7TH ANNUAL NHMRC SYMPOSIUM ON RESEARCH TRANSLATION

ENSURING VALUE IN RESEARCH

"Is cumbersome governance killing research"

Dr Antonio Penna

Executive Director
Office for Health and Medical Research

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NSW GOVERNMENT

- **“Is cumbersome governance killing research”**

Definition – Research Governance

Research governance is the system of administration and supervision through which research is managed, participants and staff are protected, and accountability is assured. Governance is not the remit of any single institution

Shaw et al, J R Soc Med 2005;98:496-502

Yes – Research Governance needs to improve ++++

- Many publications over the past 2 decades highlighting the negative impact on research of poor research governance practices and processes, causing;
  - Increasing costs
  - Delays in commencing research
  - Tainted Reputation
  - Impact on conduct of research study – particularly multi-site studies – jeopardising integrity of study

  - Issues
    - Inconsistencies – in interpretation
    - Duplication
    - Un-necessary time consuming tasks
    - Different IT systems
    - Lack of standardisation
    - Inadequate information on differences in jurisdictional regulations etc

Research Governance

- Acknowledge that the Health System is complex –and there is increasing complexity if you include all the other players in the health and medical research arena – universities, medical research institutes, NGOs
- Over the past decade there has been a significant increase in funding for medical research and a big focus on health systems research, clinical research (translational research) and implementation science.
- Research is truly becoming embedded in the Health System
- Research Governance has appeared on the scene in a less than organised way – and it is a very necessary bureaucracy and management requirement – but it need not be burdensome
- There are initiatives both at National and Jurisdictional levels trying to address this ‘burden”

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Research Governance initiatives – National

- National Aggregate Statistics
- Roles and Responsibilities document
- Clinical Trials Governance Framework – Australian Commission on Quality and Safety in the Health System
- Single Site Specific Assessment/Authorisation form
- Non disclosure agreements between sponsors and sites
- National Clinical Trials Front Door Concept
- National Mutual Acceptance

Research Governance – NSW Initiatives

- Local Health District Chief Executive Performance Agreement – Research (Clinical Trials)KPIs
- REGIS – Research Ethics Governance Information System
- Research Governance Framework (including clinical trials) in NSW Public Health Organisations (Oct 2018)
- NSW OHMR Guidelines for Low and Negligible Risk (LNR) Research Review Processes or Exemption from Ethics Review (Sept 2018)
- Early Phase Clinical Trials Framework
- Guidelines for good clinical trials management
- OHMR Clinical Trials Support Unit
- Clinical Trials Budgeting Tool
- Alignment of Indemnity insurance with rest of Australia/World!!
- Restricted Assets initiative to allow for budget roll over across financial years
- Ethical review of Quality Improvement projects
- Tele-Trials steering committee
- Permission to Contact Initiative

Research Governance Framework (Inc Clinical Trials)

- **PURPOSE**

- The purpose of this document is to bring together general principles of good practice management and conduct of health and medical research to guide the development of systems and processes within NSW Public Health Organisations (PHOs).

- **KEY PRINCIPLES**

- PHOs are expected to develop an effective research governance framework that:

- Fosters a research culture that is quality driven (see sections 5 and 7)
- Ensures researchers find it straightforward to do high-quality, ethical research
- Applies governance requirements in a way that is proportionate to the potential benefits and harms of the research (see section 4 and attachment 2)
- Enables all checks and approvals to be undertaken without duplication or unnecessary delay (See section 6)
- Expects value for money when public funds and resources are used for research
- Facilitates patient-centred research through involvement of consumers in the research process (see Attachment 2)
- Clarifies the roles and responsibilities of all stakeholders (see sections 3 and 7, and Attachment 3),

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Research Governance Framework - Content

- Background – including definitions
- Components of an Effective Research Governance Framework
- PHOs as Research Sites and Research Sponsors
- Assessment of Institutional Risk
- Development of Overarching Quality Systems for Clinical Trials
- NSW PHOs as Clinical Trial Sites
- PHOs as Clinical Trial Sponsors
  - Determining whether a PHO is the sponsor
  - The sponsor assessment process
  - Allocation or delegation of sponsor functions
  - Sponsor oversight of delegated functions

