**Checklist for Academic Medicine Trainees**

**Generic Research Issues**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| **Research Governance** |  |
| Understands Clinical trials legislation |  |
| Understands the principles of the Human Tissue Act  |  |
| Understands issues of fraud / scientific misconduct |  |
| Understands issues around misuse of research |  |
| Understands issues around complex dilemmas in scientific research |  |
| Understands how clinical research is supported and regulated within the NHS  |  |
| Research Governance ICH GCP course (record date of most recent course)  |  |
| **Research Methodology** |  |
| Understands association and causation |  |
| Understands the effect of bias in research |  |
| Understands how to allow / adjust for confounding in design and analysis |  |
| Understands the application, strengths and weaknesses of different types of research study design |  |
| Use of routine data sources |  |
| Epidemiological studies |  |
| Surveys |  |
| Observational study - Cohort study design |  |
| Observational study - Case control studies |  |
| Randomised controlled trials |  |
| Systematic reviews |  |
| Population-based genetic association studies, including twin studies, linkage and association studies |  |
| Aware of the methods of allocation in intervention studies |  |
| Understands the principle of intention to treat analysis |  |
| **Skills** |  |
| Understands the need to Identify a research supervisor and arranges regular supervision meetings |  |
| Able to formulate a good research question with appropriate aims and objectives |  |
| Able to work co-operatively and creatively with colleagues with an appropriate degree of assertiveness |  |
| Able to design appropriate documentation for recording research observations and study data |  |
| Possesses the basic information handling skills including the use of spreadsheets, databases, statistical analysis and presentation software |  |
| Communicates with co-workers and drafts a final manuscript for submission |  |
| **Behaviours**  |  |
| Understands the need to Identify a research supervisor and arranges regular supervision meetings |  |
| Able to formulate a good research question with appropriate aims and objectives |  |
| Able to work co-operatively and creatively with colleagues with an appropriate degree of assertiveness |  |
| Able to design appropriate documentation for recording research observations and study data |  |

**Statistics**

**Basic Statistical analysis**

|  |  |
| --- | --- |
| Understands key statistical concepts and techniques |  |
| **Knowledge** | **Achieved** |
| Understands key statistical concepts and techniques |  |
| * continuous and categorical data
 |  |
| * standard statistical distributions (e.g. Normal, Poisson and binomial)
 |  |
| * probability, estimation and variability.
 |  |
| * hypothesis testing and interpretation of 'p' values
 |  |
| * confidence intervals
 |  |
| * principles of making inferences from a sample to a population
 |  |
| * type I and II errors
 |  |
| * problems of multiple comparisons
 |  |
| * methods for summarising data
 |  |
| * incidence and prevalence
 |  |
| Understands how to perform basic statistical analysis |  |
| * parametric and non-parametric tests for comparing two or more groups
 |  |
| * sample size and statistical power
 |  |
| * the odds ratio
 |  |
| * relative risk
 |  |
| * regression and correlation
 |  |
| * Numbers Needed to Treat (NNTs)
 |  |
| **Skills** |  |
| Able to calculate sample size with appropriate support |  |
| Able to perform appropriate basic statistical analysis with appropriate support |  |
| Able to present data clearly  |  |

**Advanced Statistical Analysis**

|  |  |
| --- | --- |
| The trainee will be able to select prospectively appropriate statistical methods for planned experiments (including clinical trials), perform such analyses, and interpret the resulting statistical output. |  |
| **Knowledge** | **Achieved** |
| **Understands advanced statistical analysis** |  |
| Able to describe; |  |
| * methods of analysis interval outcome data including repeated measures ANOVA
 |  |
| * methods of performing multivariate analysis
 |  |
| * methods of analysing survival data including life tables and Cox proportional hazards
 |  |
| * heterogeneity
 |  |
| * meta-analysis
 |  |
| * funnel plots
 |  |
| **Skills** |  |
| Consults effectively with statisticians during the planning stage of complex experimental studies. |  |
| Determines the power of a study to evaluate differences between therapies, and estimate the sample size needed |  |
| Uses advanced statistical techniques to analyse research data |  |
| **Behaviours**  |  |
| Appreciates the limitations of statistical analysis, trial design and the need for trial validation |  |

