Diabetologia checklist for preclinical studies

Adapted from the Animal Research: Reporting of In Vivo Experiments (ARRIVE) Guidelines Checklist [1, 2] and the NIH Principles and Guidelines for Reporting Preclinical Research [3]

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|   | ITEM  | RECOMMENDATION  | Page no.  |
| Title  | 1  | Provide as accurate and concise a description of the content of the article as possible.  |   |
| Abstract  | 2  | Provide an accurate summary of the background, research objectives, including details of the species or strain of animal used, key methods, principal findings and conclusions of the study.  |   |
| INTRODUCTION  |  |  |   |
| Background  | 3  | 1. Include sufficient scientific background (including relevant references to previous work) to understand the motivation and context for the study, and explain the experimental approach and rationale.
2. **Animal studies only:** Explain how and why the animal species and model being used can address the scientific objectives and, where appropriate, the study’s relevance to human biology.
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| Objectives  | 4  | Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.  |   |
| METHODS  |  |  |   |
| Ethics statement  | 5  | Indicate the nature of the ethical review permissions, relevant licences (e.g. Animal [Scientific Procedures] Act 1986), informed consent, and national or institutional guidelines for the care and use of animals, or for the use of human tissue, that cover the research.  |   |
| Study design  | 6  | For each experiment, give brief details of the study design including: 1. The number of experimental and control groups.
2. Any steps taken to minimise the effects of subjective bias when allocating animals, cells or tissue samples to treatment (e.g. randomisation procedure) and when assessing results (e.g. if done, describe who was blinded and when).
3. The experimental unit (e.g. a single animal, group or cage of animals; single cell).

A time-line diagram or flow chart can be useful to illustrate how complex study designs were carried out.  |   |
| Experimental procedures  | 7  | **Animal studies only**For each experiment and each experimental group, including controls, provide precise details of all procedures carried out. For example: 1. How (e.g. drug formulation and dose, site and route of administration, anaesthesia and analgesia used [including monitoring], surgical procedure, method of euthanasia). Provide details of any specialist equipment used, including supplier(s).
2. When (e.g. time of day).
3. Where (e.g. home cage, laboratory, water maze).
4. Why (e.g. rationale for choice of specific anaesthetic, route of administration, drug dose used).
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|  | 8 | **Cell lines only:** Report the source, authentication and mycoplasma contamination status [3]. |  |
|  | 9 | **Studies involving antibodies:** Report source, characteristics, dilutions and how antibodies were validated [3]. |  |
| Experimental animals  | 10  | **Animal studies only**1. Provide details of the animals used, including species, strain, sex, developmental stage (e.g. mean or median age plus age range) and weight (e.g. mean or median weight plus weight range).
2. Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naive, previous procedures, etc.
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| Housing and husbandry  | 11  | **Animal studies only**Provide details of: 1. Housing (type of facility e.g. specific pathogen free; type of cage or housing; bedding material; number of cage companions).
2. Husbandry conditions (e.g. breeding programme, light/dark cycle, temperature, type of food, access to food and water, environmental enrichment).
3. Welfare-related assessments and interventions that were carried out prior to, during, or after the experiment.
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| Sample size  | 12  | 1. Specify the total number of animals or samples used in each experiment, and the number of animals or samples in each experimental group.
2. Explain how the number of animals or samples was arrived at. Provide details of any sample size calculation used.
3. Indicate the number of independent replications of each experiment, if relevant, e.g. the number of times a western blot was performed.
4. Provide sufficient information on sample collection to allow a clear distinction between independent biological data points and technical replicates.
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| Allocating animals/samples to experimental groups  | 13  | 1. Give full details of how animals or samples were allocated to experimental groups, including randomisation or matching if done.
2. Describe the order in which the animals/samples in the different experimental groups were treated and assessed.
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| Experimental outcomes  | 14  | Clearly define the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).  |   |
| Statistical methods  | 15 | 1. Provide details of the statistical methods used for each analysis.
2. Specify the unit of analysis for each dataset (e.g. single animal, group of animals, single islet).
3. Describe any methods used to assess whether the data met the assumptions of the statistical approach.
4. Give details of how data are reported, e.g. mean ± SD, median IQR.
 |   |
| RESULTS  |  |   |
| Baseline data  | 16  | **Animal studies only**For each experimental group, report relevant characteristics and health status of animals (e.g. weight, microbiological status, and drug or test naive) prior to treatment or testing. (This information can often be tabulated).  |   |
| Numbers analysed  | 17  | 1. Report the number of animals or samples in each group included in each analysis. Report absolute numbers (e.g. 10/20, not 50%[4]).
2. If any animals or data were not included in the analysis, explain why.
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| Outcomes and estimation  | 18  | Report the results for each analysis carried out, with a measure of precision (e.g. standard error or confidence interval).  |   |
| Adverse events  | 19  | **Animal studies only**1. Give details of all important adverse events in each experimental group.
2. Describe any modifications to the experimental protocols made to reduce adverse events.
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| DISCUSSION  |  |   |
| Interpretation/ scientific implications  | 20  | 1. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature.
2. Comment on the study limitations including any potential sources of bias, any limitations of the animal or model, and the imprecision associated with the results [4].
3. Describe any implications of your experimental methods or findings for the replacement, refinement or reduction of the use of animals in research.
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| Generalisability/ translation  | 21  | Comment on whether, and how, the findings of this study are likely to translate to other species or systems, including any relevance to human biology.  |   |
| Funding  | 22  | List all funding sources (including grant number) and the role of the funder(s) in the study.  |   |

* Please note all queries taken or adapted from the ARRIVE guidelines, except where otherwise indicated.
* Some items are indicated as being specific to certain types of research, e.g. animal studies, studies on cell lines. Please indicate ‘N/A’ (not applicable) for items that do not apply to your study.

**References**

1. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG (2010) The ARRIVE guidelines checklist. Animal Research: Reporting In Vivo Experiments. Available from [www.nc3rs.org.uk/arrive-guidelines](http://www.nc3rs.org.uk/arrive-guidelines), accessed 29 September 2016

2. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG (2010) Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research. *PLoS Biol* 8: e1000412.

3. National Institutes of Health (NIH) (2014) Principles and guidelines for reporting preclinical research. Available from [www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research](http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research), accessed 29 February 2016

4. Schulz KF, Altman DG, Moher D, the CONSORT Group (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 340:c332.