1. Useful Contacts

- **a. Medicines and Healthcare products Regulatory Agency**
  The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe. The MHRA is an executive agency of the Department of Health.
- **b. Health Research Authority**
  National Research Ethics Service is now part of the Health Research Authority
- **c. NHS R&D Forum**
  The NHS R&D Forum is a network for those involved in managing and supporting R&D in health and social care. Joining the Forum ensures that you receive regular email newsletters, keeping you informed of conferences and other activities of the Forum.
- **d. UK Research Integrity Office**
  The UK Research Integrity Office is an independent body which provides expert advice and guidance about the conduct of research.

2. Clinical Trials Databases and Registration

- **a. Ottawa Statement on Trial Registration**
  The Ottawa Statement is a consensus document that aims to guide the implementation of global trial registration. Endorsed by individuals and organisations throughout the international research community, the Statement recognises that public availability of information about all trials in healthcare is essential to ensuring ethical and scientific integrity in medical research.
- **b. WHO international trial search platform**
  WHO international trial search platform The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records. To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. Please note: This Search Portal is not a clinical trials registry.
- **c. ISRCTN Register - International Standard Randomized Controlled Trial Number**
  The ISRCTN Register is a register containing a basic set of data items on clinical trials that have been assigned an ISRCTN. Records are never removed from the ISRCTN Register (except in cases of duplications), which ensures that basic information about trials registered with an ISRCTN will always be available. The ISRCTN Register complies with requirements set out by the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) and the International Committee of Medical Journal Editors (ICMJE) guidelines and complies with the WHO 20-item Trial Registration Data Set.
- **d. ClinicalTrials.gov**
  ClinicalTrials.gov is a registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details.

- **e. UK Clinical Trials Gateway**
  The public access search for clinical trials provided from the UK Clinical Trials Gateway website [The NIHR's Portfolio database has been replaced by a new Central Portfolio Management System (CPMS)].
- **f. European Clinical Trials Register**
  The EU Clinical Trials Register website contains information on interventional clinical trials on medicines. The information available dates from 1 May 2004 when national medicine regulatory authorities began populating the EudraCT database, the application that is used by national medicine regulatory authorities to enter clinical trial data. The EU Clinical Trials Register website launched on 22 March 2011 enables users to search for information which has been included in the EudraCT database.
- **g. EudraCT**
  EudraCT is a database of all clinical trials commencing in the Community from 1 May 2004 onwards. It has been established in accordance with Directive 2001/20/EC.
- **h. International Committee of Medical Journal Editors (ICMJE) guidelines**
  International Committee of Medical Journal Editors (ICMJE) guidelines on clinical trials registration
- **i. International Clinical Trials Registry Platform (ICTRP)**
  The main aim of the WHO ICTRP is to facilitate the prospective registration of the WHO Trial Registration Data Set on all clinical trials, and the public accessibility of that information
- **j. IFPMA Clinical Trials Portal-Drug Company Trials**
  The International Federation of Pharmaceutical Manufacturers & Associations is a global non-profit organisation representing the pharmaceutical, biotech and vaccine manufacturing industries. The clinical trials database is world-wide so searches can return large numbers of hits. The information is also more suited to health professionals than the general public.

3. Search for Evidence

- **a. The Cochrane Library**
  Independent high-quality evidence for health care decision making
- **b. NHS Evidence**
  Evidence in Health and Social Care
- **c. Centre for Reviews and Dissemination**
  CRD is part of the National Institute for Health Research (NIHR) and is a department of the University of York. We provide research-based information about the effects of health and social care interventions via our databases and undertake systematic reviews evaluating the research evidence on health and public health questions of national and international importance. The findings of our research outputs are widely disseminated and have impacted on health care policy and practice, both in the UK and internationally.
- **d. NICE website**
  NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.

- **e. The ORRCA project**
  A database organising over a 1000 published articles on recruitment. The ORRCA project aims to help trialists discover new recruitment strategies, understand the evidence base for existing approaches and highlight areas where further research is needed. Included articles can be filtered against categories such as recruitment theme, research methods, health area, age and gender to help you find relevant research and case studies. New articles are being added to the database on a weekly basis.