**Research Modules**

**Performing Research in a Laboratory (Experimental Medicine)**

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| --- | --- |
| **Knowledge** | **Achieved** |
| Aware of laboratory safety regulations |  |
| Home Office course modules for an Animal License (if applicable)Applicants for Home Office personal licences are required to have successfully completed an accredited training programme comprising the subjects described in Modules 1 to 3 and also those in Module 4 if surgical procedures or anaesthesia are going to be used. Module 5 relates to holding a project licence, which will usually be held by the research supervisor. Some more senior trainees may choose to complete this if it relevant to their future research. (see below for details)The Personal Licence application form and further details can be downloaded from Home Office website |  |
| MODULE 1 |  |
| MODULE 2 |  |
| MODULE 3 |  |
| MODULE 4 |  |
| **Skills** |  |
| Competent and safe performance of standard Laboratory techniques |  |
| Possesses the skills necessary to perform planned research  |  |
| * The skills might include the following
 |  |
| * Tissue culture
 |  |
| * Basic molecular biology
 |  |
| * Electrophoresis and Chromatography
 |  |
| * Histological techniques
 |  |
| Writes a laboratory research protocol |  |
| Performs study measurements accurately and reliably |  |
| Records data accurately |  |
| Interprets and presents the results appropriately |  |
| **Behaviours**  |  |
| Conforms to regulations in Home Office and Animal Licences |  |
| Follows best practice in animal husbandry |  |
| Follows best practice in storage of human tissue |  |

**Home Office course modules for an Animal License**

**MODULE 1**

1.  Historical background

 Legislation and attitudes to animals and animal welfare in the United Kingdom.
2.  An introduction to ethical aspects of the use of animals in scientific procedures.

3.  The Animals (Scientific Procedures) Act 1986

 The Certificate of Designation

 The Project Licence

 The Personal Licence

 Schedule 1

 Schedule 2

Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986.
(ISBN 0 10 218290-6 from HMSO).

Home Office Code of Practice for the Housing and Care of Animals used in Scientific Procedures.(ISBN 0 10 2107890 from HMSO).

 Other codes of Practice and Guidelines

4.  Other relevant legislation

**MODULE 2**

1.  Recognition of wellbeing, pain, suffering or distress in the relevant species.

2.  Handling and restraint of the relevant species.

3.  Humane methods of killing appropriate to the relevant species.

4.  Local procedures

 Security
 Administration
 Supply of animals

 Disposal of animals

5.  Personal Health and Safety.

**MODULE 3**

1.  Biology and husbandry of the relevant species.

2.  Common diseases and recognition in the relevant species.

3.  Health monitoring and disease prevention or control

 General principles

 Principles of gnotobiology

 Local practices and procedures

4.  Introduction to anaesthesia and analgesia in the relevant species.

5.  Conduct of minor procedures in the relevant species

 Common methods of dosing

 Common methods of sampling

 Minor procedures not requiring sedation, analgesia or general anaesthesia

 Other minor procedures involving sedation, analgesia or brief general anaesthesia.

**MODULE 4**

1.  Surgical anaesthesia and analgesia in the relevant species.

2.  Conduct of surgical procedures

 Principles of surgery

 Common surgical procedures

Post-surgical care and monitoring

**Epidemiology research**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| Understands how to use routine vital and health statistics to describe the distribution of disease in time and place and by person |  |
| Understands measures of disease burden (event-based and time-based)  |  |
| Understands sources of variation, its measurement and control; common errors in epidemiological measurement, their effect on numerator and denominator data and their avoidance; |  |
| Understands how to analyse health and disease in small areas |  |
| Understands strengths and weaknesses of cross-sectional, analytical studies, and intervention studies (including randomised controlled trials) |  |
| Understands sample size |  |
| Understands clustered data |  |
| Understands nested case-control studies |  |
| Understands methods of sampling from a population |  |
| **Behaviours**  |  |
| Uses appropriate statistical methods in the analysis and interpretation of epidemiological studies, including life-table analysis |  |
| Adheres to the ethics and etiquette of epidemiological research |  |

