BEING AUDIT READY
TIPS FROM REG!

May 2017
What is a research audit?

A **systematic and independent** examination of research related activities, and documents, to determine whether the following were conducted according to the protocol, GCP and applicable regulatory requirements:

- Research study related activities
- Study documentation and data management

*Ref: ICH-GCP- Section 1.6*
Auditing vs Monitoring

**Auditing**

- Snapshot in time of compliance
- Systematic independent
- By Sponsors or RGO

**Monitoring**

- On-going routine assessment
- Not independent
- By Sponsors or research teams

*Inspection:*
Audits conducted by Regulatory Agencies (TGA, FDA, EMA)
Why do we audit research projects?

• A requirement of the National Statement (2007) and Good Clinical Practice (GCP) Guidelines
• To ensure research quality and manage risk by
  o ensuring research is conducted in line with legislative, ethical and organisational requirements
  o allowing an opportunity for the early detection and correction of non-conformances, thereby preventing breaches and/or other significant events from occurring.
  o ensuring data integrity is not compromised
• To raise researchers’ awareness and promote their accountability

We aim to protect study participants, the research team and the institution
Why do you need to comply?

• Organisational requirement
• Researcher responsibilities: Australian Code of Conduct of Responsible Research
• Promote quality and validity of study data
• Obtain reliable, auditable and acceptable results
• Enhance research team accountability and scientific reputation
• Ensure safety and efficacy (for drug/device trials)
# How do we select projects for audit?

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| - Risk-based  
- Random selection  
- HREC (or REG Director request) | - Based on suspicions of non-compliance, or  
- Complaints or serious incidents |
| - Study-oriented audit | - Investigator-oriented Audit |
| - Review compliance, with conditions of ethics approval, and ongoing documentation management | - Verify the complaint, or reassure no problems exist |

**When to expect an audit visit?**
- any time during the conduct of the research project

**Follow-up Audits:**
- may occur depending on the initial audit outcomes
What does the RCH audit process involve?

Pre-Audit
• Initial email notification sent (4 weeks prior)
• Confirmation of audit date/time/location with PI
• Detailed e-mail with preparation requirements (study documentation, database access, space, etc.)

Audit Day
• 2-4 hours
• Opening interview with PI and other team members, as applicable
• Documentation and facilities audit
• Closing interview

Post-audit
• Draft written report sent to PI detailing findings and recommendations
• PI has 2-4 weeks to respond and make any required changes
• Finalised report presented to PI, HREC and REG Director
What we check

- Study Administration & Management
- Study Conduct & Ethics compliance
- Study Documentation
- Study Participants and Informed Consents
- Data Management and Storage
Our References

Legislation and Guidelines

- NHMRC National Statement for Ethical Conduct in Human Research
- Good Clinical Practice (GCP) (with TGA annotations)
- Australian Code for the Responsible Conduct of Research
- Human Tissue Act (Vic) (1982)
- NHMRC Guidelines Approved under Section 95A of the Privacy Act 1988
- Victorian Health Privacy Principles (extracted from Health Records Act 2001)

Campus Policies & Procedures

- RCH Investigator’s Responsibilities in Research
- RCH Informed Consent in Research
- RCH Research: Tissue – collection use & storage for research
- Managing Essential Documents for Clinical Research Procedure

These documents can be viewed on the ‘Researcher resources’ page of the REG website
Main Findings over the past 2 years

| Study Administration & Management | • Inadequate PI oversight  
|                                  | • No evidence of research team communications  
|                                  | • Absence or incomplete delegation/training logs  
|                                  | • No evidence of maintained funding |

| Study Conduct | • Violations from approved protocol  
|              | • Modifications in the processes or documents not approved by HREC  
|              | • Failure of safety reporting to HREC  
|              | • Changing in study investigators not reported to HREC  
|              | • Absence of follow-up with HREC request of interim results  
|              | • Non compliance with monitoring plans listed in protocol (e.g. DSMB not established...) |
## Main Findings (continued)

| Study Documentation                  | • Study binder missing essential documents  
|                                    | • HREC approval letters and correspondence not retained  
|                                    | • Superseded versions not filed  |
| Study Participants and Informed consents | • Non compliance with eligibility criteria  
|                                    | • Missing or incomplete consent forms  
|                                    | • No enrollment /screening logs  |
| Data/Sample Management & Storage    | • Errors/omissions in data collection forms  
|                                    | • Absence of governance procedure that address sample collection, storage, retention periods, use and disposal  |
Levels of findings

**Critical**
- Significantly affect participants safety, rights or data validity
  - For example:
    - deficiency in safety monitoring
    - unreported SAEs
    - undetected protocol violation

**Major**
- Significant shortcomings in the project/procedures
  - For example:
    - repeated inconsistencies
    - isolated cases of non-compliances with protocol, SOPs and/or guidelines

**Minor**
- Isolated non-conformance
  - Random/non serious
  - For example:
    - non-compliance with CRF processing
    - Inaccurate filing
# Be Audit Ready from Day 1

## Study Management
- PI has total oversight and access to all study documents and databases
- Use the CRDO study binder/file template to store essential documents (electronic or hard copies)
- Training & Delegation logs complete and updated
- Keep record of team meetings, study funding and agreements

## Ethics & Governance
- Diarise ethics reporting dates
- Maintain all correspondence and approval certificates
- Submit any changes to the protocol, documents, or agreements
## Be Audit Ready From Day 1

### Participant Information & Consent Forms
- Obtain signed consent forms for all enrolled participants
- Keep record of information sheet version provided to each participant
- Restrict access to the current approved documents
- Document any corrections/omissions using file notes

### Data Integrity and Privacy
- Hard copies stored securely in locked cabinets
- All computer stored files are password protected and regularly backed-up
- Ensure trackable software for database use
- The code-key of identified data is stored separately at all times with access controlled
- Document any corrections/omissions using file notes
Always think of

- Training
- Protocol
- Communications
- Storage/Security
- Patient Privacy
- REG

PI Oversight
More Hints and Tips

• “If it’s not documented, it didn’t happen”

• Mistakes, omissions and corrections are expected - Document to ensure transparency and accountability.

• **Self-Monitoring:** Perform regular documentation/compliance checks

• Undertake regular protocol training as a team – ensure any new staff are trained.

• Attend **CRDO workshops** and check their resources

• Check **REG website** for news, trainings, updates and resources

*Document, document, document…..*  
*If Unsure, ask for guidance*
**Always Remember:**

**The 12 Golden Rules of Good Clinical Practice**

1. Obtain ethical approval & governance authorisation
2. Know & follow your protocol
3. Select, train & log study personnel
4. Ensure participant consent is fully informed
5. Ensure quality data
6. Ensure study equipment is appropriate
7. Document drug/device accountability (for clinical trials)
8. Ensure quality of lab evaluations (where applicable)
9. Timely safety assessment & reporting (where applicable)
10. Predict and monitor recruitment
11. Maintain comprehensive files & archives
12. Keep everyone fully informed

*From “The 12 Golden Rules of Good Clinical Practice” by David Hutchison*
## We are here to help

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<tr>
<th>REG Team</th>
<th>CRDO Team</th>
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<tr>
<td><a href="mailto:rch.ethics@rch.org.au">rch.ethics@rch.org.au</a></td>
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