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**STUDY PROTOCOL**

**Sample Size as an Ethical Issue:**

**An assessment of Research Ethics Committee submission forms**

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Projected contributor roles according to the Contributor Roles Taxonomy (CRediT) are detailed in Appendix E

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**Background**

Research in medicine and psychology often aims to make an inference about a population based on a sample from that population. To effectively make such a statistical inference, a study requires an adequate sample size to detect an effect size of interest. If researchers run studies without considering how sample size and effect size play into the inferential statistics they will conduct, they will often end up running studies that cannot answer their research questions. Thus, an appropriate sample size should be determined prior to conducting a study and should be reported and justified in related publications (e.g., as stated in the CONSORT statement and APA Guidelines—Schulz et al., 2010; American Psychological Association, 2020, p. 83-84).

Sample sizes, however, are commonly stated rather than justified. A few studies that assessed published literature found that articles justified their sample size in 15% of observational studies and 29% of interventional studies in the fields of medicine, surgery, obstetrics and gynaecology, paediatrics and pharmacology (Tripathi et al., 2020); in 55% of cluster randomised trials (Rutterford et al., 2015); and in 0 of 100 human EEG studies (Larson & Carbine, 2017).

The absence of sample size justification indicates that low-powered studies are likely common. In the field of neuroscience for example, a review of 730 studies included in 49 meta-analyses reported a median statistical power of 21% (Button et al., 2013). Other studies report similar estimates of statistical power for the fields of psychology (mean = 24%, Smaldino et al., 2016) and clinical trials (median = 23%: Lamberink et al., 2018). Low power can also inflate published effect sizes (Button et al., 2013; Vasishth et al., 2016) and lead to an unreliable literature.

To conduct effective studies, researchers can benefit from selecting an appropriate sample size to answer their hypotheses *before* beginning a study. Several guidelines and some journal submission checklists request sample size justifications (e.g., CONSORT, Nature Publishing Group, 2019), but researchers generally only confront these requests *after* conducting their study. Alternatively, Research Ethics Committees and funding agencies can provide input regarding a study before it starts. Thus, these bodies could potentially encourage researchers to select an appropriate sample size prior to conducting a study.

In this study, we will collect the template ethics submission forms from Research Ethics Committees (RECs—we use this term interchangeably with Institutional Review Boards; IRBs) and assess the information they request from researchers about the sample size in the studies they propose. Whether checking for adequate sample size falls under the scope of RECs is debatable. One could argue that RECs should only concern themselves with participant well-being. Alternatively, one could argue that RECs have a responsibility to balance potential risks with potential benefits—and that studies with sample sizes too small to answer a researcher’s hypothesis can only entail little benefit. In many cases, researchers would be better suited than a REC to define what constitutes an appropriate sample size. A statistical expert would often be best, but may be present neither among the research group or the REC. For the present study, we do not take a stance on whether RECs should evaluate sample size. Instead we simply describe whether ethics submission forms request this information.

**Study Objective**

This study is descriptive; we have no hypotheses, but we have specific objectives.

1. To provide descriptive statistics regarding whether RECs at research intensive universities in select English speaking countries request information on sample size.

1. To explore whether national level organisations in these countries provide ethical review and whether those bodies request information on sample size.

**Study Design**

This is a descriptive cross-sectional study.

**Sampling**

We will assess the ethics submission forms from the RECs at 10 Universities in each of the UK, USA, Canada, and Australia. We will sample universities with the greatest Research and Development expenditure or research funding, as outlined in the four bullet points below. We selected this sample size to be commensurate with the requirements of the MSc Applied Neuropsychology programme at the University of Bristol, in which the first author (SP) is enrolled. We will only provide descriptive statistics of this sample and not perform inferential statistics about the larger population of universities—and thus, do not require a formal sample size calculation.

* *United Kingdom –* The total research expenditures of higher education providers in 2019/2020 published by the Higher Education Statistics Agency (HESA; see Table 8 with the search options “2019/2020”, “Research grants and contracts” and “207 Total Research grants and contracts”, sorted by the “Total expenditure” column in a descending order) <https://www.hesa.ac.uk/data-and-analysis/finances/table-8>
* *United States* – The R&D expenditures at higher education institutions of 2020 published by the US National Center for Science and Engineering Statistics (see p.84, Table 20, “2020” column) <https://ncses.nsf.gov/pubs/nsf22311/assets/nsf22311.pdf>
* *Australia –* The R&D expenditures are for higher education institutions of 2018 published by the National Department of Education, Skills and Employment (see Excel Sheet “HERD time series 2018”, Tab 2 “ Total Expenditure by HEP”, sorted by column S “2018” in a descending order)

<https://www.dese.gov.au/research-block-grants/resources/higher-education-expenditure-rd-herd-university>

* *Canada –* The sponsored research income of 2020 obtained from Research Infosource Inc. (see web Table, sorted by “FY2020 $000” column in a descending order) <https://researchinfosource.com/top-50-research-universities/2021/list>

For access to the archived ranking lists, please see:

