The Health Research Regulations 2018:
Explicit Consent Checklist

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The Health Research Regulations 2018 which came into operation on 8 August 2018 require that those who are processing personal data for the purposes of health research shall ensure that a number of measures are taken to safeguard the fundamental rights and freedoms of the data subject (i.e. research participant). One such required measure is to obtain the **explicit consent** of the data subject for the processing of their personal data for the purpose of the specified health research prior to the commencement of the research (see definition of this term below). The only limited exception to the requirement to obtain explicit consent is if researchers have obtained a "consent declaration" under the Health Research Regulations 2018.

Further, an amendment to the Regulations is expected shortly, with respect to retrospective chart reviews. This amendment will permit retrospective chart reviews to proceed without explicit individual patient consent once certain criteria are adhered to.

For the avoidance of doubt, please note that the Health Research Regulations also apply to research which commenced prior to the introduction of the Health Research Regulations 2018.

The checklist below is provided to assist you to ascertain if you have explicit consent in line with the Health Research Regulations and GDPR.

In order to have valid explicit consent, you must be able to respond "yes" to all of the questions (save for questions 6 and 10, which may not apply to your study).

Consent Checklist

GDPR Consent Requirements	**Insert Yes/No (or not applicable if required under Questions 6 and 10)**
1. Has the data subject (research participant) given an unambiguous indication of her/his wishes? *The GDPR is clear that consent requires a statement from the data subject or a clear affirmative act, which means that the data subject must have taken a deliberate action to consent to the particular processing. It must be obvious that the data subject has consented to the particular processing.*	
2. Has the consent been freely given? "*Freely given" implies real choice and control for data subjects. As a general rule, the GDPR prescribes that if the data subject has no real choice, feels compelled to consent or will endure negative consequences if they do not consent, then consent will not be valid.* *A phrase such as "your participation is entirely voluntary, and your care will in no way be affected if you chose not to participate/chose to withdraw" would suffice.*	
3. Have you ensured that there is no imbalance of power when seeking consent? *Consent can only be valid if the data subject is able to exercise a real choice, and there is no risk of deception, intimidation, coercion or significant negative consequences (e.g. extra costs) if he/she does not consent.*	
4. Have you made the request for consent prominent and separate from your other terms and conditions? *Article 7(4) GDPR indicates that, inter alia, the situation of "bundling" consent with acceptance of terms or conditions, or "tying" the provision of a contract or a service to a request for consent to process personal data that are not necessary for the performance of that contract or service, is considered highly undesirable. If consent is given in this situation, it is presumed to be not freely given (recital 43).*	
5. Have you included the purpose of each of the processing operations for which consent is sought? *i.e. Have you clearly explained why you are collecting the data and what it will be used for?*	
6. Where multiple purposes exist in the research project, have you given separate distinct ('granular') options to consent separately to different purposes and types of processing?	

A research project may involve multiple processing operations for more than one purpose. In such cases, the data subjects should be free to choose which purpose they accept, rather than having to consent to a bundle of processing purposes. *Please note the Health Research Regulations 2018 allow for the fact that it may be difficult to fully specify the purposes of the research at the outset. Regulation 3(1)(e) provides that explicit consent from the individual may be obtained "for the purpose of the specified health research, either in relation to a particular area or more generally in that area or a related area of health research, or part thereof". For further information see: https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/consent/broad-consent/*	
7. Have you included what (type of) data will be collected and used *Examples: name, addresses, blood type, medical condition etc.*	
8. Have you informed data subjects of the data controller's identity (or if there is more than one the name of each data controller)? *The institution employing the Principal Investigator is a Data Controller and should be readily identifiable on the PIL/IC Form as the organisation managing the research participant's personal data.* *In a case where the consent sought is to be relied upon by multiple (joint) data controllers or if the data is to be transferred to other data controllers who wish to rely on the original consent, these organisations should all be named.*	
9. Have you provided a full list of the categories of recipients i.e. more information may be needed to allow the data subject to genuinely understand the processing operations at hand*[1] *The PIL/IC Form needs to acknowledge that data may be shared with others if applicable (e.g. with other academic collaborators/ with commercial companies) and for what purpose but specific named individuals do not need to be identified. The PIL/IC also needs to indicate if any data will be sent to a country outside of the European Economic Area.*	
10. If applicable: Have you included information about the use of the data for automated decision-making in accordance with Article 22 (2)(c)?See: https://gdpr-info.eu/art-22-gdpr/ *Note: automated decision-making is not equal to automated processing. Automated decision-making means making decisions that are made without human intervention. Automated processing is processing of*	