4. Useful Toolkits

- **a. Clinical Trials Tool Kit**
  Guides you through the requirements when testing the safety or efficacy of a medicinal product.
- **b. Experimental Medicine Tool Kit**
  Covers a diversity of interventional studies, identifying appropriate regulatory frameworks & supporting a risk-based approach to study management
- **c. Data and Tissues Tool Kit**
  Practical guidance on the regulatory and governance requirements when using personal information and/or human tissue samples in research.
- **d. UK Stem Cell Tool Kit**
  For those who wish to develop a programme of stem cell research and manufacture. It applies only to the regulation of human stem cells and their use in the laboratory and clinical settings.
- **e. Information Governance Toolkit**
  The IG Toolkit is an online system which allows NHS organisations and partners to assess themselves against Department of Health Information Governance policies and standards. It also allows members of the public to view participating organisations' IG Toolkit assessments.
- **f. The Compliance Health check**
  Compliance Health check Consulting UK Ltd (CHCUK) specialises in providing compliance support to organisations involved in the following research areas: GCP, NIS, Dietary Supplements, Tissue Research.
- **g. Offender Health Research Network Toolkit**
  The OHRN Toolkit aims to outline a clear pathway to successfully undertake health research in the criminal justice system. The toolkit is available to download
- **h. The Global Health Research Process Map**
  The Global Health Research Process Map is an open-access online resource which aims to provide the guidance, training and support that researchers need to run their own studies, wherever they are in the world.

5. Find Summaries of Product Characteristics and PILs of UK licensed medicines

- **a. electronic Medicines Compendium (eMC)**
  The electronic Medicines Compendium (eMC) contains information about UK licensed medicines.

6. The Medicines for Human Use (Clinical Trials) Regulations 2004 and Amended Regulations 2006 and Amendment (2) 2006

- **a. The Medicines for Human Use (Clinical Trials) Regulations 2004**
  The Medicines for Human Use (Clinical Trials) Regulations 2004
- **b. MHRA Forum: Good Clinical Practice (GCP)**
  The GCP forum has been created as a tool to help those involved in clinical trials of Investigational Medicinal Products to comply with the clinical trials legislation and GCP requirements. It provides the ideal opportunity for extended communication between researchers and allows users to put forward their comments and get “real-life” examples of ways in which they can manage robust quality procedures that ensure compliance and which dovetail with their own business needs and resources. This forum should not be used for direct questions to the GCP Inspectorate/Clinical Trials Unit, reporting serious breaches or making formal complaints. These should follow the formal routes that are already in place. Please read the Good Clinical Practice (GCP) Forum introduction and rules before posting on this forum.
- **c. Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products**
  MHRA risk-adapted approaches guidance: Additional resources now available Following the guidance on risk-adapted approaches to the management of clinical trials of investigational products, which launched in 2011, the Medicines and Healthcare products Regulatory Agency (MHRA) has now developed further resources to support this activity. These additional resources include illustrative examples of risk adaptive approaches, as well as a series of FAQs designed to help clinicians and researchers better understand the process and requirements. This guidance and resources now form part of the MHRA Good Clinical Practice (GCP) Forum and can be accessed here.
- **d. The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010**
  The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010
- **e. The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006**
  The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006
- **f. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006**
  The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- **g. UK Department of Health. Good Clinical Practice for clinical trials**
  UK Department of Health. Good Clinical Practice for clinical trials

7. EU Clinical Trial Legislation and Guidelines including Clinical Trials Guidelines and ICH GCP Guidelines (E6)

- **a. EudraLex - Volume 10 Clinical trials guidelines**
  Volume 10 of the publications "The rules governing medicinal products in the European Union" contains guidance documents applying to clinical trials.

