

## Sample Size Calculation

Grant funding bodies want to be convinced that applicants are familiar with the methodologies outlined in their grant application and are well qualified to undertake the proposed work. If undertaking a randomised controlled trial they will expect to see the inclusion of a statistician, if utilising qualitative research the application should include an appropriately qualified researcher in the specified qualitative methodology.

Research studies come in many shapes and sizes and one sample size calculation does not fit all. Involvement of an experienced statistician or the Clinical Trials Unit at the earliest opportunity is highly recommended.

### What is sample size?

Clinical studies are usually performed in a sample of a larger target population. Depending on the design of the study, the statistician may want to know the size of the target population, such as how many surgical operations are currently performed or how many people have a specific disease.

Identifying and listing every member of any target population is usually impossible and a more accessible subset is selected called the study population. The sample size is the number of participants from the study population that will be needed to answer the research question and to detect a clinically relevant effect.

Study participants consent to taking part on the basis that the research has the potential to lead to increased knowledge. If the sample size is too small, the investigator may not be able to answer the study question, but if the sample size is too large it may lead to a waste of resources, time and money, and subject participants unnecessarily to experimental procedures.

### What types of study need sample size calculations?

All studies should have a sample size justification, however not all studies need to have a sample size calculation. If the desired population for your study is very rare, you might decide to study every case you can find.

For pilot, feasibility and qualitative studies, while a sample size justification is important, a formal sample size calculation may not be appropriate.

### Qualitative Research

Qualitative studies often use purposeful or criterion-based sampling to identify and select individuals or groups of individuals that are knowledgeable or experienced in the phenomena of interest.

When determining sample size for qualitative studies consider the following:

1. What sample size will reach saturation or redundancy?

Thematic/data saturation usually means that data should be collected until there are fewer surprises in the data and no more patterns or themes are emerging.

Theoretical saturation is mainly used in grounded theory, saturation does not mean the point at which no new ideas emerge, but that categories are fully accounted for, the differences between them are explained and the relationships between them are tested and validated, which results in a theory emerging.

Redundancy

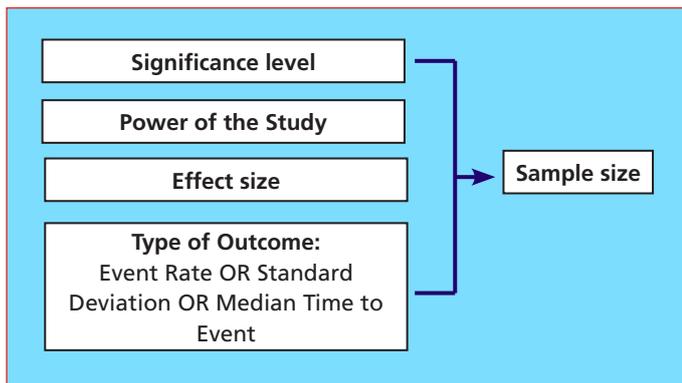
This is the point the researcher has seen and heard the same thing over and over again and therefore any new information provided becomes redundant.

2. How large a sample is needed to represent the variation within target population?

Make sure the sample is large enough to assess an appropriate amount of diversity or variation within the population of interest

## Quantitative Research

Sample size generally depends on the following:



### Significance Level

Significance level answers the question ‘how confident can we be that the results have not arisen by chance?’ Depending on the statistical test, the probability (p-value) of observing your sample results, or results more extreme, **given that the null hypothesis is true will be calculated**. The null hypothesis is the “devil’s advocate” position, it assumes that whatever you are trying to prove did not happen. When the null hypothesis is true and you reject it, you make a type I error.

### Power of the Study

Power is the likelihood that a study will detect an effect when there is an effect there to be detected. With insufficient power, a treatment may be deemed ineffective because no difference in outcome is detected when the treatment is actually effective but the sample size was too small to discover it. This is called a Type II error.

### Effect Size

When a difference is statistically significant, it does not necessarily mean that it is big, important, or helpful in decision-making, it simply means you can be confident that there is a difference. If the effect size is large between the study groups then the sample size required for the study is small; conversely if the effect size is small, the sample size required is large. Determining what constitutes a clinically significant effect is up to the researcher.

### Type of Outcome

Sample size approaches depend on the type of primary outcome measure. Most commonly in clinical trials, these measures are binary, continuous or time to event.

### Underlying Event Rate

For a binary outcome measure, the event rate, or prevalence rate, within the population is needed and is estimated from previously reported studies.

### Standard Deviation

For a continuous outcome, the variability of the measure is needed and is estimated using the Standard Deviation. Because the variance is usually an unknown quantity, investigators often use an estimate obtained from a pilot study or use information from previous studies.

### Median Time to Event

For a time to event, or survival, outcome measure, the median time to event in the population is needed. This may be estimated from previously reported studies, or review of clinical data.

## What other things do you need to consider?

### Attrition

Some participants who enrol in the study may drop out, while others may have incomplete data. To address this, an “attrition rate” is decided at the beginning and the sample size is increased to compensate.