[1] Section 3.3.1. of Article 29 Working Party Guidelines on Consent under Regulation 2016/679

personal data using e.g. a computer to enter or store the data, but not to make any decision regarding the data.	
11. Can individuals refuse to consent without detriment? *The controller should be able to prove that the data subject had a free or genuine choice about whether to consent and that it was possible to withdraw consent without detriment.*	
12. Has the option to withdraw consent been communicated to the data subject? *Article 7(3) of the GDPR prescribes that the controller must ensure that consent can be withdrawn by the data subject as easily as giving consent and at any given time.*	
13. Have you used clear, plain language that is easy to understand? *If you have sought a language review from NALA or consulted with a patient association regarding the content of your PIL/IC, this would help.*	
14. Can you <u>demonstrate</u> that consent has been actively given? *In Article 7(1), the GDPR clearly outlines the explicit obligation of the controller to demonstrate a data subject's consent. The burden of proof will be on the controller, according to Article 7(1). Paper and electronic consent forms must be stored as long as the data is stored.*	

Definition of Key Terms

The following terms used throughout this guide have specific legal meanings under the GDPR. In order to understand your rights fully, please read the following glossary of key terms:

Adequacy Decision

The first thing to consider when transferring personal data to a third country is if there is an "adequacy decision". An adequacy decision means that the European Commission has decided that a third country or an international organisation ensures an adequate level of data protection.

Consent

Some types of processing are carried out on the basis that you have given your consent. Under the GDPR, consent to processing must be freely given, specific, and informed. You cannot be forced to give your consent, you must be told what purpose(s) your data will be used for and you should show your consent through a 'statement or as a clear affirmative action' (e.g. ticking a box).

Data Controller

A "data controller" refers to a person, company, or other body which decides the purposes and methods of processing personal data.

Data Processor

A "data processor" refers to a person, company, or other body which processes personal data on behalf of a data controller.

Data Protection Officer (DPO)

The GDPR requires data controllers and data processors to appoint a Data Protection Officer (DPO) in certain circumstances. A data controller can also voluntarily decide to appoint a DPO.

Health research

Regulation 3.(2) of the Regulations defines 'health research' as follows:

(a) …"health research" means any of the following scientific research for the purpose of human health: (i) research with the goal of understanding normal and abnormal functioning, at molecular, cellular, organ system and whole body levels; (ii) research that is specifically concerned with innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury; (iii) research with the goal of improving the diagnosis and treatment (including the rehabilitation and palliation) of human disease and injury and of improving the health and quality of life of individuals; (iv) research with the goal of improving the efficiency and effectiveness of health professionals and the health care system; (v) research with the goal of improving the health of the population as a whole or any part of the population through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status;
(b) Health research referred to in clause (i) to (v) of subparagraph (a) may include action taken to establish whether an individual may be suitable for inclusion in the research.

Personal data

The term “personal data” means any information relating to a living person who is identified or identifiable (such a person is referred to as a “data subject”). If the information can be used on its own or in combination with other information to identify a specific person, then it counts as personal data.

The GDPR gives examples of identifiers, including names, identification numbers, and location data. A person may also be identifiable by reference to factors which are specific to their identity, such as physical, genetic or cultural factors.

Processing

The term “processing” refers to any operation or set of operations performed on personal data. Processing includes storing, collecting, retrieving, using, combining, erasing and destroying personal data, and can involve automated or manual operations.

Profiling

Profiling is any kind of automated processing of personal data that involves analysing or predicting your behaviour, habits or interests.

Special categories of personal data

Certain types of sensitive personal data are subject to additional protection under the GDPR. These are listed under Article 9 of the GDPR as “special categories” of personal data. The special categories are:

1. personal data revealing racial or ethnic origin,
2. political opinions,
3. religious or philosophical beliefs,
4. trade union membership,
5. genetic data and biometric data processed for the purpose of uniquely identifying a natural person,
6. data concerning health,
7. data concerning a natural person’s sex life or sexual orientation.

Processing of these special categories is prohibited, except in limited circumstances set out in Article 9 of the GDPR.