HRCDC
Health Research Consent Declaration Committee

GUIDANCE NOTES TO SUPPORT AN APPLICATION TO PROCESS OR FURTHER PROCESS PERSONAL DATA FOR THE PURPOSES OF HEALTH RESEARCH

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1. INFORMATION POINTS

- The HRCDC is a body formed under statutory instrument (S.I. No. 314 of 2018 as amended by S.I. No. 188 of 2019).
- The information provided by you in connection with the application form is subject to the Freedom of Information Act, 2014.
- All references to Regulations herein, are those cited in the Health Research Regulations.
- Please also reference the Assisted decision-making act and amendment. ADMA 2015, ADMA as amended 2022.
- All references to Articles within the application form, are those cited in General Data Protection Regulation (GDPR); Regulation (EU) 2016/679.
- Detailed data protection guidance can be viewed on the Data Protection Commission website.
- Detailed guidance on the application process and FAQs can be viewed on the HRCDC website.
- Specific links to GDPR Articles through https://gdpr-info.eu/ is for information purposes and ease of reference only.
- The details of the Standard Operating Procedures of the HRCDC and Secretariat can be viewed on the HRCDC website.
- **Please consult with the data controller's Data Protection Officer prior to submission.**

2. GENERAL

- These Guidance Notes have been prepared to assist the data controller organisation with making an application to the Health Research Consent Declaration Committee (HRCDC) for a consent declaration.
- The notes will provide guidance on the various sections of the application form and how it should be approached.
- While such notes are provided for each section, this guidance is not intended to provide an exhaustive list of examples of how each section should be approached.
- It is advised to be open and informative on the particulars of your study and the personal data processing activities that will occur, so the HRCDC has the necessary information fully consider the application. This will avoid the Secretariat and/or HRCDC requesting further information and resulting in a delayed decision. It is the responsibility of the Applicant/data controller to ensure that their responses accurately and honestly reflect the research and data processing activities to occur.
- Please ensure all questions are fully considered and adequately addressed to ensure completeness and quality and facilitate the HRCDC to forming a decision.
- Applications for a consent declaration can only be made by a data controller of the research seeking a declaration (or where there are joint data controllers by the joint data controllers) and must be signed off by the data controller(s).
- The data controller(s) **must** engage with their **Data Protection Officer** (DPO) prior to completing and submitting the application.

- Please consult with https://hrcdc.ie/wp-content/uploads/2020/06/Decision-Tree-23.06.2020-v3.pdf, for further information.
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- The Applications log is publicly available and maybe a useful resource to understand the decisions made by the HRCDC, why conditions were attached to declarations, and reasons why applications were made to the HRCDC by researchers.

3. THE ROLE OF THE HRCDC

- The HRCDC will require information demonstrating that the public interest in carrying out the health research significantly outweighs the public interest in requiring the explicit consent of the research participant. It is important that any public interest test considers how best to balance the public interest with fundamental rights and freedoms of the research participants.
- One of the key objectives of data protection is to "protect the fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data".
- Therefore, anything that limits patient confidentiality and consent - such as a consent declaration, must itself have very strong countervailing public interest grounds. The role of the HRCDC is to robustly and independently scrutinise applications and to test grounds so as to protect public trust and support health research.
- Therefore, the HRCDC should be satisfied that any declaration made, based on the information provided by the applicant, will uphold the right to data protection of research participants.
- The consent declaration process is not there as an alternative to seeking consent. The HRCDC will require evidence to support a claim that obtaining consent is not feasible.
- A declaration is made specifically for the purpose of processing personal data, for health research. Please note that personal data includes pseudonymised data.
- The scope of a consent declaration, if made, may be for a defined part of the research project rather than the entirety of the project and the application should be prepared accordingly (e.g. consent may be or will be obtained for part of the data processing within the study, but not others)
- The **Applications Status Log** is publicly available and maybe a useful resource to understand the decisions made by the HRCDC, why conditions were attached to declarations, and reasons why applications were made to the HRCDC by researchers.

4. APPLICATION FORM GUIDANCE

LAY SUMMARY OF RESEARCH

- Please do not exceed the maximum word count. This lay summary is intended for the HRCDC public records and must set out a clear and easy to follow summary of the research study.
- It should briefly also explain why a consent declaration is required for the study.
- Overly technical or commercially sensitive information should not be avoided.

