# Clinical Data Research Hub

Welcome to the Clinical Data Research Hub (CDRH), a coordinating centre for clinical research, hosted by the Liggins Institute and supporting the ON TRACK Network. In collaboration with the Department of Obstetrics and Gynecology, and Department of Paediatrics: Child and Youth Health, University of Auckland.

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Randomisation and databases: www.ligginstrials.org

## CDRH Guides
- Planning a Trial
- Clinical Trial Terminology
- Study Protocol
- Ethics
- Trial Committees
- Authorship
- Data Sharing
- Mori Responsiveness
- Standard Operating Procedures

## Randomisation
- CDRH Randomisation Site
- CDRH Study Numbers
- Randomisation Plans

## Data Management
- REDCap FMHS
- REDCap Liggins
- REDCap Resources
- Variable Naming Convention
- Study Reports

## Analysis
- Normal Distribution Calculator
- OpenEpi - Open Source Statistics
- Medcalc Calculators
- SAS Guides
- NZDep2013 Index of Deprivation
- Trial Analysis
- Data Cleaning
- Diagnostic Tests

## Follow-up
- Bayley Scales Age Calculator
- LifePath Follow-up SharePoint
- NZ Travel Calculator
- Definitions for Follow-up Studies

## CDRH Admin
- Redmine
- CDRH SharePoint (runs best in IE)
- Liggins VPN Access
- University of Auckland Staff Intranet

## Consensus Statements and Checklists
- Equator Network
- INQUIRE Framework for Evaluating Research Quality

## Protocols
- SPIRIT 2013 Statement
- SPIRIT 2013 Explanation and Elaboration

## Outcomes
- COMET - Core Outcome Measures in Effectiveness Trials
- COS - Prevention of Preterm Birth
- Neonatal Infection Case Definition (Brighton Collaboration)

## Reporting
- CONSORT 2010 - Reporting Parallel Group RCTs
- CONSORT 2010 - Extension to Cluster RCTs
- CONSORT 2010 - Extension to Noninferiority / Equivalence RCTs
- StIRONG Checklist - Reporting of Neonatal Nutrition and Growth
- STROBE Statement - Reporting Observational Studies
- STROBE Statement - Explanation & Elaboration
- STARD 2015 - Diagnostic Accuracy Studies
- TIDieR Checklist - Reporting of Interventions
- Very Preterm Birth Studies (Pediatrics 2016)

## Analysis
- Guidelines for the Content of Statistical Analysis Plans (JAMA 2017)

## Data & Safety Monitoring
- DAMOCLES - Charter for Clinical Trial Data Monitoring Committees
- ERGIN 2011 - Standards Requirements for GCP-Compliant

## Laboratory
- Liggins Institute Analytical Capabilities

## Training
- NIH Protecting Human Subjects certificate
- NIH GCP course
- ROCHE GCP course (runs best in Firefox)
- Cultural Competency
- Infection control
- Definition of Research and Audit
- Classification of Observational Studies
- Introductory Online Statistics Course

## Key Links
### ANZ
- Australia & New Zealand Clinical Trials Register (ANZCTR)
- Health and Disability Ethics Committees NZ (HDEC)
- Health Research Council NZ (HRC)
- IMPACT Clinical Trials Network
- MedSafe NZ
- Neonatal Unit Contacts NZ
- Online Forms NZ (HDEC / SCOTT)
- DHB Research Contacts
- Therapeutic Goods Agency (TGA) Australia
- Kidz First Neonatal Research
- Cure Kids Portal
- Ministry of Health NZ
- ACC Act 2001: Clinical Trials

### International
- Cochrane Neonatal
- Cochrane Pregnancy
- Cochrane Childhealth
- Global Obstetrics Network (GoNET)
- ICH GCP
- NIH Clinical Research Toolkit
- Trial Forge UK
- Trial Managers Network
• Space statistics
• LiFePATH Admin
• CDRH Randomisation Demo (code: 991000tst)
• CDRH Data Environment

Data Management in Multinational Clinical Trials
• NAESS 2019 - Neonatal Adverse Event Severity Scale (INC)

Synthesis & Translation

• PRISMA-P 2015 - Preferred Reporting for Systematic Review and Meta-analysis Protocols
• PRISMA 2009 - Preferred Reporting Items for Systematic Reviews and Meta-analyses
• PRISMA-IPD 2015 - Preferred Reporting Items for a Systematic Review and Meta-analysis of Individual Participant Data
• PRISMA Extension 2015 - Network Meta-analyses
• PRISMA-C Extension 2016 - Systematic Reviews and Meta-analyses of Newborn and Child Health Research
• PRISMA-DTA - Preferred Reporting Items for a Systematic Review and Meta-analysis of Diagnostic Test Accuracy Studies
• MOOSE - Reporting of Meta-analysis of Observational Studies in Epidemiology
• GRADE - Grading Quality of Evidence and Strength of Recommendations
• GRADE - Non-Randomised Studies
• AGREE II - Assessing Quality and Reporting of Practice Guidelines
• PROSPERO Registration of Systematic Reviews - Checklist
• ROBINS-I - Risk of Bias In Non-randomized Studies of Interventions
• Risk of Bias Tool for Observational Studies
• Meta-analysis of Animal Studies
• Median to Mean Calculator
• Cochrane Handbook 2019
• WHO Guideline to Rapid Reviews