### Cluster Studies

In cluster studies participants are nested within larger units, or clusters, such as GP practices, hospitals or communities. The intervention is applied at that level, while the outcomes are usually measured at the patient level. Similarities between participants in clusters reduces the variability of their responses. Consequently the sample size has to be increased in order to detect a difference between the intervention and control groups.

## Where can you go for further information and/or help?

East Midlands RDS

[www.rds-eastmidlands.nihr.ac.uk](http://www.rds-eastmidlands.nihr.ac.uk)

Clinical Trials Unit

[www.ukcrc-ctu.org.uk](http://www.ukcrc-ctu.org.uk)

Clinical Trials Toolkit

[www.ct-toolkit.ac.uk/routemap/trial-planning-and-design](http://www.ct-toolkit.ac.uk/routemap/trial-planning-and-design)

NIHR Research Design Service East Midlands and Yorkshire & the Humber. Sampling and Sample Size Calculation

[http://www.webpages.uidaho.edu/ed571/571-Modules/M3/NIHS-Sampling\\_Sample\\_Size\\_calculation.pdf](http://www.webpages.uidaho.edu/ed571/571-Modules/M3/NIHS-Sampling_Sample_Size_calculation.pdf)

NIHR Research Design Service London. Justifying sample size for a feasibility Study

<http://www.rds-london.nihr.ac.uk/How-to-design-a-study-find-funding/Statistics/sample-size-feasibility-study.aspx>

O’Reilly M, Parker N. ‘Unsatisfactory Saturation’: a critical exploration of the notion of saturated sample sizes in qualitative research. *Qualitative Research* 2013; 13 (2) 190-197

For general enquiries contact:

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☎ 0116 252 3276 Leicester

(covering Leicestershire, Northamptonshire and Rutland)

☎ 0115 970 9310 Nottingham

(covering Nottinghamshire, Derbyshire and Lincolnshire)

## RDS East Midlands Programmed Events

### Funder focus seminars

These are lunchtime 2 hour seminars (12:30-14:30) and will typically cover a combination of

- NIHR funding stream presentation
- Spotlight on a funding call
- Spotlight on a research design
- Panel Q & A (panel members, lay people and current award holders)

### Forthcoming seminars

27 April, Nottingham

8 May, Leicester

7 November, Loughborough

5 December, Nottingham

### For more information

<http://www.rds-eastmidlands.nihr.ac.uk/events>

email: [rds.em@nihr.ac.uk](mailto:rds.em@nihr.ac.uk)

### Application workshops

These are full day events focusing on writing funding applications and will include

- Practical presentations on sections of the application
- Plain English summary
- What NIHR expect to see in a bid
- Showcase good/successful applications
- Funding panel chairs' notes and guidelines
- Timelines
- Signposting to extra support for areas such as costings
- Grant writing skills
- Q & A session with current award holders

### Forthcoming workshops.

15 June, Nottingham

3 July, Leicester

### For more information

<http://www.rds-eastmidlands.nihr.ac.uk/events>

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## Elevator Pitch

Elevator pitches are becoming increasingly popular as a way to promote and sell your research idea. The pitches tell a **story**. Stories are easier to remember, draw people in and show them what benefits your research idea can offer. Elevator pitches can also provide a test for the integrity of your idea. If you struggle to formulate your idea in a concise simple way then this technique should help. You are the expert on your research idea and you need to convey the importance and the benefits that will arise from the research to extremely busy funding panel members who may only spend a short time reading your proposal. Apart from NIHR's Invention for Innovation (i4i) programme no other funder currently demands an elevator type presentation, but you can still use the elevator pitch technique to formulate the most important elements that need to go into your plain English summary.

Traditionally an elevator pitch contains a complicated, nuanced idea, pitched into a **60 second** simple, memorable and convincing speech.

**Goal:** The goal of the elevator pitch is to generate interest and create a longer conversation about your idea. For funding applicants it is to keep the funding panel interested in your research and moving it up the ranking into the fundable projects zone.

### Delivery:

- It should be delivered in the manner you normally talk, so it doesn't appear forced, but it also needs to be **practised**. 60 seconds may be a short time for the speaker but can seem like a long time to the listener!
- It's always good to pose questions in the pitch as it provokes and engages the listener.

**Pause** – give the listener a chance to interject

### Key ingredients:

- Include only the most important things that will make the listener want to hear more (including too much information will confuse and possibly annoy the listener)
- Show why you are worth investing by:
  - **Identifying the need** – what problem exists for whom. In 2 sentences highlight the problem and focus on the **benefits** and results your idea will bring to solve it.
  - **Identify your USP (unique selling point)** use a simple, short and focused statement to talk about 1 or at the most 2 key **features** of the idea that will impact on the problem..
- Try using one of the following **formats** for your pitch:
  - Problem / Why it matters / Potential solutions / Benefits of fixing it Context / Importance / Problem / What happens next
- **Audience:** Know your audience and develop your pitch to suit. Often funding panels or fellow researchers will have some basic knowledge but they won't be experts in your field. You need to describe your idea quickly to gain their interest. This type of elevator speech may come in useful when you are looking to find other collaborators to enhance your team.