PUBLIC INTEREST CASE
- The HRCDC may only make a declaration where it is satisfied that the public interest in carrying out the research significantly outweighs the public interest in requiring the explicit consent of the data subject. This is the first time in (Irish) legislation that this exception has been provided for. - The Constitution, the common law duty of confidentiality, the European Convention on Human Rights and longstanding professional ethical practice have all referenced the public interest importance of maintaining confidentiality and data privacy - this is to enhance trust and transparency between data subject/patients and the health care and/or research team. - Any activity that limits patient confidentiality and consent - such as a consent declaration, must itself have very strong countervailing public interest grounds.

PART A: APPLICANT DETAILS	
SECTION	**GUIDANCE**
Section 1	- The Data Controller is fully responsible for and determines the how and why personal data is being collected and used (processed). *Ref Art 4 GDPR.* Employees of data controllers are not data controllers in relation to personal data that they process in their capacity as employees of the data controller. Nor are they data processors. - The application must be made by the data controller, or joint-data controllers, involved in the research study. - A consent declaration is made to a data controller or data controller(s) of the study - Correct designation of the data controller will enable the Committee to determine roles and responsibilities in relation to the research study consistent with GDPR. - A data controller the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data - If it is not clear who or what organisation is the data controller, this may delay the triaging and/or review process. **Example**: A Higher Education Institute, the HSE (legal person), Academic and teaching Hospital, Health Service provider, Voluntary Hospital, a single GP (natural person)
Section 2	If the Applicant is the Data Controller, solely in their personal capacity, this should be made clear and information provided to support that view. **Example:** sole trader, individual with private practice, not an employee of an organisation.

Section 3	The lead contact person to receive correspondence/communications in relation to this application must be specified and a telephone number and email address provided.
Section 4	- If there are joint data controllers, they must be identified, including setting out the division of responsibilities between them. - Joint data controllers are other third parties that may also be determining the how and why personal data is being used (processed) for the study. *Ref Art 26/GDPR* - All joint data controllers must sign the application form. Joint data controllers are most likely to arise in a collaborative project between institutions. **Example**: Co-investigators, collaborators, advisors, consultants in an advisory capacity and others that may also be determining the how and why personal data is being used (processed) for the study.
Section 5	- It is important to describe what joint data controller arrangements are in place between the Joint Data-Controllers to reflect the roles and responsibilities. *Art 26 GDPR* - These arrangements should in a transparent manner, outline their respective responsibilities and respective duties with respect data subjects (eg research participants) being able to exercise their data protection rights. **Example**: Joint Data controller arrangements maybe included within data transfer agreements, inter-institutional agreements, contractual arrangements, memorandum of understanding etc.
Section 6	- Data processors are third parties who carry out data processing operations on behalf of a data controller. *Art 28 GDPR* - A data processor follows the instructions of the data controller and has no control over the content and use of the data - All data processors who are processing personal data on behalf of the data controller(s) of the research study, and what their roles in the research are, must be clearly outlined. **Example:** Sub-contractors, service providers, academic institutions carrying out testing/analysis on the instruction of the data controller etc.
Section 7	- It is important to be clear what data controller-data processor relationships exist when conducting the research study. Art 28 GDPR - Care should be taken to distinguish between the data controller involved in the research and a data processor whose sole role is to process personal data under the instruction of the data controller. - It is essential to outline what legal agreements or (legal acts) are in place between the controller(s) and processor, as this is a requirement under GDPR - If there is no legal agreement in place at the time of submitting the application, please indicate the anticipated timeline as to when the legal agreements/act, will be in place.