- **b. EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines.**
  Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.
- **c. ICH GCP (E6) Guidelines**
  A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected. Ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve participation of human subjects to ensure that the RIGHTS, SAFETY and WELLBEING of the trial subjects are protected. Ensure the CREDIBILITY of clinical trial data.
- **d. ICH Harmonised Tripartite Efficacy Guidelines**
  The work carried out by ICH under the Efficacy heading is concerned with the design, conduct, safety and reporting of clinical trials. It also covers novel types of medicines derived from biotechnological processes and the use of pharmacogenetics/ pharmacogenomics techniques to produce better targeted medicines.
- **e. Information on clinical trials in the EU**
  More information on clinical trials in the EU
- **f. Pharmaceutical Legislation Medicinal Products for Human Use**
  Volume 1 of the publications "The rules governing medicinal products in the European Union" compiles the body of European Union legislation in the pharmaceutical sector for medicinal products for human use.

8. Clinical trials on medical devices for human use in the UK

- **a. The Medical Devices Regulations 2002**
  The Medical Devices Regulations 2002

9. Consumer involvement in clinical trials

- **a. Healthtalkonline**
  Healthtalkonline is the award-winning website of the DIPEx charity and replaces the website formerly at dipex.org. Healthtalkonline lets you share in other people's experiences of health and illness. You can watch or listen to videos of the interviews, read about people's experiences and find reliable information about conditions, treatment choices and support. The information on Healthtalkonline is based on qualitative research into patient experiences, led by experts at the University of Oxford. These personal stories of health and illness will enable patients, families and healthcare professionals to benefit from the experiences of others.
- **b. INVOLVE**
  INVOLVE is a national advisory group which supports greater public involvement in NHS, public health and social care research

- **c. People in Research**
  People in Research is a UK Clinical Research Collaboration project that has been led by one of its Partner organisations, INVOLVE. Its purpose is to help members of the public contact organisations that want to actively involve them in clinical research. For example, this could be by helping to decide what gets researched or possibly helping to carry out part of the research.
- **d. TwoCan Associates**
  TwoCan Associates help voluntary and statutory organisations to involve service users, patients, carers and the public in their work.

10. Funding opportunities

- **a. National Institute for Health Research**
  The goal of the National Institute for Health Research (NIHR) is to create a health research system in which the NHS supports outstanding individuals, working in world class facilities, conducting leading edge research focused on the needs of patients and the public.
- **b. NIHR Evaluation, Trials and Studies Coordinating Centre**
  NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) is home to a growing number of research programmes and is part of the National Institute for Health Research (NIHR). It is based at the University of Southampton Science Park and was established in April 2008.
- **c. Medical Research Council**
  Medical Research Council
- **d. RDFunding**
  RDFunding, a digest of health-related research funding opportunities, provides access to relevant information on funding opportunities in the field of health research. The information held is wide-ranging and covers a variety of research interests, types of awards and timescales, spanning the whole healthcare spectrum.
- **e. EU Funding Opportunities**
  European Union funding opportunities page
- **f. European Research Council**
  European Research Council

11. Associations

- **a. Society for Clinical Trials (SCT)**
  The Society for Clinical Trials is a group with representatives from Government, Academia, Industry, For-profit and Non-profit sectors.
- **b. Association of Clinical Research Professionals**
  Association of Clinical Research Professionals
- **c. Association of the British Pharmaceutical Industry**
  Association of the British Pharmaceutical Industry

- **d. The Association of Medical Research Charities**
  The Association of Medical Research Charities (AMRC) is a membership organisation of the leading medical and health research charities in the UK.
- **e. World Medical Association**
  The World Medical Association (WMA) is an international organization representing physicians.

12. Clinical Trials Insurance

- **a. JLT [Insurance Provider]**
  Life Science section
- **b. Research in the NHS: Indemnity arrangements**
  Research in the NHS: Indemnity arrangements

13. Data Protection

- **a. HSCIC Information Governance**
  HSCIC offers guidance on looking after information well according to the principles of good Information Governance (IG). This guidance is designed to help health and care organisations meet the standards required to handle care information.
- **b. Data Protection Act 1998**
  Data Protection Act 1998
- **c. ICO Guide to data protection**
  This guide is for those who have day-to-day responsibility for data protection. It explains the purpose and effect of each principle, gives practical examples and answers frequently asked questions.
- **d. Patient confidentiality and Access to Health Records**
  Department of Health Guidance: Patient confidentiality and Access to Health Records
- **e. Research involving the NHS - Retention of Records**
  Department of Health Guidance: Research involving the NHS - Retention of Records
- **f. The Information Commissioner's Office website**
  The Information Commissioner's Office is the UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

