

# Expectations of the Research Councils & other major funders

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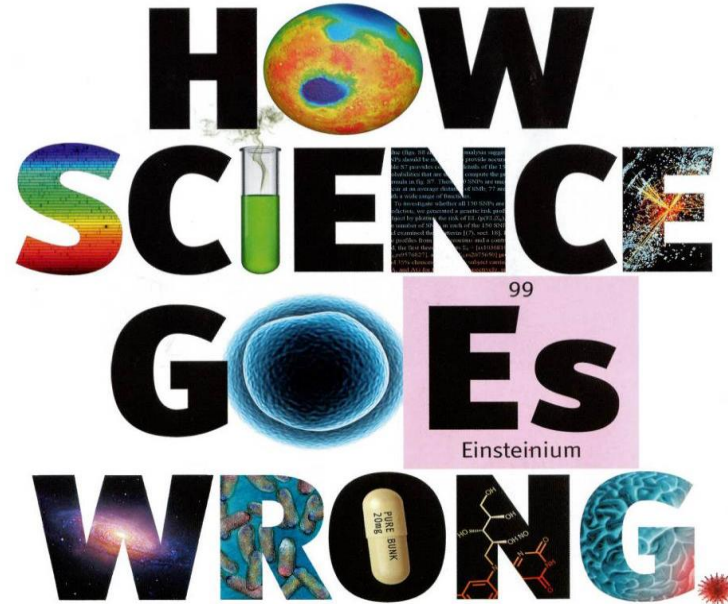
# More Rs

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- Reproducibility, Rigour and Reliability
- Research Integrity
- Responsibility in the use of animals in research

## A high profile issue

- Many papers about lack of reproducibility
- A key issue for translation and pre-clinical research
- Also important for public perception & trust in science



# Why does it matter?

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- Integrity of the scientific record
- Translation and demonstrating impact
- Accountability – effective use of (public) money
- Building and maintaining trust in science and research
- Making the case for investment in science

# Reproducibility and the conduct of research



## Data dredging

Also known as p-hacking, this involves repeatedly searching a dataset or trying alternative analyses until a 'significant' result is found.



## Omitting null results

When scientists or journals decide not to publish studies unless results are statistically significant.



## Underpowered study

Statistical power is the ability of an analysis to detect an effect, if the effect exists – an underpowered study is too small to reliably indicate whether or not an effect exists.



## Errors

Technical errors may exist within a study, such as misidentified reagents or computational errors.

## Issues



## Underspecified methods

A study may be very robust, but its methods not shared with other scientists in enough detail, so others cannot precisely replicate it.



## Weak experimental design

A study may have one or more methodological flaws that mean it is unlikely to produce reliable or valid results.

# Multiple contributing factors

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- poor experimental design
- inappropriate statistical analysis
- poor quality control
- incomplete reporting and publication bias
- competition & pressure to publish
- inadequate training & supervision

# System-wide approach needed

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- Funders
- Research institutions
- Academies
- Publishers
- Individual researchers – at all levels

# What can funders do?

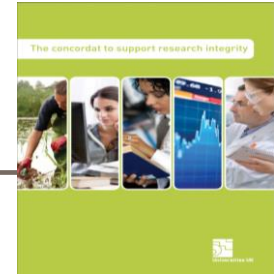
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- Policies and guidance
- Improve peer review
- Greater emphasis on methodology in funding applications
- Support for statistics and experimental design
- Promote data sharing and open science
- Promote high-quality reporting
- Promote better education and training
- Support resources



# UK Research integrity concordat

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## 5 commitments

- Maintaining highest standards of rigour & integrity
- Ensuring research is conducted according to appropriate ethical, legal & professional frameworks & standards
- Supporting a culture of integrity, good governance, best practice & researcher development
- Transparent & fair processes to deal with misconduct allegations
- Working together to strengthen integrity & regularly reviewing progress

# Good Research Practice

MRC ethics series

Good research practice:  
Principles and guidelines



Medical Research Council  
July 2012

# Good Research Practice guidance

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- Focuses on encouraging good practice - planning and carrying out trustworthy and ethical research which others can build on
- Covers all stages of research, from planning to publication
- Addresses both research misconduct and reproducibility by promoting a culture of:
  - Personal integrity
  - Honesty
  - Professionalism

# Good Research Practice Guidance (2)

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- Identify and manage conflicts of interest
- Availability of appropriate training and supervision
- Support for good experimental design and statistics
- Good data management (including long-term retention/archiving/sharing policies)
- Collaborative working: the importance of clarifying responsibilities and expectations
- Availability and awareness of ethical review mechanisms for research involving people & animals.
- Fair peer review

# Expectations for animal research

Responsibility in the use of  
animals in bioscience research:  
Expectations of the major research council and  
charitable funding bodies



# MRC Working Group 2012-13

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- Board & Panel Members including: Laboratory (animal) researchers, epidemiologists, methodologists, statisticians

## **REMIT**

- Identify concerns about the quality of information provided, particularly with regard to
  - Experimental design
  - Planned statistical analyses
  - Justification for the species and number of animals
- Determine whether referees assess these aspects
- Recommend changes to the guidance for applicants, peer-reviewers and boards
- Publicise the revised guidance to fellow board and panel members
- Review the impact of the revised guidance at subsequent triage and board rounds

# Appraisal results

(68 applications)

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Generally well justified:

- Need to use animals
- Model chosen
- Experimental rationale and planned design

Generally poorly described/justified:

- Choice of sample size (clear in just over 50% [64% awarded])
- Proposed statistical analyses (clear in 36%)
- Plans to minimise experimental bias (clear in only 11%)

## Guidance for Applicants and Award Holders 2014



Version 4  
Last updated 8 April 2014

### 8. Special considerations

#### 8.1 Clinical Staff

#### 8.2 Use of Animals

##### 8.2.1 Replacement, Reduction, and Refinement of Animal Experiments

##### 8.2.2 Proposals Involving Animal Use

##### 8.2.3 Experimental design, avoidance of bias and statistical considerations

##### 8.2.4 Peer Review

###### 8.2.4.1 Je-S section on 'Animal Research'

###### 8.2.4.2 Je-S section on 'Animal Species'

###### 8.2.4.3 Proposal attachment 'Case for Support'

###### 8.2.4.4 Je-S section on 'Resources – Animal costs'

###### 8.2.4.5 Proposal attachment 'Justification of Resources'

##### 8.2.5 Ethical and welfare standards and review

##### 8.2.6 Home Office Licences

##### 8.2.7 Mouse Strains

##### 8.2.8 Justification of Animal Use



# Example of design and statistical issues to be addressed in animal research proposals

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- the **avoidance of bias** (for example blinding of observers);
- how **randomisation** will be carried out (or why it is not appropriate)
- a clear **definition of the experimental unit** in the analysis;
- a justification of the **adequacy of the numbers of animals** (e.g. power calculation)
- the **number of different time points** at which measurements will be made on each animal
- a description of the **statistical analysis methods** & how they relate to the experimental design
- an indication of the number of **independent replications** of each experiment.

# Actions to date

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- Strengthened guidance for applicants and peer reviewers
- More space in applications for methodological detail
- Training for Board and Panel members
- RCUK “Statement of expectations for Doctoral Training” now includes training in statistics, experimental design and reproducibility
- Survey of MRC PhD students and Graduate Training leads
- UK Concordat on Open Research Data

# Things to think about

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- How do we demonstrate we value reproducible and valid results over novelty?
- How can we promote publication of null/negative results?
- Promoting and valuing data sharing/openness
- Improving support & training in experimental design and statistics

# Questions/Comments?

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