* *UK -* <https://archive.org/details/UK_HESA_Table_Uni_Ranking>
* *US -* <https://archive.org/details/us-r-d-uni-ranking-2019-2020>
* *AUS -* <https://archive.org/details/aus-r-d-uni-ranking-2018>
* *CAN -* <https://archive.org/details/can-rincome-univ-ranking-2020>

From each university we will search for four different ethics submission forms. We will look for forms for *minimal-risk* studies and for non-minimal risk studies within the disciplines of medicine and psychology. We will continue sampling universities until we collect at least one ethics submission form in medicine from 10 universities and at least one ethics submission form in psychology from 10 universities. As the RECs for medicine and psychology will most often be different bodies, we may end up with some universities where we are only able to collect the ethics submission form for one of these disciplines. If a REC does not provide publicly available ethics submission forms, we will contact that REC to request the form (see Appendix B for a template email).

Exploratory research: National level bodies

We will search whether RECs exist within national level bodies (e.g. NHS in UK, CIHR in Canada). Should they exist, we will analyse their ethics submission forms with the same coding form we used for university RECs.

**Pilot**

We iteratively updated a coding form we created with Qualtrics (see Appendix C) based on a pilot of five UK Universities that are not in the top 10 from the rankings we will sample from.

**Statistical Plan**

We will report the count and percentage of REC forms coded “yes” for the questions of: i) sample size requests; ii) sample size justification requests; iii) sample size calculations requests; iv) data management requests; v) pre-registration requests; and vi) effect size of interest or minimal clinically important difference (MCID) requests.

Results will be presented separated by country, disciplines, and risk level (see Appendix D for an example table).

**Data Management**

Upon acceptance for publication, data will be stored as open data on the University of Bristol Research Data Repository (<https://data.bris.ac.uk/data/>). Open data are made available, free of charge, to anyone interested in the project, or who wishes to conduct their own analyses of the data.

**Publication Policy**

The findings from this research study may be published in an appropriate scientific journal (and made available open access), and/or presented at an appropriate meeting.

**Study Personnel**

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**Conflicts of Interest**

There are no relevant conflicts of interest.

**Upload date**

This protocol was uploaded to osf.io on 23/06/2022

**References**

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**Appendix A: Extraction Criteria**

| **Table 1:** Extraction criteria from ethical application forms. These questions are fully operationalized in the coding form provided in Appendix C. | | |
| --- | --- | --- |
| **Measurement name** | **Explanation** | **Possible values** |
| Coder Initials | The initials of the coder. | SP/RTT/Other |
| Country of Origin | From which country the form is from. | UK/USA/CAN/AUS |
| Type of Organisation | What type of organisation is the form from? | National/University |
| Name of Organisation | The name of the organisation. | Open text |
| Organisation Rank | The ranking number based on R&D and allocated research income. Not applicable to national-level bodies. | Open text |
| Type of Risk Form | Whether the ethics application form is for minimal / non-minimal risk studies. | Minimal / Non-minimal |
| Type of Discipline | Which discipline is the form from? | Medical / Psychological / Both / Unsure |
| Name of Discipline | The name of the discipline. | Open text |
| Sample Size | Whether the number of participants has been requested. | Yes/No |
| Sample Size Justification | Whether the reason for the size of the sample has been requested. | Yes/No |
| Sample Size Calculations | Whether statistical calculations have been requested to support the sample size justification (e.g., a power analysis or precision analysis). | Yes/No |
| Effect size of interest/MCID | Whether the effect size of interest or minimal clinically important difference (MCID) have been requested. | Yes/No |
| Data Management | Whether data management plans have been requested. | Yes/No |
| Preregistration | Whether preregistration/prospective registration has been advised/requested (e.g., to clinicaltrials.gov or the Open Science Framework). | Yes/No |
| Access Date | The date the form has been accessed. | Date |
| Additional Comments | Any additional comments about the REC coding or study in general. | Open text |

**Appendix B: Email template for requesting ethics submission forms from universities (if the forms are inaccessible)**

Email Subject: Request for Research Ethics Committee [or Institutional Review Board] submission form

Dear [name]

I am emailing to ask if you could share with me your Research Ethics Committee’s submission form (in other words, the form that a researcher in your institution must complete to request ethics approval to run a study).

I was unable to find this form publicly available online.

I am requesting this as part of a MSc research project conducted at the University of Bristol, UK. We are surveying the content of Research Ethics Committee submission forms across universities in different countries.

If your Research Ethics Committee has different forms for minimal-risk and non-minimal-risk studies, could you please share both of these with us.

We thank you for your time and help, it is greatly appreciated. We hope to hear back from you soon.

