**Applicant Pre-Submission Checklist & Guidance Notes**

The following pre-submission checklist has been developed by the Secretariat to assist the Applicant with the application process when seeking a declaration from the HRCDC.

The checklist below reflects the information required by the HRCDC to enable them to make a fully informed decision with respect to the declaration being sought by the Applicant. This checklist further reflects the requirements set out in the Health Research Regulations, 2018 (See footnotes and reference list of Regulations, page 3)

It is essential the Applicant consults with their Data Protection Officer prior to submitting.

**Part A: Applicant Details**

The Data Controller(s) and Joint-Controller is specified[[1]](#footnote-1)

Data Processor(s) are specified[[2]](#footnote-2)

Funders/Sponsors are specified[[3]](#footnote-3)

Any person (other than a joint data controller or data processor) with whom it is intended to share any of the personal data obtained or further processed (including where it has been pseudonymised or anonymised)[[4]](#footnote-4)

Ethics Approval has been granted[[5]](#footnote-5) **-** **Provide copy**

Jurisdiction of processing addressed

**Part B: Nature of Health Research & Personal Data**

Nature and Use of data being processed

The duration of the data processing/use of data, with start and end points

Evidence that the data use is restricted to those processing the data for research

Evidence of data minimisation[[6]](#footnote-6)

There will be no disclosure of personal data unless required by law or subject has given his or her explicit consent to the disclosure[[7]](#footnote-7)

Reference any data linkages[[8]](#footnote-8)

Evidence that anonymization of data is not possible[[9]](#footnote-9)

Evidence that data processing will not damage/distress the data subject[[10]](#footnote-10)

Evidence of public/patient engagement or consultations (the research objectives/ feasibility of obtaining consent)[[11]](#footnote-11)

Exit strategy where no declaration shall be required

Rationale for non-consent[[12]](#footnote-12)

**PART C: Legal basis for the processing of personal data**

Applicant meets one of the legal basis under Article 6[[13]](#footnote-13)

Applicant meets one of the conditions under Article 9(2)[[14]](#footnote-14)

**Part D: The Public Interest Case**

Statement that the Public Interest outweighs the requirement for explicit consent[[15]](#footnote-15)

**PART E: Information requirements, data security arrangements & training**

A Data Protection Impact Assessment (DPIA) has been completed[[16]](#footnote-16) - **Provide copy**

The Data Controller’s DPO(s) has been consulted[[17]](#footnote-17) - **Provide** **feedback**

Evidence of transparency arrangements[[18]](#footnote-18)

Evidence of controls in place to limit and log access to the data[[19]](#footnote-19)

Measures to protect the security of the personal data concerned[[20]](#footnote-20)

Arrangements to anonymise, archive or destroy personal data[[21]](#footnote-21)

Other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation[[22]](#footnote-22)

Evidence of data subject engagement - **Provide feedback**

Data protection law training has been completed by the health researchers[[23]](#footnote-23)

**PART F: Signatures - Data Controller(s)**

Signature of Applicant

Signature of Co-Applicant

**OTHER: Maybe requested by Secretariat**

Evidence of Patient Information Leaflet - **Provide copy**

Contractual arrangements between data controllers/processors **- Provide copy**

Pre-submission advice - **Append**

**Reference list of Regulations**

1. **Regulation 5(4)(b):** Written information that clearly identifies the controller/joint controller and the division of responsibilities.
2. **Regulation 3(1)(b)(iv):** Written information demonstrating specification of any data processors involved.
3. **Regulation 3(1)(b)(v):** Written information demonstrating specification of any person who provides funding for, or otherwise supports the project.
4. **Regulation 3(1)(b)(vi):** Written information demonstrating specification of any person with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.
5. **Regulation 5(4)(c)(vii):** Written information demonstrating that ethical approval from a research ethics committee has been received.
6. **Regulation 3(1)(c)(iii)**: Written information demonstrating measures that demonstrate compliance with the data minimisation principle in Article 5(1)(c).

**Regulation 5(4)(c)(iii):** Written information demonstrating that collection and use of personal data will go no further than is necessary for the attainment of the research objective .