	- It is advisable to consult with your organisation's legal counsel as appropriate. **Example:** Data Sharing Agreement, contractual clauses, Interinstitutional agreement with relevant contractual clauses etc.
Section 8	- Please indicate any Sponsor for the research activity (where appropriate). - This is relevant for a Clinical Trials of Medicinal Products under the Clinical Trials Directive (and the new Clinical Trials Regulations). **Example:** Pharmaceutical companies, or in the case of academic-led trials, clinical trials networks.
Section 9	- You are required to specify any person (other than a joint data controller or data processor with whom it is intended to disclose any of the l data obtained (whether personal/pseudonymised data or anonymised data) - The purpose of sharing this data and how the data will be shared, whether it is anonymised or pseudonymised, should be outlined - Please note, in answering this question, that disclosure of personal data (which includes pseudonymised data) obtained under a consent declaration can only be with the consent of the data subject or if it is required by law. A consent declaration, if made for a particular study, cannot cover the further processing of the personal data for other separate studies; this includes the sharing/disclosure of pseudonymised data to another third party. A separate consent declaration application for consideration maybe required in such a scenario.
Section 10	- If it is proposed to process any personal data outside of the State (Ireland), you must specify the countries in which this processing of data will take place. *Chapter V/GDPR* - - This section is linked to Sections 6 and 9 above i.e., the countries outside of Ireland where personal data may be processed should align with these sections. - If any of those countries are outside of the European Economic Area, you must specify the basis for the transfer of the personal data to those countries for processing - - If an adequacy decision is not in place for the country where you intend to transfer data, please confirm there is a transfer impact assessment in place. There is no requirement to send the agreement to us, confirmation of this agreement in place is sufficient. - Detailed guidance can also be found here: www.dpc.ie
Section 11	- It is a requirement under the Health Research Regulations, that research ethics approval is obtained before personal data can be processed for health research purposes.

	- The HRCDC cannot consider applications if REC approval, or provisional approval, has not been granted; provisional approval may not be acceptable depending on the matters raised by the REC and/or if these remain unresolved or outstanding. - Please attach a copy of outcome letter from all RECs that have been involved in approving the study. If the study is awaiting REC approval from other study sites, please indicate when REC approval, if granted is anticipated. If provisional REC approval is in place, please provide a copy of the Applicant responses to the queries/matters raised by the REC(s) - It may be a condition of a consent declaration made, that processing of personal data cannot commence at a study site, until the final approval has been obtained from the REC. The final letter confirming REC approval must be provided to the HRCDC. - Please also note that in the case of a successful application, the HRCDC must always be advised of any material change to the ethical approval granted. Subject to the nature of the changes then an amendment request form may need to the submitted to the HRCDC for consideration.

PART B: NATURE OF HEALTH RESEARCH AND PERSONAL DATA INVOLVED	
SECTION	**GUIDANCE**
Section 1	- It is important for the HRCDC to understand the commencement of processing of personal data for the research study. Equally, the duration of the study must be provided, or an estimated timeline. - This information will help inform the HRCDC how long a consent declaration should be made for, if one is made.
Section 2	- You should be as succinct as possible when describing the nature, objective and deliverables of the research and the parts of the research for which the consent declaration is sought. - Please provide non-confidential or commercially sensitive information if possible. Please do not use overly technical language information.
Section 3	- The design and methodology are required to inform the HRCDC about the research activities involved and how data processing is being carried out in the context of the study - Please provide non-confidential or commercially sensitive information if possible. Please do not use overly technical language.
Section 4	- It is important for the HRCDC understand the type of personal data which will be obtained and used for the research. Ref Art 4, 9 GDPR - This will inform the HRCDC as to whether the data is of a sensitive nature, such as genetic data, if appropriate safeguards are in place and weighing up the public interest with obtaining consent.

	Example of data: names, date of birth, age, gender, clinical data, phenotype data, addresses, socio-economic data, ethnicity etc. - Please ensure it is clear what sources personal data is being obtained from. This will ensure there is clarity regarding the data controller of the data **Examples of Sources:** Medical records, Hospitals, Health Service providers, Registries, databases, questionnaires, social media etc. - It is important to ensure the data controller of the personal data you wish to process for the research study has been consulted. Equally, it should be stated what the likelihood is that the personal data can be obtained for processing, if a consent declaration is made. **Example:** A University seeking access to a Hospital records - is the Hospital willing to share this data under appropriate terms and conditions, should a consent declaration be made? - If the data controller of the personal data is sharing personal data with the data controller of the research study, consideration should be taken as to whether appropriate sharing arrangements will be in place, setting out terms and conditions of use for the purse of safeguarding the personal data, such of purpose limitation . - It is important to discuss this with the data controller of the personal data **Example:** Data sharing agreement, memorandum of understanding, terms of use etc
Section 5(i)	- Data processing activities can be extremely broad and varied. It is important to clearly describe all data processing activities that will be carried out during the life cycle of the research. *Ref Art 4(2)/GDPR)* - Data often have a longer lifespan than the research project that creates them. It is important to consider all data processing activities that may extend beyond the research lifecycle. - A simple data flow diagram should be provided if possible. **Example:** activities such as: accessing, reviewing, collecting, recording, storing, adapting, pseudonymisation, anonymisation, analysis, linking, combining, sharing, transfers, archiving and destruction, retaining.
Section 5 (ii)	- Genetic / Genomic data requires adequate safeguards to be in place during the research due to the highly sensitive nature of this personal data. Large data sets are usually generated as a result of the analysis techniques and it is important for the HRCDC to satisfy itself the security of the data is managed effectively during the research. Please ensure information on how the data will be managed, transferred securely between different institutions. (if applicable) Please also consider third parties involved in this data flow and please refer also back to Part A Q9.

