TRAIN-THE-TRAINER-CONCEPT ON RESEARCH DATA MANAGEMENT

Template: Checklist Requirements for a consent according to GDPR

To check	Yes	No
Overall		
Is consent obtained before the collection and use of personal data?		
Does the consent relate only to data processing that is not already legitimised		
by law? (The legal consequences of "unnecessary" consent are controversial.)		
Form		
Is the unambiguousness or the proactive act of consent guaranteed? Consent		
must be given unambiguously, i.e. by an active act of the person giving		
consent (e.g. by ticking a box).		
Is informed consent "part of a larger document"?		
If so, it must be clearly distinguishable from the other facts of the document:		
Are requirements for the "visual" highlighting of the data protection consent		
respected?		
Has a duplicate copy of the document been provided for?		
(Keep the original with the person responsible, the copy with the person		
concerned)		
Has the opportunity for questions been granted?		
In this respect, the following wording is recommended: "I had the opportunity		
to ask questions. These were answered fully and comprehensively"		
The name of the person who answered the questions, if applicable, should be		
handwritten on the consent form.		
Voluntariness		
Did the person concerned have a real choice between approval or rejection?		
Is it guaranteed that the fulfilment of a contract or the provision of a service		
was not made dependent on consent if consent is not absolutely necessary for		
fulfilment (prohibition of tying)?		
Informedness		
Has the person concerned received all the necessary information (including		
advantages and disadvantages)? In particular:		
- data use (purpose, objective, benefits, chances and risks)		
- persons who may have access to data		
- the types of data processed		
- data transfer (to whom, if necessary, storage at which location, country)		
Is all the information specified in Art. 13 GDPR or Art. 14 GDPR provided? In		
particular:		
- contact person and contact details (person responsible, data protection		
officer,) - legal basis of the agreement		
- recipient		
- storage duration		
- rights of the person concerned (access, correction, deletion, withdrawal of		
consent)		
Are the person responsible and his or her representatives clearly identified?		
Are all necessary contact details available to the person concerned?		
Is there a (comprehensible) explanation of the consequences that a refusal to		
give consent may have for the person concerned?		
When processing special categories of data (Art. 9 GDPR), does the		
declaration of consent explicitly refer to these data?		
Definiteness		
Does the informed consent relate to a specified case? General consents are		
invalid; separate consents must be obtained / given for different purposes.		

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Is the declaration of consent clearly separated from any other (data protection-		
related) information?		
It should be avoided that the person concerned cannot recognize whether and,		
if so, to what he or she actually consents or should consent due to the lack of		
clarity of the document.		
Revocability		
Does the consent form indicate that consent may be revoked at any time?		
Does the consent form indicate that revocation always applies only to the		
planned processing that takes place after revocation?		
Is the revocation of consent (at least) as simple as giving consent itself?		
Is there a (clear) indication of the consequences of revocation?		
Informed consent of minors		
Is Art. 8 for processing by means of "information society services" respected?		
If parental consent is given: at the latest when the person concerned comes of		
legal age, further processing is only permitted with the consent of the person concerned.		
Is there a mechanism to stop the processing of data at the point in time "x"?		
Verifiability		
Is there proof that the consent was given by the person concerned?		
Is there proof that consent has been given in a form sufficient to meet the		
requirements of the GDPR?		
Is the consent granted recorded? If so:		
Have sufficient technical and organisational measures been taken to protect		
the records? (evidence)		
Is it possible to access the granted consent at any time?		

Source:

Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e. V. (GMDS) (2016). EU DS-GVO: Anforderungen an eine Einwilligung.

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