

RSU034

RAG and RSU Guidance on Essential and Sample Size Criteria

1. The Northern Ireland Longitudinal Study (NILS) is a high quality linked dataset combining the 1981, 1991, 2001 and 2011 Censuses with routinely collected administrative data to enable research on the population which is of relevance to health and social care in Northern Ireland. Access to the database is limited to approved research projects only.
2. Research on the NILS is administered within an approval process managed by the NILS Research Approvals Group (RAG). Deborah Lyness, Head of VARS, chairs this independent Group with membership drawn from academia with relevant public sector representation.
3. There are two essential assessment criteria that the RAG and RSU use:
 - **Health and Social Care Research:** Does the project relate to Health & Social Care research?
 - **Longitudinal Nature:** Is there a longitudinal aspect to the research?
4. Following a review of the criteria used to approve a project, it was decided that the previous 18 criteria, including two essential criteria, would be modified to 10. These 10 criteria are assessed using the RSU090 RAG Marking Template and Guidance document before and throughout the RAG meeting. The Research Support Unit (RSU) approve 5 criteria including the longitudinal aspect of the project before it goes to RAG. During the RAG meeting the other 5 criteria are assessed including the health and social care aspect.
5. In addition there is a requirement to have information on the sample size for a project.
6. This short document details the two essential criteria and the requirement for sample size information and gives guidance to prospective researchers in making an application.

NILS Research Approvals Group Guidance:

Essential Criterion Health and Social Care Research: Does the project relate to Health & Social Care Research?

1. The Health and Social Care research criterion is required as the demographic data in the Northern Ireland Longitudinal Study (NILS) has been constructed and processed for the purposes of commenting on aspects of health and social care of the population of Northern Ireland as per the Health and Personal Social Services (Northern Ireland) Order 1972 (sections 43 and 63). Any research based off the NILS data outside of this focus is not allowed under the terms of the Data Protection Act.
2. When assessing applications under this criterion, the NILS RAG use the World Health Organisation definition of health: namely health is
 - "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity." (WHO: 1946)
3. Given this wide definitional context there are two different ways for a project to meet the Health and Social Care criterion:
 - a. A project would meet the criterion, if it is directly linked to a physical or mental health issue; (e.g. a project related to morbidity or mortality, which has a specific disease focus). However, researchers must outline this health and social care issue in their application in sufficient detail with reference to the current evidence base in terms of published academic papers, reports and policy documents to enable the RAG to pass this criterion.
 - b. A project that is not directly related to a physical or mental health issue clearly has a higher hurdle to meet this criterion (e.g. a project related to entrance to the labour market). However researchers can still meet the criterion by linking their research to the wider social determinants of health and social care (http://www.who.int/social_determinants/en/). Researchers will need to make detailed explicit reference to this in their application. Examples of references that researchers should familiarise themselves with, and make use of, in their justification for access to the NILS include: the Marmot Review "the Wider Social Determinants of Health" and "The Spirit Level" and the impact of inequality in society.

NILS Research Support Unit Guidance:

Essential Criterion Longitudinal Nature: Is there a longitudinal aspect to the research?

1. NILS research must be longitudinal in nature. This requires the research proposal to be focussed on analysis over time. Thus research solely focused on a cross-sectional analysis (e.g. using a single Census dataset and no other data) would **not** meet the criterion.
2. This criterion has been included to avoid researchers using the NILS as a cross-sectional Census dataset, when there are other datasets available for this (e.g. the Census Samples of Anonymised Records).
3. Given this context, it is relatively clear how projects would meet this criterion. Examples include:
 - a. a project that is looking at the link between two or more Censuses would meet this criterion; and
 - b. a project looking at another dataset, such as mortality, and linking this to previous Census characteristics would meet this criterion.
4. Again researchers must outline the significance of the longitudinal aspect of their research in sufficient detail for the NILS Research Support Unit to assess this criterion.

NILS Research Approvals Group and Research Support Unit Guidance:

Sample Size: Is the sample size of any subgroup targeted sufficient? Are any relevant privacy implications sufficiently mitigated?

1. The NILS RAG requires detail on the size of any population/sample to be analysed. This is initially approved by the RSU before RAG. This information is used to directly assess two criteria:
 - a. Is the sample size of any targeted subgroup sufficient?
 - b. Are any relevant privacy implications sufficiently mitigated?
2. In addition, the clear specification of the population/events and any subgroups to be analysed indicates to the RAG that the researcher has formulated an analysis plan. This therefore gives RSU and RAG more information for assessing criteria 3 and 5 respectively:
 - a. The researcher has done preliminary work which indicates a good understanding of the NILS sample by providing numerical estimates of sample size, and power calculations to demonstrate the robustness of their proposed analysis.
 - b. The researcher understands and seeks to ensure that any privacy implications are sufficiently mitigated in order to maintain the public and academic confidence in the NILS and ensure the integrity of NISRA.
3. Whilst not essential criterion they should be given detailed consideration in the application process as it would be very difficult for the RAG to approve a project with a small number of cases/events given the NILS/NIMS disclosure safeguards. To allow a project to go forward which has a sample size which is critically low is academically suspect and ethically wrong as it wastes time and effort for no return. As an example, any findings from a small sample could be pure stochastic variation and run the risk of identifying individuals.
4. If this information is not provided then some excellent projects may be rejected by the RAG purely because a limited piece of analysis has not been done.
5. Therefore the size of the population and number of events in the proposed study need to be clearly stated **and either**:
 - a. The size of any subgroups which may be the focus of analysis should be clearly specified; **or**
 - b. A power calculation to demonstrate the robustness of any proposed analysis.

6. As a rule of thumb, a critical sample size of around 30-50 events per annum (anything less than this will be given much more detailed scrutiny by the RAG).
7. It is the role of the researcher in the first instance to provide this information supported by the NILS-RSU. In the majority of cases information to determine sample sizes is available from public sources. The source of any figures should be included. An extremely useful source of information on 2001 and 2011 Censuses, births, deaths, migration and others is the Northern Ireland Neighbourhood Information Service (NINIS) www.nisra.gov.uk/NINIS. In some rare instances it may be hard to work this out (especially in very novel pieces of work) if that is the case then the researcher should say so in the application form.

NILS Research Approvals Group

July 2023