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UREC-DP Review Checklist

UREC-DP uses this checklist to guide the reviews of REDP applications that involve the processing of Special Categories of Personal Data (SCPD). It assists UREC-DP to ensure that SCPD is processed by researchers in an appropriate manner.

FRECs may use this checklist to facilitate their reviews of REDP forms, and they may distribute it to researchers who may refer to it while filling in their REDP forms. However, it should be noted that this is not intended as a research ethics review checklist. The issues listed are necessary for approval solely from a data protection perspective. This checklist should therefore complement and not replace the research ethics and data protection review criteria and procedures that are employed by the FRECs.

The checklist is made up of 5 Parts. The following outcomes are possible:

a) **UREC-DP review not required** - If all the answers to the questions in Part 1 are 'No', then UREC-DP review is not required.
b) **Approval** - If all the answers to the questions in Parts 2-5 are 'Yes' or 'N/A', then it is likely that UREC-DP will recommend approval of the application.
c) If any of the answers to the questions in Parts 2-5 are 'No' or 'Partial', then UREC-DP will recommend one of the following outcomes, depending on the extent of the issues:
    i) **Conditional Approval**: If only minor issues are indicated, approval is granted on condition that the amendments are carried out by the Researcher, endorsed by the supervisor (if the Researcher is a student) and verified by the FREC.
    ii) **Approval Withheld**: If major concerns are indicated, the Researcher must submit a point-by-point response to the issues raised in the UREC-DP report, together with any amended documents as required, for further review by UREC-DP.

Note: Data protection is important for all studies that process personal data, not only those that process SCPD. The FRECs should therefore be guided by good data protection practices on all applications. For applications that contain SCPD, UREC-DP review is needed after FREC review. Anonymous data (such as online surveys that record no identifiers, including email and IP addresses) do not constitute personal data and do not require UREC-DP review. For further details, please refer to the 'Data Protection' FAQs on the UREC website (www.um.edu.mt/research/ethics/faqs) and the Research Ethics Review Procedures, Art. 5.3.

PART 1 | General	**Yes**	**No**	**Partial**	**N/A**
Does this project constitute research as per Senate's definition? *If not, then no review required.*				
Does this research involve the processing of Primary SCPD? *If Yes, please complete Parts 2, 3, 4*				
Does this research involve the processing of Secondary SCPD? *If Yes, please complete Part 5*				
Does this research require the IDPCs approval (i.e., are the SCPD that are to be processed of a genetic, biometric or health-related nature)?				
PART 2 | Recruitment of Participants	**Yes**	**No**	**Partial**	**N/A**
Is the recruitment process clear?				
Does recruitment take place through an appropriate intermediary? *NB the intermediary must not be directly involved in the research and must have the right to access the participants and/or their data*				
Does the researcher provide evidence / confirmation that the intermediary has accepted to fulfil this role in the study?				
Are the participants legally able to give consent? If not please answer the two questions below.				
Is consent obtained from the legal guardians?				
Is an appropriate assent form for participants included? Or, if not possible, is assent obtained verbally?				
PART 3 | Collecting of Primary SCPD	**Yes**	**No**	**Partial**	**N/A**
Is the DP principle of minimality respected in this study in the processing of personal identification information? *NB ID Card Numbers, names and other personal identification information should only be processed if necessary, and should not be recorded on data collection sheets. A code / pseudonym should be assigned instead.*				

