Line managers and Principal Investigators are to ensure that they and their staff who work on research studies have the necessary expertise and experience in order to conduct them in a safe, ethical, and high quality manner. This is in addition to the credentialing requirements. It is the responsibility of the line managers and staff to each keep a written copy of the training records, which needs to be made available upon request by Research Development and Governance Unit (RDGU).

| **Name:** | <insert> |
| --- | --- |
| **Key Role in Research at Epworth:** | Principal Investigator / Sub-Investigator / Research Nurse / Study Coordinator / Trial Manager / Clinical Trials Assistant <delete not applicable> |
| **Type of Research involved in:** | Clinical Trial (CTN) / Clinical Trials (non-CTN) / non-Clinical trials <delete not applicable> |

**Getting Started**

Researchers must be aware of and familiar with the following sites, and acknowledge that they have bookmarked the following:

|  |  |  |
| --- | --- | --- |
| **Site** | **Link** | **Tick when bookmarked** |
| **Research Roadmap at the Knowledge service**   * Overview and Guidance of conducting research at Epworth | <https://epworth.libguides.com/eksresearchroadmap> |  |
| **Epworth Resource for Researchers**   * Contains Epworth Research Handbook, Research Policy, Quality Management System (QMS) protocol, Standard Operating Procedures (SOP), forms and templates | <https://www.epworth.org.au/working-with-us/research/resources-for-researchers> |  |
| **National Health and Medical Research Council (NHMRC) Research Policy**   * Contains National Guidelines of Research Conduct. | <https://www.nhmrc.gov.au/research-policy/research-integrity> |  |
| **International Conference on Harmonisation Good Clinical Practice (ICH-GCP)** | <https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice> |  |
| **National Statement on Ethical Conduct in Human Research (National Statement)** | <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018> |  |
| **National Clinical Trials Governance Framework (NCTGF)** | <https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework> |  |

**Compulsory training (role-dependent):**

The following outlines required training for researchers according to their roles, with the timeline indicated as ‘weeks since role commenced’\*. If training is not applicable or required, researchers must provide explanation for the exemption approved by the line manager. To assist with monitoring the deadlines, it is highly recommended for researchers and line managers to set a reminder of timelines on their calendars.

| **Training material** | **Target staff** | **Training method**  **(read/e-learning/face-to-face)** | **Resource** | **Weeks since role commenced\*** | **Date Complete** | **If not completed, please explain or provide comments\*\*** |
| --- | --- | --- | --- | --- | --- | --- |
| Australian Code for the Responsible Conduct of Research | All researchers | Read | <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018> | 1 |  |  |
| Good Clinical Practice (to be renewed every 3 years) | All researchers | Either face-to-face training, or online | Face-to-face: Please contact RDGU.  Online: <https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice/> | 1 |  |  |
| Introduction to clinical trials (ACTEC) | Clinical trial research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=26> | 2 |  |  |
| Running Clinical trials from start to finish (ACTEC) | * Clinical trial Investigators * Clinical research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=27> | 2 |  |  |
| The regulatory environment of clinical trials  (ACTEC) | Clinical trial research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=28> | 3 |  |  |
| Ethics and governance application process (ACTEC) | Clinical trial research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=29> | 3 |  |  |
| Trial Regulatory Requirements in Australia (ACTEC) | Clinical trial Investigators | Online | <https://actec.myopenlms.net/course/view.php?id=34> | 3 |  |  |
| Meet with RDGU for overview of Epworth Research Governance | All researchers (Highly recommended) | Face-to-face or teleconference | Email: research@epworth.org.au | 4 |  |  |
| Epworth SOP Training | All researchers | Read | For CTN-Clinical trial investigators and support staff: Create account in SiteDocs Portal and read the SOPs assigned  For all other investigators and research support staff, go to “**Master Training Curricula**” tab found in <https://www.epworth.org.au/working-with-us/research/resources-for-researchers>  A training log (Appendix A) must be maintained and made available on request. | 4 |  |  |
| Trial Feasibility and Start-up Process | Clinical trial Investigators | Online | <https://actec.myopenlms.net/course/view.php?id=35> | 5 |  |  |
| Safety reporting in clinical trials (ACTEC) | Clinical trial research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=30> | 6 |  |  |
| Safety Monitoring and Reporting in Trials  (ACTEC) | Clinical trial Investigators | Online | <https://actec.myopenlms.net/course/view.php?id=36> | 6 |  |  |
| Protocol Compliance & Serious breaches (ACTEC) | * Clinical trial Investigators * Clinical research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=37> | 7 |  |  |
| PI Oversight and Trial Management (ACTEC) | Clinical trial Principal Investigators | Online | <https://actec.myopenlms.net/course/view.php?id=38> | 7 |  |  |
| Monitoring and Auditing Clinical Trials | Clinical research support staff | Online | <https://actec.myopenlms.net/course/view.php?id=31> | 9 |  |  |
| Safe Transport of Infectious Substances by Air Course (to be renewed every 2 years) | Researchers involved in laboratory work | Online | <https://www.caaa.com.au/safe-transport-of-infectious-substances/> and contact RDGU for payment arrangement | 12 |  |  |
| Local Laboratory Induction | Researchers involved in laboratory work | Online and Face-to-face | Contact Laboratory Manager, Hayley Johnston (ER-MOCI@epworthorg.au), (03)95162381 | 12 |  |  |
| Data Privacy (by OAIC) | All researchers | Online | **[https://education.oaic.gov.au/elearning/privacy-in-practice/welcome.html#top](https://education.oaic.gov.au/elearning/privacy-in-practice/welcome.html" \l "top)** | 14 |  |  |
| Chapter 3 of NHMRC Management of Data and Information in Research | All researchers | Read | <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf> | 14 |  |  |
| Chapter 9 of OAIC Guide to Health Privacy | All researchers | Read | <https://www.oaic.gov.au/privacy/privacy-guidance-for-organisations-and-government-agencies/health-service-providers/guide-to-health-privacy> | 14 |  |  |
| De-identifying data | All researchers | Read | <https://ardc.edu.au/resource/identifiable-data/> | 14 |  |  |

\*This is based on the number of weeks for a full-time staff after first research project commenced/staff on-boarded. Please adjust accordingly for part-time staff.

\*\*If training is not applicable to your role, please put ‘N/A’. If a different deadline was agreed upon between you and your managers, please include that as a reason for it in this column too.

|  |  |
| --- | --- |
| **I hereby confirm that the above training record is correct:** | |
| **Signature:** | **Date:** |
| **Print Name:** |  |

**Once you have completed this log, please send it to your line manager and save a copy. This must be available upon request by RDGU.**

**Appendix A: SOP training log**

| **Document ID** | **Document Name (including version and date)** | **Training Method**  (Read / Face-to face) | **Date of Training**  (dd/mmm/yyyy) | **Signature** |
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