Section 6	- It is important for the HRCDC to understand why personal data is required for the purpose of the study, rather than fully anonymised data. - In this regard, pseudonymised or de-identified data may also be considered personal data and should not be confused with irrevocably anonymised data. *Recital 26 GDPR* - Full guidance from the Data Protection Commission can be found here.
Section 7	- You must describe how the personal data used for the study, will not be processed in such a way that will damage or distress the research participants. - Consider particular risks that are presented by processing the data, such as; accidental destruction, loss, unauthorised access and alteration, unauthorised disclosure of the data etc.
Section 8	- The purpose of a consent declaration is to allow the data controller concerned to obtain and use personal data for the research specified in the application. - A consent declaration does not permit personal data to be disclosed further unless such information is anonymised - If it is intended to disclose personal data, please indicate clearly to what data is being disclosed, to whom, and for what purpose. Please also detail the data safeguards in place for this data.
Section 9	- It is important to indicate if data linkage of the personal data will be a component of the research study. - Data linkage activity should be noted in the data protection impact assessment and data protection risks should be highlighted. **Example:** Linking data to the Central Registries Office, or Hospital In-Patient Enquiry (HIPE)
Section 10	- The HRCDC will need to understand at what point in the research study a consent declaration is no longer required. Timelines are very important and maybe linked to the duration of the study. - Please consider at what stage during the research study, personal data will be rendered irrevocably anonymised to the Data Controller(s), returned or destroyed, or when future consent maybe obtained etc. - Where relevant, consider at what point the master list/key that codifies the personal data, will be destroyed, how the master list/key will be destroyed and - If you require a consent declaration over several years, or indefinitely, please set out the reasons why.

PART C: CONSENT	
SECTION	**GUIDANCE**

Section 1	- This section must be answered comprehensively in order for the HRCDC to understand why a declaration is being sought, as an alternative to seeking explicit consent from the individuals. As much detail as possible should be given where possible - Please substantiate the rationale with supporting evidence where possible. If attempts have been made to consent individuals, please explain, and outline the outcome. If there has been no response from individuals after attempting to seek consent, this should be outlined. - If seeking a declaration to process data of individuals who have since been lost to follow up, please explain. - If attempts to seek consent would significantly undermine the scientific integrity of the project, please explain. For eg, if there is a requirement for inclusion of all individuals in a defined cohort, such as those with a rare condition. - If consent is not possible to obtain due to lack of decision-making capacity, please complete Part C, Section 4 where relevant. -
Section 2	- Give an estimation of the projected number of participants in the research study in Ireland. This is important to note in the context of international studies for example clinical trials/ The HRCDC need to understand in what way consent from the research participant(s) was formally considered at the design stage or any stage of the research. - Specifically, was consent discussed with a research ethics committee, subject matter experts, peers and or collaborators etc.
Section 3	- Please outline if any of the research participants have decision making agreements in place. (Assisted Decision Making Act 2015 and as amended in 2022) If these types if agreements are in place they must mention research specifically. • If assisted decision, co-decision- or decision-making representative arrangements are in place, then this equates to explicit consent and application to the HRCDC is not necessary for this cohort of participants. (providing the agreements mention health esearch) • All other arrangements for example, legally appointed representative, do not qualify as explicit consent and so are considered proxy assent and may be used as a data safeguard.
Section 4(i)	- The HRCDC must be satisfied that appropriate protocols are in place to determine that the research participant lacks decision making capacity. - Information on who is making this determination, their training and experience should be outlined. If a specialist assessment is required, please indicate.