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Research Governance Framework – Content (cont)

- List of Attachments
  - Key Attributes of a Research Governance Framework
  - Overview of Public Health Organisations Clinical Trial Responsibilities
  - Competencies of the Research Support Office
  - Questions to Ask as a PHO – Sponsor
  - Clinical Trial Sponsor Governance Checks
  - Sponsor Considerations: Examples of Clinical Trial Management Activites

Key Attributes of a Research Governance Framework

Attachment 3: Competencies of the Research Support Office

- These competencies are designed to highlight what a research support team needs to know, understand and be able to do, in order to provide an effective service for health research in their institution.
- **How to use the competencies**
-
- These competencies recognise the diversity of roles of the research office within and between institutions and can be adapted to suit individual requirements. Each competency has three levels to reflect a range of abilities from a new or inexperienced team member to a proactive leader of activity. The skills under each level are cumulative. The expectation is that Columns A, B and C would represent the competencies that will enable staff within an institution to effectively support the successful delivery of both externally and internally sponsored trials.

Attachment 3: Competencies of the Research Support Office

The competencies are an aid to identifying and developing skills, but do not dictate specific roles. It is for managers and team members to decide how they are used and to what level. This document provides a foundation for:

- Clarifying those activities for which an institution is accountable to provide a more consistent approach to managing research studies
- Developing common job descriptions
- Assessing current skill levels
- Working towards new skills and objectives
- Determining who should focus on specific competencies within the organisation
- Staff appraisal, performance review and personal development

The ultimate goal is to inform the development of an organisation's governance structure, which may extend beyond the traditional role of a Research Governance Officer. .

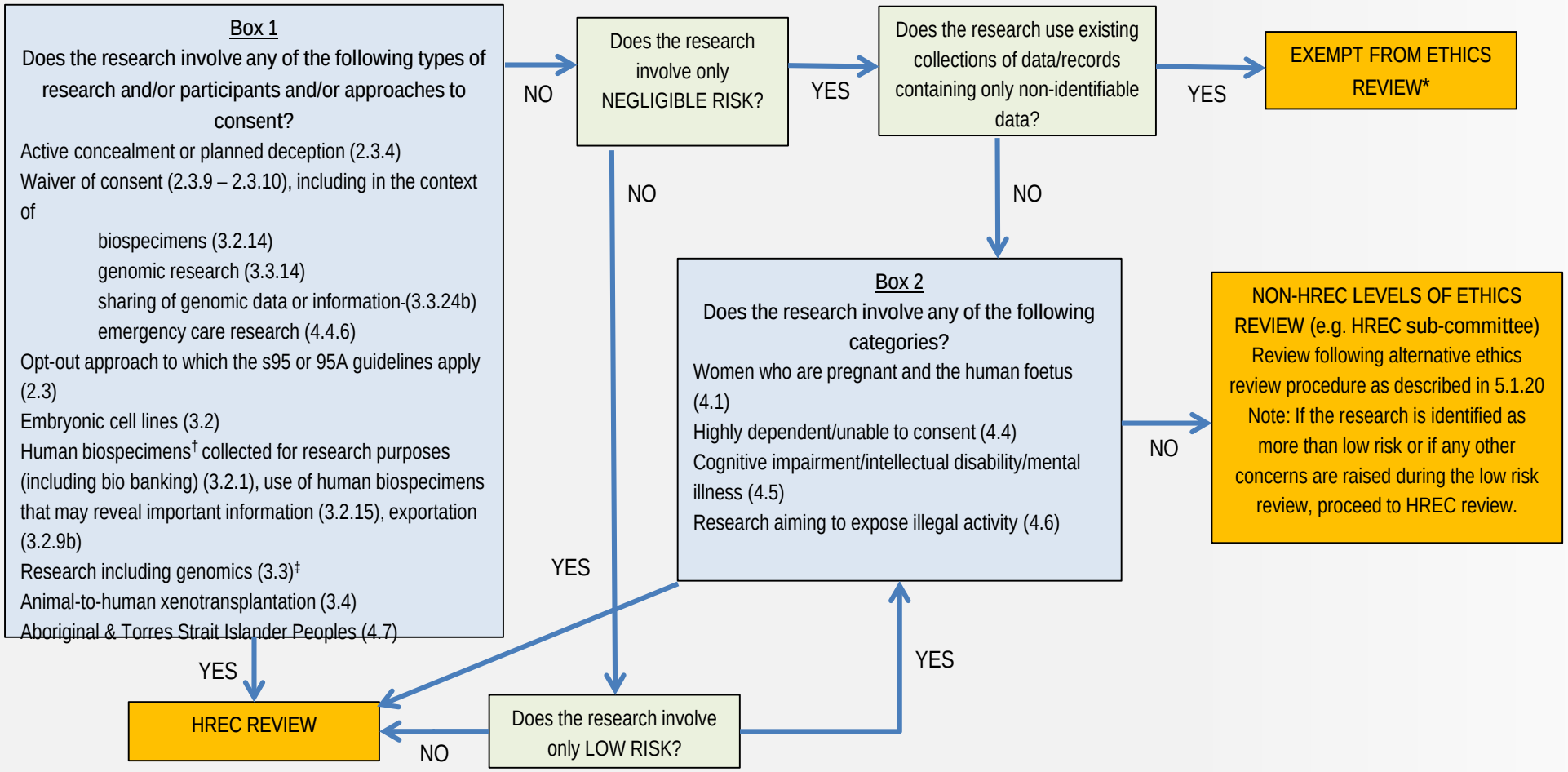
Adapted from: Competencies for R&D staff – November 2013 (Framework for Research Support Services)

