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| **IRB Number** |       |
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| The purpose of this worksheet is to provide support for the research community, convened IRB or Designated Reviewers when conducting research in one of the countries of the European Economic Area. This worksheet may be used for guidance and does not have to be completed or retained.Note: Section 1 should be considered when drafting the Letter of Information and the Consent Document.  Sections 2 to 4 should be considered when completing the sections in the protocol template for submission in eIRB+ which refer to the collection, management, protection and ongoing handling of personal and other research data. |
| 1. Transparency: The information to be provided to participants in the Letter of Information and the Consent Document indicates:
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| [ ]  | The purposes for which the personal data/special category data will be processed. |
| [ ]  | The people or organizations with whom the personal data/special category data will be shared. |
| [ ]  | The legal basis for the processing of the personal data/special category data. Note: For the majority of human research, it is typical that 'public interest' is the appropriate legal basis. |
| [ ]  | Any international transfers of their personal data/special category data. N/A: [ ]  |
| [ ]  | When the personal data/special category data will be erased.Note: The GDPR requires that data is not kept as identifiable personal data for longer than is necessary in relation to the purposes for which it is processed. However, personal data processed solely for research purposes may be stored for longer periods, provided there are appropriate safeguards in place. This longer period is not defined in the GDPR. In addition, data retention must be compliant with the Northwestern University Data Retention Policy, which stipulates that research data and records should be retained for a minimum of three years after the end of the research or longer if required by research funders, regulators or state or local laws. For NU policies see: Retention of University Records Policy (<https://policies.northwestern.edu/docs/RUR_Appendix_A061913.pdf>) and Research Data: Ownership, Retention and Access (<https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/4/1207/files/2020/02/research-data-policy.pdf>).  |
| [ ]  | Their rights in research conducted under GDPR: |
| [ ]  | Right of access: i.e., the right to know what is known about the person. |
| [ ]  | Right to erasure (also known as the right to be forgotten), i.e. to be removed entirely from the research and the database. |
| [ ]  | Right to restrict data processing i.e., “stop filming me” |
| [ ]  | Right to withdrawal of consent |
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| 1. Collection of a minimal amount of information / data:
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| [ ]  | The items of personal data / special category data to be collected the minimum necessary to achieve the research objectives. N/A: [ ]  |
| [ ]  | The potential for using anonymized or coded data been considered. N/A: [ ]  |
| [ ]  | Access to the personal data/special category data of participants be restricted to authorized persons. N/A: [ ]  |
| [ ]  | Participant data be kept in the form of fully identifiable data for a fixed period of time. N/A: [ ]  |
| [ ]  | There a clear rationale for the length of time data will be kept as fully identifiable data. N/A: [ ]  |
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| 1. Data Security:
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| [ ]  | Personal data / special category data be collected, transmitted and stored securely. N/A: [ ]  |
| [ ]  | The level of security to be provided appropriate to the risks represented by the processing. N/A: [ ]  |
| [ ]  | Arrangements are in place for the secure disposal and/or destruction of personal data / special category data when it is no longer required. N/A: [ ]  |
| [ ]  | Participant data will be kept in the form of fully identifiable data for a fixed period of time. N/A: [ ]  |
| [ ]  | There a clear rationale for the length of time data will be kept as fully identifiable data. N/A: [ ]  |
| 1. Other security measures:
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| [ ]  | If the data is to be shared with another organization, there is (or will be) a written agreement such as a Data Use Agreement, Data Transfer Agreement, or Material Transfer Agreement with the other organization, setting out the respective roles and responsibilities of each and how individual participants may exercise their rights in respect of their data. N/A: [ ]  |
| [ ]  | Is it likely that your use of personal data/special category data will cause substantial damage or substantial distress to any of the participants? If yes, it is the requirement in the GDPR that personal data may not be used for research purposes if it is likely to cause substantial damage or substantial distress to an individual. |