	• Capacity to provide consent is a matter that should be determined on a case-by-case basis, it is important that researchers are still satisfied that the person has the capacity to provide explicit consent with regards the particular study at the time of assessing capacity. Please also reference the Assisted decision-making act and amendment. ADMA 2015, ADMA as amended 2022.
Section 4(ii)	- Where proxy assent is being used as a suitable safeguard, briefly outline what measures are in place to ensure that the identified proxy is the most appropriate individual who can communicate on behalf of the participant and understands the participant's will and preference. - This individual may not necessarily be next-of -kin, but maybe a carer or friend, but should understand the will and preference of the research participant. - NOTE: proxy (next-of-kin relative, friend) assent for data processing on behalf of an individual that lacks decision making capacity has no lawful basis. However, it maybe used as a suitable safeguard, in additional to seeking a consent declaration.
Section 5	- If deferred consent is being obtained, it should be outlined when it is anticipated to obtain consent and what will happen to personal data and associated biosamples if the research participant does not regain capacity. - Understanding when deferred consent will be obtained, will also determine the duration of the consent declaration. This will tie in with Part B, Section 11, exit strategy.

PART D: LEGAL BASIS FOR THE PROCESSING OF PERSONAL DATA

- This information set out in this section informs the legal basis for the research study.

- Please consult with your organisation's Data Protection Officer, as required.

-Further guidance can be found here; www.dpc.ie

- A lawful ground for the processing of personal data in Article 6 can be identified, and that in the case of processing Article 9 type data (which includes health and genetic data) that a condition in Article 9 can be found.

- These grounds and conditions are separate from the safeguards including explicit consent in the Health Research Regulations.

- Public authorities, in particular, should be aware that the Recitals to the GDPR states that they should not rely on consent as an Article 6 ground given the disparity of power that exist between a public authority and a data subject.

- Further, the text of Article 6 prohibits public authorities from relying on "legitimate interests" as a lawful ground for processing.

PART E: INFORMATION REQUIREMENTS, DATA SECURITY ARRANGEMENTS AND TRAINING	
SECTION	**GUIDANCE**
Section 1	- Transparency is a core data protection principle. It can be summarised as requiring the data controller to take such steps, as necessary, to ensure that the research participant will be not be surprised as regards what may happen to his or her personal data held by the data controller. - Further information on transparency can be found here. Please also consult with your Data Protection Officer. - Transparency measures must be outlined, explaining how the research participant would not be surprised that the data controller organisation(s) for the studies might wish to use his/her personal data for health research. - Supporting documentation/evidence should be provided where possible. Consider for example, data protection policies, public notices, publicity campaigns, information leaflets, websites etc.
Section 2	- It is important for the HRCDC to understand what security measures are in place to safeguard the personal data. - It should be very clear who has access, how access is being logged, how access is being controlled to mitigate for data breaches and risks such as unauthorised alteration, disclosure or erasure of personal data. - The technical measures to safeguard the personal data should be clearly outlined, such as encryption techniques, passwords, pseudonymisation techniques, firewalls etc. - It should be clearly described how the personal data will be safeguarded once the study is complete. **Example:** will the personal data be anonymised, archived or destroyed? Is so, what protocols are in place for this to happen? Will the master key/list be destroyed, including all paper and electronic copies? Will destruction be witnessed? Will all the technical and organisational measures be tested and evaluated to ensure robustness of these measures?
Section 3	- Technical, organisational and other safeguards will not be effective if those involved in the research are not aware of the data protection obligations placed on them. For that reason, confirmation that training in data protection law has been provided to those using personal data for health research should be provided. - Provide information on the training in data protection law and practice that has been provided to those individuals involved in carrying out the research
Section 4	- A Data Protection Impact Assessment (DPIA) form must be completed and provided. - Further information can be found here. - Any data linkages associated with the research and the data protection risk associated with those linkages should be identified and the data protection risks outlined.

	- Evidence of review from the data protection officer fromt eh data controller (s) must be provided. - Any actions taken in relation to that advice must be outlined. **NOTE:** Where there are multiple data controllers; One single DPIA will suffice for the study. However, the DPOs from each data controller organisation must provide feedback on the DPIA

PART G: SIGNATURES - DATA CONTROLLER (OR PERSON DUTY AUTHORISED TO SIGN ON BEHALF OF DATA CONTROLLER)

- The application must be signed by an individual duly authorised by the data controller organisation.
- It is important that the application is signed by appropriate competent authority at corporate/management level authority, as having read and acknowledged the application.
- Where there are joint data controllers, they must sign individually.

NOTES ON CONSENT

Why has consent not been sought, Why is it possible not to re-consent?