A1. Supporting the Growth and Delivery of Clinical Research within Own Institution			
	A	B	C
A1.1 National objectives and priorities.	Is aware of national objectives and priorities for research.	Advises and promotes to stakeholders the national objectives and priorities for research.	Develops local strategy for research in line with national objectives and priorities.
A1.2 Local strategic direction.	Is aware of the local strategy for research in their institution.	Advises and promotes to stakeholders the local strategy for research through presentations and training and champions research within the institution.	Sets the local strategy for research in line with national objectives and priorities and ensures its implementation. Champions research at an executive level.
A1.3 Promotion of research.	Actively promotes research. Helps develop materials for promotional or educational forums for research.	Promotes the use of research in evidence-based practice to all relevant stakeholders and the importance of research to the community, patients and the institution. Develops and updates the RO's website to ensure appropriate web-based information is available to all stakeholders.	Develops a research management culture that understands and promotes the benefits of research to the community, patients and the institution.
A1.4 Chief executive/Board engagement to support research activity.	Understands the need and benefits of CE/Board level engagement in research.	Acts as the conduit for any communication requiring Board consideration/sign off. Understands the importance of keeping the Board aware of the institution's research performance metrics through the appropriate communication lines.	Maintains board engagement to continually strengthen the culture of research-led clinical practice. Identifies and presents opportunities and risks at executive level.

NSW OHMR Guidelines for Low and Negligible Risk (LNR) Research Review Processes or Exemption from Ethics Review

- This Guideline represents NSW Health's Office for Health and Medical Research's (OHMR's) interpretation of the *National Statement on Ethical Conduct in Human Research* (the "National Statement") as it applies to low and negligible risk research. It is intended to provide greater consistency amongst HRECs and others in interpreting and clarifying some of the concepts contained in the National Statement. It should not be used as a substitute for reading and applying those concepts as directly expressed in the National Statement and other related documents.