14. European Forum for Good Clinical Practice

- **a. European forum for GCP**
  The European Forum for Good Clinical Practice (EFGCP) is a non-profit organisation established by and for individuals with a professional involvement in the conduct of biomedical research. Its purpose is to promote good clinical practice and encourage the practice of common, high-quality standards in all stages of biomedical research throughout Europe. The website has a comprehensive library of relevant documents that you may find useful.

- **b. Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe**
  EFGCP Report on The Procedure for the Ethical Review of Protocols for Clinical Research Projects in Europe and Beyond

15. European Regulatory Agencies

- **a. European Medicines Agency**
  The European Medicines Agency is a decentralised agency of the European Union, located in London. The Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union.

16. GCP Resources and Quality Tools

- **a. NIHR GCP Resources Document and GCP Quality Tools**
  A compilation of links to useful on-line GCP resources and Quality Tools.

17. Glossary of Clinical Trials Terms

- **a. ClinicalTrials.gov Glossary**
  Glossary of Clinical Trials Terms

18. International Collaboration

- **a. European Clinical Research Infrastructures Network (ECRIN)**
  The European Clinical Research Infrastructures Network (ECRIN) is a sustainable, not-for-profit infrastructure supporting multinational clinical research projects in Europe.
- **b. Irish Clinical Research Infrastructure Network**
  The MMI partners created the Irish Clinical Research Infrastructure Network (ICRIN) to engage with the constituent teaching hospitals to develop a national clinical research infrastructure, to harmonise clinical research processes, to connect with European networks, to develop education and training programmes and to support investigators conduct multi-centre clinical studies.
- **c. KKS Network (Germany)**
  The network offers a wide range of scientific services on a regional and national basis to scientists in universities, hospitals and industry. Initiated by the Federal Ministry for Education and Research (BMBF), the KKS Network [KKSN - Network of the Coordinating Centres for Clinical Trials] is a platform for transparent, patient-oriented development of new drugs and therapeutic principles in Germany.
- **d. Swiss CTU-Network**
  Switzerland has six clinical research centres, known as Clinical Trial Units (CTUs), that are supported by the Swiss National Science Foundation (SNSF).
- **e. The UK Research Office**
  The UK Research Office

- **f. The Global Health Network**
  The Global Health Network is a hub joining together a collection of websites to support research by sharing knowledge and methods. Each has been established to create a subject specific online community of researchers who can build collaborations, develop documents, share resources and exchange information.

19. Medical Research Involving Children

- **a. Medical research involving children**
  NIHR Medical research involving children
- **b. The European paediatric legislation**
  Debate: The European paediatric legislation: benefits and perspectives

20. NIHR and Devolved Nations Clinical Research Infrastructure

- **a. NIHR Clinical Research Network Coordinating Centre**
  NIHR Clinical Research Network Coordinating Centre
- **b. NIHR Research Design Service**
  The NIHR Research Design Service (RDS) supports researchers to develop and design high quality research proposals for submission to NIHR and other national, peer-reviewed funding competitions for applied health or social care research.
- **c. NIHR Clinical Research Network Portfolio**
  NIHR Clinical Research Network Portfolio
- **d. MRC Network of Hubs for Trials Methodology Research**
  The HTMR Network aims to promote and encourage collaborative methodological research relevant to trials and to enable implementation of the most effective and appropriate methods to improve the quality of trials and, ultimately, patient care.
- **e. Health and Social Care Information Centre**
  Health and Social Care Information Centre (HSCIC)

21. Open access electronic journals

- **a. Applied Clinical Trials**
  See the latest Applied Clinical Trials digital edition!
- **b. British Medical Journal**
  BMJ is a partially open-access peer-reviewed medical journal
- **d. The Qualitative Report**
  An online bi-monthly journal dedicated to qualitative research since 1990
- **e. Trials Journal**
  Trials is an open access, peer-reviewed, online journal that encompasses all aspects of the performance and findings of randomized controlled trials.