The guiding principle in health research is that individuals capable of giving explicit informed consent have a right to choose freely whether to participate in research. Consent protects the individual's freedom of choice and respects the individual's autonomy. Seeking informed consent from research participants also serves the purpose of promoting trust and integrity in research.

However, it is recognised that obtaining consent or re-consenting an individual to use their personal data may not be feasible or even ethical in some circumstances. Therefore, a waiver, or in the context of the Health Research Regulations, 2018, a declaration may be appropriate.

This is further supported by Guideline 10 of Ethical Guidelines for Health-related Research Involving Humans[1], which provides for a modification or waiver of informed consent to research if the research would not be feasible or practicable to carry out without the waiver or modification; if the research has important social value; and if the research poses no more than minimal risks to participants

Rebers et al[2] have conducted a comprehensive review of the range of arguments and circumstances under which the informed consent requirement in intervention research might be waived.

- 'Reasonable efforts' to seek consent may be as follows;
  - Carrying out a pilot study to understand whether consent is possible to seek
  - Engagement with appropriate focus groups/patient groups/patient advocates to determine whether seeking consent is possible
  - No contact details exist, but an evidence-based case must be made.

- A strong rationale for not seeking consent maybe as follows;
  - There maybe concerns regarding decrease of data validity and quality that may arise, which may compromise the integrity of a study.
  - If the inclusion rate is highly compromised because of seeking consent, which in turn may compromise the integrity of an extremely valuable study.
  - If there is a concern that seeking consent would lead to an 'observer'/'hawthorne' effect (the modification of the subject's/patient's behaviour knowing they are part of a study).
  - Cluster randomised trials are an increasingly important methodological tool in health research, but they do pose challenges to seeking consent requirement.
  - The use of biological samples and data outside the purpose originally described in the consent form maybe considered as 'secondary use'. Depending on the size of the sample collection, age of the collection and donor type, it may not be ethical or feasible to re-consent. In cases where it is unknown whether some donors may or may not have passed away, may be relocated elsewhere.
  - The risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions or in certain circumstances.

- A poor rationale for not seeking consent

[1] The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) International Ethical Guidelines for Health-related Research Involving Humans 2016. Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

[2] Rebers, Susanne et al. "Exceptions to the Rule of Informed Consent for Research with an Intervention." *BMC Medical Ethics* 17 (2016): 9.

- The potential to cause distress or annoyance
- Lack of resources to seek consent or other practical problems
- General reasons of impracticalities

NOTES ON PATIENT & PUBLIC INVOLVEMENT

Examples of strong PPI Engagement cases;

- PPI and engagement representatives are involved with the study from the outset, they maybe members of a study steering committee.
- The study also has a social media presence and each of the patient and public members has established links with wider patient groups which will be utilised to facilitate dissemination of the project findings.
- The researcher has approached community organisations, or patient focus groups, or charities etc, for input and feedback. Engagement with groups will be involved for the lifetime of the study.
- Transparency around the project is evident (website, articles, posters, public notices etc)

Examples of poor PPI Engagement cases:

- The application did not describe any PPI activity in this area.
- No focus groups were involved in the planning of the research.
- The views of the patient cohort that the research relates to, are not outlined.
- No evidence of transparency for the public eg no website, no dissemination planned.

NOTES CONDITION ATTACHED TO A CONSENT DECLARATION

- Improve transparency and ensure that future information sheets have sufficient content to ensure data protection rights of patients.
    - eg "*future publications of the information sheet would include a contact telephone number to enable patients to raise a dissent*"
    - eg "*update patient-facing information platforms (websites/videos/poster) to inform patients that data made by used for additional purposes*"
    - eg "*requested that the study would be included on the website"*

- Improve Security/Technical and Organisation measures
    - eg "*legal contracts are executed prior to the transfer of any data*" to ensure there are binding commitments (legal representations and warranties) from the recipient data controller never to attempt to re-identify a data subject
    - eg "confirm data security policy and procedures"
    - eg "*provide a data management plan*"

- Consistent PPI engagement throughout the lifetime of the study

    - eg "*Patient and public involvement and engagement activity should be undertaken on an ongoing basis in order to seek views on the study progress, findings and subsequent dissemination*"
    - eg "*the annual report must provide an overview of the PPI engagement that has occurred over the life time of the study*"

- Ethics approval
    - eg "*Favourable opinion from a Research Ethics Committee*"
    - eg "*provision of ethics application*"