Figure 1: Flowchart for Low and Negligible Risk Review



* *Institutions that do not have separate procedures for reviewing research that is exempt from ethics review would review this sub-set of research under their established LNR review processes.*

† *Research involving the use of human biospecimens that still meets the definition of low risk after 3.2.2-3.2.3 are considered, may qualify for a non-HREC level of ethics review.*

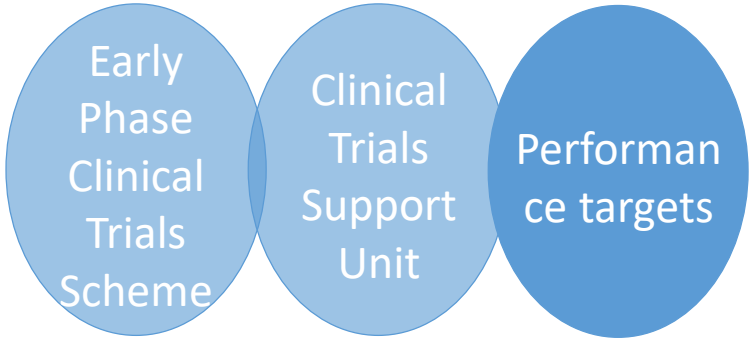
‡*As a general principle, research including genomics will require review by an HREC; however, if no information that can identify an individual is used and no linkage of data is planned, the research may be determined to carry low risk (3.3).*

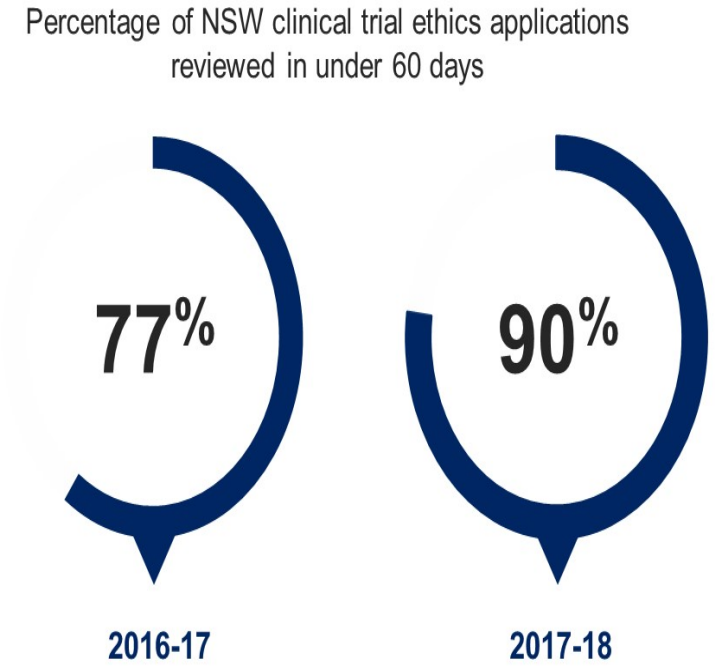
OHMR Metrics Program

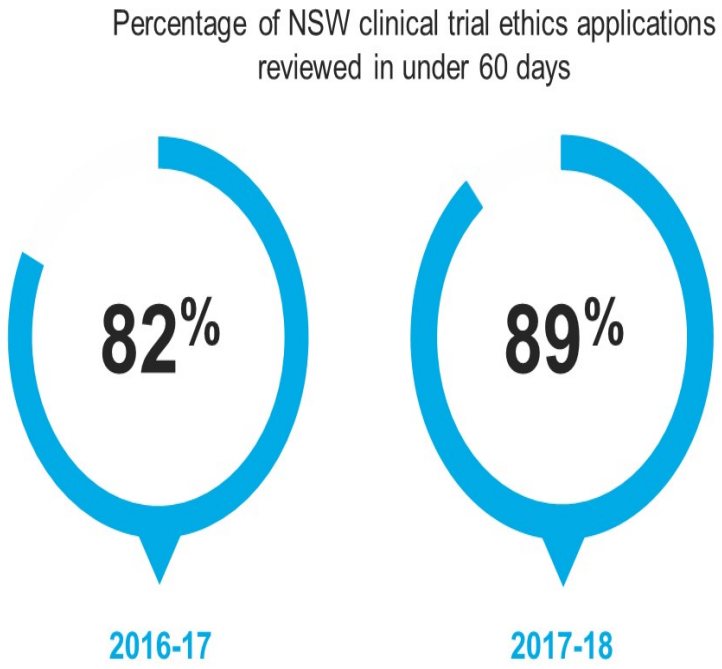
- Australian health and medical research ecosystem creates significant value for the wider economy and society and is fundamentally critical to provide better value health care.
- There is a growing need to provide quality and validity measures to ensure a consistent performance in research at all sites.