22. Patient Safety

- **a. National Patient Safety Agency**
  The National Patient Safety Agency leads and contributes to improved, safe patient care by informing, supporting and influencing the health sector.
- **b. NIHR Patient Safety & Service Quality Research Centres**
  The NIHR Patient Safety & Service Quality (PSSQ) Research Centres drive improvements in the safety, quality and effectiveness of the services the NHS provides to its patients and the public. The PSSQ Research Centres bring together NHS professionals with academic experts from a wide range of backgrounds, including management and the social sciences, to focus on investigating ways to improve the care of patients.

23. Personal Information in Medical Research

- **a. MRC Personal Information in Medical Research**
  Personal Information in Medical Research

24. Regulatory Affairs Database

- **a. Regulatory Affairs Database**
  The TREAT-NMD Regulatory Affairs Database is a valuable source of advice to people who are involved in the planning of mono- or multi-centre clinical trials within different European countries. The current version contains the contact addresses of national authorities as well as national legislation and documents from 13 European countries. Additionally, European regulations and other important international documents and guidelines are provided (e.g. from ICH and EMEA). The database is open for public use and can be accessed online, a login/username is not required

25. R&D Permissions

- **a. NIHR Coordinated System for gaining NHS Permission**
  Information on the NIHR Coordinated System for gaining NHS Permission with all relevant publications (i.e. Operation Guideline and Manual etc.) available for download via the Publication box on the right

26. Research governance framework for health and social care

- **a. Research governance framework for health and social care: Second edition**
  The Research Governance Framework for Health and Social Care (RGFHSC) sets out the broad principle of good research governance.
- **b. Research Governance Frameworks for Scotland, Wales and Northern Ireland**
  Here you can download the Research Governance Frameworks for Scotland, Wales and Northern Ireland

27. Research Involving Adults Lacking Capacity

- **a. MRC Ethics Guide: Medical research involving adults who cannot consent**
  MRC Ethics Guide: Medical research involving adults who cannot consent
- **b. MRC ethics guide: Medical research involving children**
  MRC ethics guide: Medical research involving children

28. Research Methods

- **a. Research Methods Knowledge Base**
  The Research Methods Knowledge Base is a comprehensive web-based textbook that addresses all of the topics in a typical introductory undergraduate or graduate course in social research methods. It covers the entire research process including formulating research questions; sampling (probability and nonprobability); measurement (surveys, scaling, qualitative, unobtrusive); research design (experimental and quasi-experimental); data analysis; and, writing the research paper. It also addresses the major theoretical and philosophical underpinnings of research including: the idea of validity in research; reliability of measures; and ethics.

29. Safety reporting

- **a. MHRA electronic reporting site for SUSARs**
  This site can be used to report Suspected Unexpected Serious Adverse Reactions (SUSARs) that have occurred during a Clinical Trial of a medicinal product.
- **b. Safety reporting - SUSARs and ASRs-MHRA webpages**
  Safety reporting - SUSARs and ASRs

30. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines

- **a. ICH Guidelines**
  ICH Guidelines

31. UK Clinical Ethics

- **a. National Research Ethics Service**
  National Research Ethics Service
- **b. WMA Declaration of Helsinki**
  WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

32. UK Regulatory Agencies

- **a. Medicines and Healthcare products Regulatory Agency (MHRA)**
  The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. The MHRA is an executive agency of the Department of Health.

- **b. The Human Tissue Authority**
  The Human Tissue Authority (HTA) is a watchdog that supports public confidence by licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. They also give approval for organ and bone marrow donations from living people

33. UKCRC Registered CTUs Network

- **a. Resource finder**
  This site offers a resource for clinical researchers and funders wishing to identify Clinical Trials Units (CTUs) that have expertise in centrally coordinating multicentre clinical trials, as well as in trial design, data management, and analysis. It provides comprehensive information and direct access to high quality CTUs across the UK which have achieved UKCRC Registration status.