**Systematic review**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| Aware of the Cochrane Collaboration, evidence based medicine and how it influences policy |  |
| Understands the hierarchy of research evidence - from well conducted meta-analysis down to small case series, publication bias |  |
| **Skills** |  |
| Able to use electronic bibliographical databases and their limitations | . |
| Able to access grey literature |  |
| Able to select appropriate studies to include in a systematic review |  |
| Able to combine data from several studies |  |
| Performed appropriate meta-analysis |  |
| Able to clearly present the results of a systematic review |  |

**Performing a Clinical Research study on human subjects**

|  |  |
| --- | --- |
| The trainee will be able to undertake and complete a clinical research study  |  |
| **Knowledge** | **Achieved** |
| Able to describe:- |  |
| * the expected effect and method of action of the proposed treatment
 |  |
| * appropriate use of controls
 |  |
| * appropriate safety measures
 |  |
| * appropriate measurement methods
 |  |
| * use of outcome measures
 |  |
| **Skills** |  |
| Able to demonstrate competence in the clinical and / or other skills necessary to perform planned research | . |
| Selects a trial design appropriate to the research question.  |  |
| Writes research protocol including consent forms and patient information leaflets |  |
| Writes and submits Research Ethical Committee proposal in terms that are understood by the lay members of an REC |  |
| Able to recruit subjects for studies and obtain valid informed consent (or assent) |  |
| Performs clinical measurements reliably |  |
| Records data accurately |  |
| **Behaviours**  |  |
| Consults appropriately |  |
| Recognises the primacy of subject safety |  |

**Performing a Clinical trial**

|  |  |
| --- | --- |
| The trainee will be able to design clinical trials and contribute to their execution and dissemination. |  |
| **Knowledge** | **Achieved** |
| Able to describe:- |  |
| Principles of good clinical practice (GCP), as set out in the ICH (International Conference on Harmonisation) and the European Clinical Trials Directive. |  |
| Different trial designs, eg parallel versus cross-over  |  |
| Principles of controlled experiments, randomization, use of placebo and blinding |  |
| The responsibilities of investigators and their sponsors  |  |
| Detection and reporting of suspected unexpected serious adverse drug reactions (SUSARs) |  |
| The role of the Data Safety Monitoring Board  |  |
| Types of early stopping rules used in clinical trials  |  |
| **Skills** |  |
| Performs and / or supervises clinical measurements.  | . |
| Keeps records to the standard required by GCP.  |  |
| Able to assess causation of adverse events  |  |
| Able to understand and interpret in-trial adverse event data  |  |
| Able to weigh adverse event data against risk of terminating trial prematurely |  |

|  |  |
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| **Behaviours**  |  |
| Does not embark on a human investigation where an external sponsor has ultimate control over the right to publish or otherwise disseminate resulting information. |  |
| Maintains meticulous attention to detail.  |  |
| Exhibits balanced approach to interpretation of safety data  |  |
| Maintains a professional relationship with study sponsors and their employees (CROs etc). |  |

**Health Service Research including Health Economics**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| Understands the role of epidemiology and other methods in defining health service needs  |  |
| Understands how to formulate and interpret utilisation and performance measures |  |
| Understands study design for assessing effectiveness, efficiency and acceptability of services including measures of structure, process, service quality, and outcome of health care |  |
| Understands measures of health status, quality of life and health care; population health outcome indicators |  |
| Understands principles of evaluation, including quality assessment and quality assurance |  |
| Understands The confidential enquiry processes |  |
| Understands how to use Delphi methods |  |
| Understands the methods of economic evaluation in health care research |  |
| **Skills** |  |
| Can design a study to assess the appropriateness and adequacy of services and their acceptability to consumers and providers | . |
| Can interpret health economics evidence |  |
| **Behaviours**  |  |
| Sensitive to quality of life issues  |  |

**Qualitative Research**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| Understands qualitative research methodology  |  |
| Understands qualitative research methodology including  |  |
| * semi-structured and in-depth interviewing
 |  |
| * focus groups
 |  |
| * participant observation
 |  |
| * action research
 |  |
| * use of texts and documents
 |  |
| * use of audio and video recording
 |  |
| Understands the ethical issues which may arise in qualitative research |  |
| Understands the issues of reliability and validity in the analysis of qualitative data:  |  |
| Understands how to critically analyse qualitative data and studies. |  |
| **Skills** |  |
| Writes a robust qualitative research proposal. | . |
| Able to successfully collect data for a qualitative study |  |
| Able to appropriately use the software suitable for qualitative analysis |  |
| Able to transcribe and code qualitative data |  |
| Able to analyse and interpret qualitative data |  |
| Completed a qualitative research report |  |
| Presentation of results |  |