  - As of 1st of July 2016, OHMR has been collecting consistent data from NSW PHOs in research ethics and governance timelines.
  - Two of these measures have been included to the Chief Executive Service Agreements as research KPIs.

Clinical Trials







REGIS

- National attempt to have one IT system failed
- NSW will have its IT system REGIS fully implemented by the end of this financial year.
- REGIS will steam-line all ethics and SSA approval processes – all on line
- By April 2019, use of REGIS to submit SSA at each site will become standard. Once the SSA application is completed by the PI in REGIS, the nominated Head/s of department/s will receive an email notification requesting they document their support decision within REGIS.
- LHDs will have an escalation protocol to manage delays in sign off
- Performance dashboards for all actors
- Regular metrics

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Early Phase Clinical Trials Framework

Vision:

NSW is a centre of excellence that provides a high quality and efficient environment to conduct early phase clinical trials, with the ultimate aim of improving health outcomes for NSW residents.

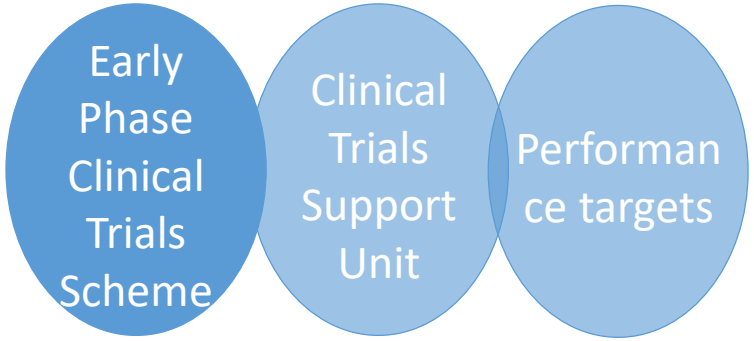
The Framework comprises two key elements:

- NSW Health Early Phase Clinical Trials Human Research Ethics Committees
- Quality recognition scheme for early phase clinical trial sites and investigators in NSW

NSW Health Early Phase Clinical Trials Human Research Ethics Committees

- These committees will be appointed to review early phase clinical trials
- Mandated for use where NSW Public Health Organisation sites are involved
- Value to the health sector:
  - Support decision making for public health organisations as sites can have confidence in specialist ethics review
  - Increase the speed and reduce the administrative burden for early phase trial approval
  - Streamline ethics application timelines – 30 working day benchmark (aim for 20 working days benchmark)
  - Build early phase trial capability
  - Increase attractiveness of NSW to sponsors

Clinical Trials



- Consistent, high quality ethics approach to commence early phase clinical trials.
- NSW Health has appointed the following HRECS to the Scheme:
  - Bellberry Limited
  - Sydney Children's Hospital's Network HREC.
- Review of all applications within 30 working days, with a target to work towards 20 working days.

Quality Recognition Scheme

- Quality recognition scheme will recognise sites and investigators that have the capability to conduct early phase trials at a high standard
- Clinical trial sites and units, and associated investigators will be awarded recognition and provided support to work towards recognition
- Value to the health sector:
  - Support decision making for Public Health Organisations who can have confidence that a trial site meets a high standard of conduct, built in requirements for good clinical governance
  - Ensure the operational conduct of early phase trials is aligned with best practice nationally and internationally
  - Increase attractiveness of site to potential sponsors

