locations

- Location of contract partners – please specify countries:
- Is a shared responsibility of the data planned according to Art. 26 GDPR?¹
- Is there a processing according to Art. 28 GDPR?²
- Should the recipient's data/results generated with/from the material be shared between contracting partners?

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?
- Is the recipient of the material a commercially operating company?
- Is a commercial use of the material planned by the material recipient? If yes: Which commercial use:
- Is a commercial use of the data/results generated with/ from the material planned by the material provider?
- Is a commercial use of the modifications containing the material planned?
- Please confirm that the material/data will not be transferred to a third party
- Please confirm that the data/results generated with/from the material will not be shared with a commercially operating third party

¹ Art. 26 GDPR 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 GDPR refers to Processor: processing on behalf of a controller on the basis of a contract (such as a sequencing service provider)