1. **Regulation 5(4)(c)(iv):** Written information demonstrating that there will be no disclosure of the personal data unless that disclosure is required by law or data subjects have given explicit consent.
2. **Regulation 5(4)(d):** a copy of the result of the DPIA that has been carried out, with particular reference to the possibility of data linkages and details of any consultations undertaken with data subjects.
3. **Regulation 5(4)(c)(i):** Written information demonstrating that the research requires that the personal data specified be processed rather than anonymised data
4. **Regulation 5(4)(c)(ii):** Written information demonstrating that the personal data will not be processed in a way that causes, or will likely cause damage or distress to the data subject.
5. **Regulation 5(4)(d):** A copy of the result of the DPIA that has been carried out, with particular reference to the possibility of data linkages and details of any consultations undertaken with data subjects.
6. **Regulation 5(4)(e):** Written information demonstrating that the public interest in carrying out the health research significantly outweighs the public interest in requiring explicit consent of the data subject together with a statement setting out the reasons why it is not proposed to seek the consent of the data subject for the purposes of the health research.
7. **Regulation 5(4)(a)(i):** Written information that clearly identifies that the controller has a valid a lawful basis for processing personal data.
8. **Regulation 5(4)(a)(ii):** Written information that clearly identifies that the controller meets one of the conditions in Article 9(2).
9. **Regulation 5(4)(e):** Written information demonstrating that the public interest in carrying out the health research significantly outweighs the public interest in requiring explicit consent of the data subject together with a statement setting out the reasons why it is not proposed to seek the consent of the data subject for the purposes of the health research.
10. **Regulation 5(4)(d):** A copy of the result of the DPIA that has been carried out, with particular reference to the possibility of data linkages and details of any consultations undertaken with data subjects.
11. **Regulation 5(4)(c)(vi):** Written information demonstrating that a data protection officer has been appointed in relation to the research.
12. **Regulation 3(1)(d):** Written information demonstrating that arrangements to ensure that personal data are processed in a transparent manner are identified and in place.
13. **Regulation 3(1)(c)(iv):** Written information demonstrating that controls to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data are in place.

**Regulation 3(1)(c)(v):** Written information demonstrating that controls to log whether and by whom personal data have been consulted, altered, disclosed or erased are in place.

1. **Regulation 3(1)(c)(vi):** Written information demonstrating that measures to protect the security of the personal data concerned are in place.
2. **Regulation 3(1)(c)(vii):** Written information demonstrating that arrangements to anonymise, archive or destroy personal data once the health research has been completed are in place.
3. **Regulation 3(1)(c)(viii):** Written information demonstrating that other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures are in place.
4. **Regulation 3(1)(b)(vii):** Written information demonstrating that provision of training in data protection law and practice to those involved in carrying out the health research are in place.

1. Regulation 5(4)(b) [↑](#footnote-ref-1)
2. Regulation 3(1)(b)(iv) [↑](#footnote-ref-2)
3. Regulation 3(1)(b)(v) [↑](#footnote-ref-3)
4. Regulation 3(1)(b)(vi) [↑](#footnote-ref-4)
5. Regulation 5(4)(c)(vii) [↑](#footnote-ref-5)
6. Regulation 3(1)(c)(iii) and Regulation 5(4)(c)(iii) [↑](#footnote-ref-6)
7. Regulation 5(4)(c)(iv) [↑](#footnote-ref-7)
8. Regulation 5(4)(d) [↑](#footnote-ref-8)
9. Regulation 5(4)(c)(i) [↑](#footnote-ref-9)
10. Regulation 5(4)(c)(ii) [↑](#footnote-ref-10)
11. Regulation 5(4)(d) [↑](#footnote-ref-11)
12. Regulation 5(4)(e) [↑](#footnote-ref-12)
13. Regulation 5(4)(a)(i) [↑](#footnote-ref-13)
14. Regulation 5(4)(a)(ii) [↑](#footnote-ref-14)
15. Regulation 5(4)(e) [↑](#footnote-ref-15)
16. Regulation 5(4)(d) [↑](#footnote-ref-16)
17. Regulation 5(4)(c)(vi) [↑](#footnote-ref-17)
18. Regulation 3(1)(d) [↑](#footnote-ref-18)
19. Regulation 3(1)(c)(iv) and Regulation 3(1)(c)(v) [↑](#footnote-ref-19)
20. Regulation 3(1)(c)(vi) [↑](#footnote-ref-20)
21. Regulation 3(1)(c)(vii) [↑](#footnote-ref-21)
22. Regulation 3(1)(c)(viii) [↑](#footnote-ref-22)
23. Regulation 3(1)(b)(vii) [↑](#footnote-ref-23)