**Research in Medical Education**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| Understands qualitative research methodology including  |  |
| * semi-structured and in-depth interviewing
 |  |
| * focus groups
 |  |
| * participant observation
 |  |
| * action research
 |  |
| * use of texts and documents
 |  |
| * use of audio and video recording
 |  |
| Understands the ethical issues which may arise in medical education research |  |
| Understands the issues of reliability and validity in the analysis of qualitative data:  |  |
| Understands how to critically analyse qualitative data and studies. |  |
| **Skills** |  |
| Writes a robust research proposal. | . |
| Able to successfully collect data |  |
| Able to appropriately use the software suitable for qualitative analysis |  |
| Able to transcribe and code data |  |
| Able to analyse and interpret data |  |
| Completed a research report |  |
| Presentation of results |  |

**Personal Research Outcomes**

|  |  |
| --- | --- |
|  | **Achieved** |
| Submitted research grant application |  |
| Successful small grant application  |  |
| Successful application for research fellowship |  |
| Successful large grant application  |  |
| Poster presentation(s) Regional meeting(s) |  |
| Poster presentation(s) National meeting(s) |  |
| Poster presentation(s) International meeting(s) |  |
| Platform presentation(s) Regional meeting(s) |  |
| Platform presentation(s) National meeting(s) |  |
| Platform presentation(s) International meeting(s) |  |
| Scientific writing – Abstract(s) published |  |
| Scientific writing – Paper(s) published |  |
| Scientific writing – Paper(s) published in high impact journal(s) |  |
| Scientific writing – Thesis written |  |
| Scientific writing – Book chapter(s) or book(s) |  |
| Awarded higher degree |  |

**Research leadership**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| Understands the sources of research grant income relevant to chosen field of research |  |
| **Skills** |  |
| Peer review others research papers | . |
| Peer review grant applications |  |
| Supervise others research  |  |
| Media skills |  |
| Commercialisation of research outputs |  |
| **Behaviours**  |  |
| Effective networking and collaboration |  |

**Translational Medicine/Research**

|  |  |
| --- | --- |
| **Knowledge** | **Achieved** |
| **Understands the scope of Translational Medicine:-** |  |
| Understanding pathways of disease from use of human and animal disease models  |  |
| Development of diagnostic methodology |  |
| Development of research methodology, biostatistics and informatics |  |
| Identification of targets for therapeutic intervention |  |
| Development of novel therapeutic agents, devices or procedures |  |
| Performance of evaluative research and clinical trials,  |  |
| Understands the purpose and operation of clinical research centres and networks  |  |
| Understands the potential benefits to society |  |
| * Public Health Innovation
 |  |
| * Healthcare innovation
 |  |
| * Patient benefit
 |  |
| * Better treatment outcomes
 |  |
| Recognises the opportunities:- |  |
| * Understand what opportunities exist for partnership funding for certain initiatives from charities, industry and public bodies which promote innovation
 |  |
| * Understand the benefits of and potential need to collaborate with industry
 |  |
| Recognises the challenges posed by:- |  |
| * Regulation
 |  |
| * Scientific aspects of the Human Fertilisation and Embryology Bill for Stem cell research
 |  |
| * Animal Rights
 |  |
| * Intellectual Property Rights
 |  |
| Recognises the benefits to society achieved by bringing discoveries in science closer and faster to the clinic and to society in general.  |  |
| Able to identify how previous research has lead to  |  |
| * better prevention
 |  |
| * better diagnostics
 |  |
| * better public health strategies
 |  |
| Able to identify how research findings may contribute to productivity and the national economy |  |
| **Behaviours**  |  |
| Recognises the need to train other clinical research scientists |  |
| Contributes to the training of future clinical research scientists  |  |
| Encourages a milestone-driven, goal-oriented approach to conducting research |  |
| Success achieved in one or more relevant areas  |  |
| * Training other people to perform research
 |  |
| * Developing a new treatment or diagnostic technique
 |  |
| * Contributing to the development of infrastructure and research capacity development
 |  |