Is the DP principle of minimality respected in this study in the processing of research data? *NB Data collected should not be in excess of what is required for the study.*				
Part 4 | Informed Consent Form / Information Sheet	**Yes**	**No**	**Partial**	**N/A**
Is there a short explanation of the research aim/s?				
Is there a description of what participation will involve and what procedures will be followed?				
Is the expected duration of the participants' involvement outlined?				
Is there information on any foreseeable risk of physical and/or psychological harm/discomfort to participants				
If risks are foreseen, are participants informed about where they may obtain support?				
If more than minimal risk is involved, are participants informed about any available medical treatments if injury occurs, where further information may be obtained, and who to contact in the event of a research-related injury?				
If no risks are foreseen, is this clearly stated?				
Is there information on any benefits to participants or to others which may reasonably be expected from the research?				
If no benefits are foreseen, is this stated?				
Is there a statement that participation is voluntary, that invited participants may refuse to participate or withdraw from the study at any time and without giving a reason, and that this would involve no penalty or loss of benefits to which they are otherwise entitled?				
Is there information on what is done with the data gathered about / from participants who withdraw their consent? *NB this should ideally be deleted altogether if it is identifiable and technically possible to erase without rendering impossible or seriously impairing the achievement of the research objectives. This is in line with the exemptions provided for in the GDPR Article 17(3)(d). Otherwise, it should be retained in an anonymised form.*				

Is there sufficient information about the pseudonymisation or anonymisation procedures that is easily understood by the general public?				
Is there information about how the data will be securely stored? *NB personal data should be encrypted and stored in a separate location from the pseudonymised / anonymised research data.*				
Is there information about who will have access to the data? *NB This should be limited to those who need it for the research purposes (e.g., researcher, supervisor and examiners).*				
Is there information about when the personal data will be erased (or anonymised)?				
If participants are identifiable in research publications, did they explicitly consent to being identified?				
Is there a statement informing research participants about their rights under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation to obtain access to, rectify, and where applicable object to the processing of personal data or ask for the data concerning them to be erased?				
Is there the name and surname of **the *researcher* and** (where applicable) **the *supervisor/s***?				
Is there the email address of **the *researcher* and** (where applicable) **the *supervisor/s***? *NB UM email addresses should be provided by applicants and supervisors who are UM students or staff.*				
Is there a daytime phone number of **the *researcher* and/or** (where applicable) **the *supervisor/s***? *NB A daytime phone number is important so that participants who do not have access to email have an alternative channel of communication with the research team. If the researcher and supervisor/s do not wish to share their personal phone numbers, they could include their Department's number where participants may leave a message, provided that they then follow up as necessary.*				
Is there a clear declaration of consent to be signed by the participants?				

Is the DP principle of minimality respected in this study in the processing of personal identification information? *NB ID Card Numbers should not be recorded on consent forms unless necessary for research purposes, in which case justification must be provided.*				
PART 5 | Processing of Secondary SCPD	**Yes**	**No**	**Partial**	**N/A**
Is the data obtained by the researcher in an anonymised form? *If yes, then there is no need to proceed further in this section. If no, please carry on to the next questions.*				
Does the research satisfy at least one of the following conditions? a) The participants have consented to their data being processed in this manner / for this purpose b) An appropriate intermediary (someone who has the right to access the data and contact the participants) will obtain consent from the participants c) The data will be processed under the legal base provided in the GDPR, that stipulates that SCPD may be processed if it is necessary for scientific research purposes.				
Are sufficient safeguards in place to pseudonymise / anonymise the data as soon as possible?				
Will the personal data be stored securely and separately from the pseudonymised data? *NB Secure data storage includes encryption.*				
Will access to the data be limited to those who need it for the research purposes (e.g., researcher, supervisor and examiners)?				
Will the *personal* data be erased within a reasonable, stipulated timeframe? *NB 'Anonymous'/ 'anonymised' data (information which does not relate to an identified or identifiable natural person, or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable) be kept indefinitely.*				
Is it ensured that participants are NOT identified / identifiable at publication stage (to anyone who is reading the publication/s)? *NB: This is particularly important when researching niche populations (e.g., "a well known sportswoman who represented their country in the heptathlon")*				

UREC-DP Review Outcome

- ❑ UREC-DP Review Not Required (No SCPD)
- ❑ Approval
- ❑ Conditional Approval
- ❑ Approval Withheld

After UREC-DP Review Outcome

(If applicable) Under which legal basis is a recommendation of approval / conditional approval being made:

- ❑ Informed Consent
- ❑ Retrospective Study (secondary data) to be carried out for scientific research purposes in accordance with Article 89(1) of the GDPR.