NSW Budget Costing Tool

Purpose of this Project

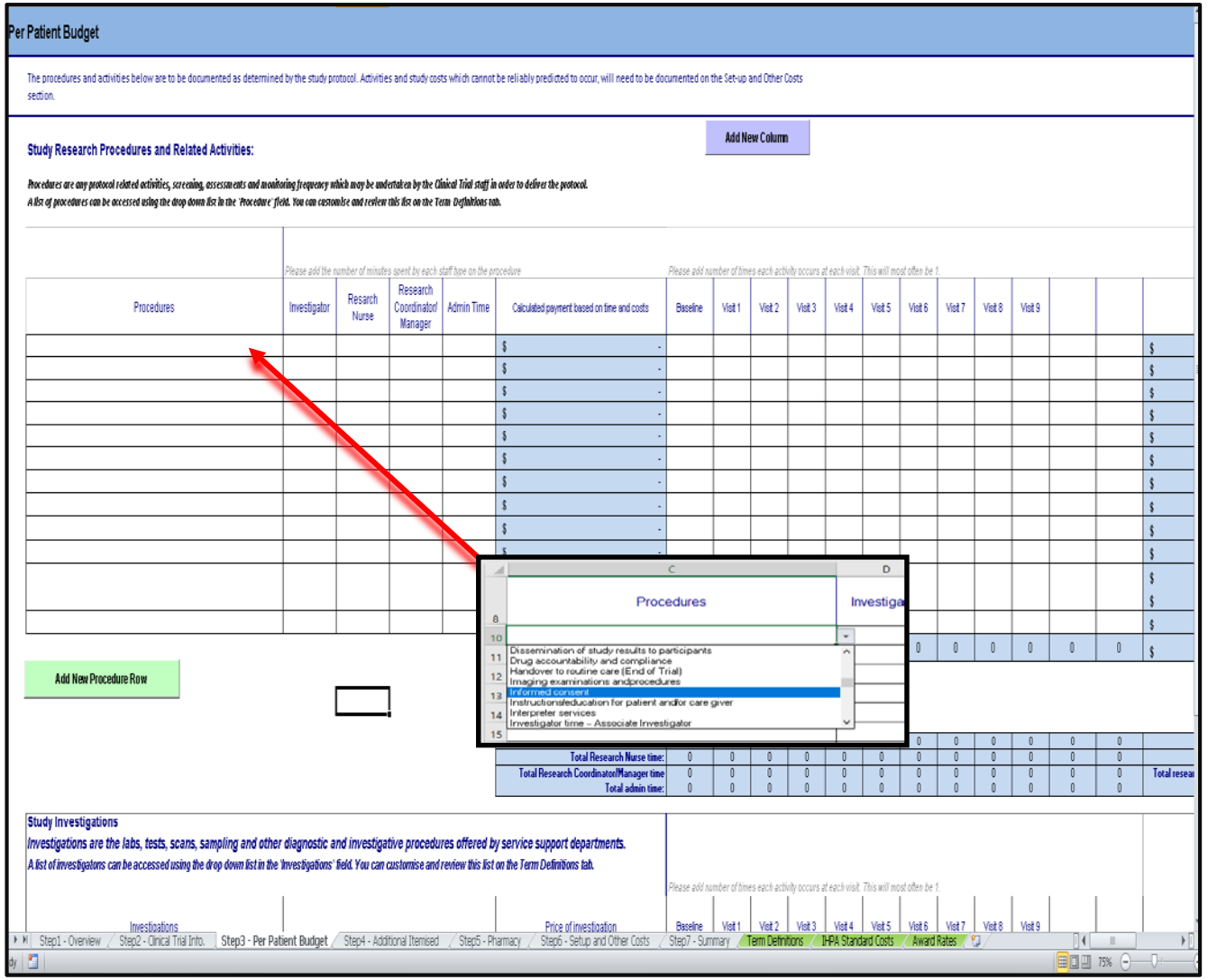
- Lack of accuracy and transparency in budgeting and finance processes for clinical trials identified in a recent consultation (CTSU project)
- A standard costing tool was requested by the Sector to support improved finance processes
- It is an Excel spreadsheet with clear and consistent methodology to calculate trial costs
- Enables all sites to be aware of the potential financial implications of research they conduct

Version 1 of the Budget Tool

Pre-populated procedures/investigations

Built by SLHD and based on the successful NIHR Costing Tool

Launched after Sector consultation and incorporation of feedback



OHMR – support structure

- Clinical Trials Support Unit
- Translational Research Unit – grants and support for implementation and scaling
- Research Ethics Governance Unit

Further information

w **www.medicalresearch.nsw.gov.au**

t **02 9391 9228**

e **MOH-OHMR@health.nsw.gov.au**

@MedResearchNSW