The public on the other hand will need a much simpler explanation.

### Tips for success:

- Keep it short (less is more)
- avoid jargon and abbreviations
- be enthusiastic, but don't over promise
- relate to the bigger picture, something that your audience can appreciate or relate to
- avoid information overload
- use analogies and/or strong images
- relate your research to something the listener knows and/or cares about
- practice your speech at any opportunity

Research pitch examples::

- Jonathan Lam (stem therapy after a stroke)  
[www.youtube.com/watch?time\\_continue=1&v=gw3LN\\_pK\\_rU](http://www.youtube.com/watch?time_continue=1&v=gw3LN_pK_rU)
- Andrea Legary (Colon rectal cancer screening pitch)  
[www.youtube.com/watch?v=QK3ZdaoKXNQ](http://www.youtube.com/watch?v=QK3ZdaoKXNQ)
- Storytelling: How to tell a Research Story  
[www.youtube.com/watch?v=K7pVmBFd7VY](http://www.youtube.com/watch?v=K7pVmBFd7VY)

# NOTICEBOARD

## NIHR BioResource calling for researchers to sign up and access their volunteers

The NIHR BioResource is a resource of over 100,000 volunteers, both with and without health conditions, who are willing to be approached to take part in research studies. With the capacity to support more studies, the BioResource is looking for eligible research projects to sign up and use the service.

The NIHR BioResource speeds up the process of study recruitment by targeting specific cohorts of people based on the data, samples and health-related information provided and according to study criteria provided by researchers. Each volunteer has provided a blood or saliva sample and completed a health questionnaire to match them to relevant studies.

Applications are considered for studies looking to recruit participants based on their genotype and/or phenotype and will be reviewed by the NIHR BioResource Scientific Advisory Board. If approved, the BioResource will work with the research team to ensure that the ethics submission and volunteer paperwork are in line with recruitment via the BioResource before screening their extensive database and inviting eligible volunteers to take part in the study.

There are eight NIHR BioResource centres located across Cambridge, Leicester, London, Newcastle and Oxford.

<https://bioresource.nihr.ac.uk/>

## Patient and Public Involvement Award EM AHSN

East Midlands Academic Health Science Network (EMAHSN) have opened a third round of funding, following previous successful bursaries for up to a further ten East Midlands groups. Each successful group will receive £1,500. This is a vital contribution for many groups and will contribute towards meeting running costs. The funding will support their fantastic work to promote innovations and the adoption and spread of best practice within patient, carer and public involvement in healthcare delivery and health research across the East Midlands.

Groups can apply for funding up until the 5 May 2017. EMAHSN launched the fund because it recognises that many voluntary groups find it difficult even to cover basic costs such as travel and members' out-of-pocket expenses. Many groups exist to make sure that experiences of patients and public are at the heart of future decisions about health services – something that is central to EMAHSN and that it wants to encourage and sustain.

Applications for the grants will be considered by the East Midlands PPI Senate, an independent expert group of patients and public with varied health service user experience. The senate supports health and social care organisations to embed patient engagement.

<http://emahsn.org.uk/public-involvement/patient-and-public-involvement-grants>

## NIHR to launch a streamlined application process

The NIHR is launching a streamlined application process for researchers applying for funding. The streamlined, two-stage form will be rolled out across NIHR research and training programmes from May 2017.

The revised standard application form will ask for information once, at the point it is required to make either shortlisting or funding decisions. Any information provided during Stage 1 of the process will be automatically available for Stage 2 to avoid repetition and facilitate completion of the application. Applicants will be provided with clear, concise guidance about how to use the forms, including resources provided by INVOLVE about how to set out public involvement plans and present a Plain English Summary

<http://www.nihr.ac.uk/news/nihr-to-launch-a-streamlined-application-process/5880>

## Improving how patients and the public can help develop NICE guidance and standards

The National Institute for Health and Care Excellence (NICE) has launched a set of new proposals to improve the way we involve lay people in developing their guidance and standards. The draft proposals are now available and they are asking what people think of the proposed new principles and ways of working before they are finalised.

<https://www.nice.org.uk/Media/Default/About/NICE-Communities/Public-involvement/public-involvement-review-consultation-paper.pdf>

## Fast Track Impact Magazine

The magazine for researchers who want to be more productive and achieve real-world impacts from their research. Containing all the latest news and research, learn how to become more productive and influential online, better understand and track your impacts, and learn new tips to enhance your impact.

<http://www.fasttrackimpact.com/magazine>

**The NIHR Research Design Service for the East Midlands provides free support to researchers undertaking health related research. A team of research advisors is able to help with developing and submitting research protocols to national peer-reviewed funding streams.**

To subscribe to our newsletter visit:

<http://www.rds-eastmidlands.nihr.ac.uk/#Signup>