Best wishes,

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**Appendix C: Qualtrics Pilot Study Extraction Form**

**Start of Block: Extraction**

In parentheses you’ll find the recoded values e.g. SP **(1).**

**Q1.0 What are your initials?**

**o SP (1)**

**o RTT (2)**

**o Other (3) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |
| --- |

**Q1.1 From which country is this form?**

**o UK (1)**

**o USA (2)**

**o Canada (3)**

**o Australia (4)**

|  |
| --- |

**Q1.2 From what organisation is this form?**

**o National (1)**

**o University (2)**

**Q1.3 What is the name of the organisation?**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Q1.3.1 What is the R&D/Research-Income rank of the organisation? If it is a national-level body (e.g. NHS) and not a higher education provider (e.g. University), please input "n/a". If it is a higher education institution, please type the rank in numerical values (e.g. first = 1).**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Q1.4 Is this a minimal or non-minimal risk form?**

**o Minimal (Low) (2)**

**o Non-minimal (High) (1)**

**o Both (3)**

**o Ambiguous (5)**

**o Other (4) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Q1.5 From which discipline is this form?**

**o Medicine form (1)**

**o Psychology form (2)**

**o Both (3)**

**o Unsure (4)**

**Q1.5.1 What is the name of the discipline? (e.g. Social Psychology, Neuropsychology, Medicine, Sociology etc.)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Q1.6 Has the number of participants been explicitly requested? If the form includes a question that asks for the “methodology” but does not specifically mention the number of participants, we will code this as \*not\* asking for the number of participants.**

**o Yes (1)**

**o No (0)**

|  |
| --- |

**Q1.7 Has the sample size justification been explicitly requested? If the form includes a question that asks for the "methodology" but does not specifically mention the reason for sample size, we will code this as \*not\* asking for sample size justification. To code 'yes' for this question, the form does NOT need to ask specifically for a numerical/statistical justification"**

**o Yes (1)**

**o No (0)**

|  |
| --- |

**Q1.8 Have statistical calculations for sample size estimation been explicitly requested or advised? This is whether the form has prompted or has asked for the use of calculations (e.g. power or precision analyses) to justify the sample size.**

**o Yes (1)**

**o No (0)**

|  |
| --- |

**Q1.9 Has the effect size of interest or minimal clinically important difference (MCID) been explicitly requested? If the form includes a question that asks for the "methodology" but does not specifically mention effect size of interest, MCID, or another equivalent term, we will code this a \*not\* asking for the effect size.**

**o Yes (1)**

**o No (0)**

|  |
| --- |

**Q1.10 Has the use of data management plans been explicitly requested or advised? If the form includes a question that asks for the “methodology” but does not specifically mention data management plans, we will code this as \*not\* asking for data management plans.**

**o Yes (1)**

**o No (0)**

|  |
| --- |

**Q1.11 Has registration or preregistration (e.g., to the OSF or a clinical trials registry) been explicitly requested or advised? If the form includes a question that asks for the “methodology” but does not specifically mention pre-/registration, we will code this as \*not\* asking for pre-/registration.**

**o Yes (1)**

**o No (0)**

|  |
| --- |

**Q1.12 What is the date you accessed the documents?**

|  | **Month** | **Day** | **Year** |
| --- | --- | --- | --- |
|  |  |  |  |
| **Please Select: (1)** | **▼ January (1 ... December (12)** | **▼ 1 (1 ... 31 (31)** | **▼ 1900 (1 ... 2049 (150)** |

**Q1.13 Do you have any additional comments about coding this specific REC form or about this study in general?**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**End of Block: Extraction**

**Appendix D: Examples of Statistical Tables**

**Table 1 (example)**

*Percentage and number of REC forms coded “yes” for the requests stated below, divided by the type of discipline, countries and type of risk forms.*

| **Requests** |  | |  | |
| --- | --- | --- | --- | --- |
| **Minimal Risk** | **Non-minimal Risk** | **Medical** | **Psychology** |
| Sample size report   * US * UK * CAN * AUS | 5/10 (50%)\*  3/8 (38%)  6/10 (60%)  0/7 (0%) |  |  |  |
| Sample size justification   * US * UK * CAN * AUS |  |  |  |  |
| Sample size calculations   * US * UK * CAN * AUS |  |  |  |  |
| Effect size of interest/MCID   * US * UK * CAN * AUS |  |  |  |  |
| Data Management   * US * UK * CAN * AUS |  |  |  |  |
| Pre-Registration   * US * UK * CAN * AUS |  |  |  |  |
| **Total** |  |  |  |  |

\*This is an example of how the data will be presented. It is **NOT** real data. *REC =* Research Ethics Committees, *MCID* = Minimally Clinical Important Difference.

**Appendix E: Contributor Roles Taxonomy (CRediT) \*projected\* roles (**[**https://casrai.org/credit/**](https://casrai.org/credit/)**)**

Conceptualization: R.T.T.

Data curation: S.P., R.T.T

Formal analysis: S.P., R.T.T.

Funding acquisition: NA

Investigation: S.P., R.T.T.

Methodology: S.P., R.T.T.

Project administration: S.P., R.T.T.

Software: S.P., R.T.T.

Supervision: R.T.T., M.R.M

Validation: S.P., R.T.T.

Visualization: S.P., R.T.T.

Writing - original draft: S.P.

Writing - review & editing: S.P., R.T.T., M.R.M