

Restructure – Consultation Document (Procedure reference: PD2014_016)

Endocrinology Clinical Research Unit (ECRU) Restructure Proposal

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Contents

Stage 1 – Service Review	3
1.1 The Need for Change	3
1.1.1 Description of Service.....	3
1.1.2 Background.....	3
1.1.3 Current Structure.....	3
1.2 Restructure Plan.....	3
1.2.1 Reason and Purpose of the Restructure.....	3
1.2.2 Proposed New Structure and cost benefit analysis.....	4
1.2.3 Likely impact on services and functions	5
1.2.4 Likely impact on budget and funding	5
1.2.5 Likely impact on employees	5
1.2.6 Current and proposed FTE establishment;.....	5
1.2.7 Current and proposed position descriptions.....	5
1.2.8 Current and proposed organisational charts	5
1.2.9 Proposed method of filling positions in the new structure;	5
Stage 2 – Consultation and Communication Strategy	6
2.1 Notification to employees.....	6
2.2 Notification to Union/Industrial Bodies and other relevant parties.....	6
Stage 3 – Implementation	6
Stage 4 – Review and evaluation methodology and timeframes including success indicators;	6
4.1 Final audit of overall plan by management accountant.....	6

Stage 1 – Service Review

1.1 The Need for Change

1.1.1 Description of Service

The Endocrinology Clinical Research Unit (ECRU) is a service within the Department of Diabetes, Endocrinology, and Metabolism at Royal North Shore Hospital. Its mission is to provide a cohesive, quality-controlled approach to investigator-based and externally-funded clinical research. At any one time, the unit is involved in numerous pharmaceutically-sponsored international clinical trials, NHRMC and/or MRFF grant-funded trials, as well as investigator-initiated studies encompassing all areas of endocrinology including diabetes, bone and mineral diseases, pituitary disorders, menopause, obesity, thyroid and endocrine cancers.

1.1.2 Background

ECRU has been conducting clinical trials and research studies for the Department of Endocrinology since the late 1990s, for the Menopause Clinic since 2000, and the NSLHD's COVID-19 trials from 2020. Since the MD program has been introduced by the University of Sydney, ECRU staff also assist with medical student projects that are being conducted within or for the department. At any one time, up to 30 clinical trials and research studies are being managed concurrently by the unit.

In December 2022, a service review of the ECRU was undertaken. The review determined that the clinical trials now being offered to and conducted by the ECRU, have over the years, become more multifaceted, complicated, and require management by more experienced and skilled Clinical Trials Coordinators.

1.1.3 Current Structure

Staffing in ECRU consists of:

- 1 x Permanent Clinical Research Manager (0.75FTE) classified as Health Manager, Level 3 (HM3) under the Health Managers (State) Award
- 2 x Permanent Clinical Trial Coordinators (1.2FTE) classified as Health Manager, Level 1, (HM1)
- 2 x Temporary Clinical Trial Coordinators (2.0 FTE) classified as Health Manager, Level 1, (HM1), contracts renewed annually as required
- 1 x Temporary Research Data Support Officer (0.8FTE) classified as Administration Officer, Level 4 (AO4) under the Health Employees' Administrative Staff (State) Award, contract renewed annually as required

1.2 Restructure Plan

1.2.1 Reason and Purpose of the Restructure

The ECRU is proposing to increase the position grading by 1 level, of both the Clinical Trials Coordinator position (from HM1 to HM2) and that of the Research Data Support Officer (from AO4 to AO5). The Endocrinology Clinical Research Unit has, over the years, experienced an increase in work volume and complexity including the requirement to

undertake much more complex studies including within the areas of cancer, rare disease, and high volume recruitment numbers in clinical trials. Because of its renowned experience and expertise, the unit is being asked to be the lead site for a number of trials in Australia or be the only site for Australia/New Zealand, especially for pharmaceutically sponsored international, multicentre clinical trials on thyroid cancer as well as rare disorders. Currently, our unit is the lead site for Australia for 4 cancer clinical trials and 6 clinical trials in rare disorders.

The service review determined that the position of Clinical Trial Coordinator (HM1), advertised as a position where previous clinical trial experience was preferred, did not attract any senior clinical trial coordinators to the role. Having to hire staff inexperienced in clinical trials, especially in a research unit which conducts complex, international clinical trials, meant the coordinator could not function independently without supervision for an extended period of time, requiring further training and education resources.

It is envisaged that any future recruitment for positions within the ECRU will attract more senior and experienced staff. There are numerous examples within NSW Health of Clinical Trial Coordinator positions being classified as HM2, where the ECRU aims to bring parity to the positions within its service in order to best serve our community.

As part of the service review it was determined that the position of Research Data Support Officer (AO4) has increased in its complexity where the position has seen an increase in the volume of the creation and management of databases than originally anticipated.

NSW Health has launched a clinical trial management system (CTMS) for all NSW public hospitals and health services conducting clinical trials. The CTMS is a software system which will manage clinical trials in NSW. The system maintains and manages planning, performing and reporting functions, along with participant trial information, and tracking deadlines and milestones.

The electronic infrastructure of the CTMS system will also assist the state's clinical trials sector through reduced administrative burden, increased visibility of clinical trial activity, and improved financial management.

The Research Data Support Officer (AO4) will now be required to perform data entry into the CTMS for all studies conducted within the research unit. They will also be required to manage and update entries in the CTMS, and this carries a higher level of complexity to the data entry tasks relied upon at the initial establishment of the position in November 2021.

No change in the Clinical Research Manager position grading has been requested.

1.2.2 Proposed New Structure and cost benefit analysis

The proposed changes have been discussed with Carol Zeng, the acting District Research Finance Business Manager, to ensure that the funding cost centre— RNS Endocrinology Clinical Trials, currently in a favourable position with a surplus, can fund all the proposed changes.

The Concept Brief (**TAB A**) for the review of the Clinical Trial Coordinator and Research Data Support Officer positions has been approved by:

- Prof Roderick Clifton-Bligh, Head of Department
- Carol Zeng, then Acting NSLHD District Research Business Manager (approval confirmed by Selin Armutcu, current NSLHD District Research Business Manager)
- Jacqueline Ferguson, Director of Finance, NSLHD

- Dr Chris Dennis, Medical Executive Director

1.2.3 Likely impact on services and functions

- **On Patients:** Study participants will be managed by more knowledgeable and proficient Clinical Trial Coordinators and a Research Data Support Officer resulting overall in a more favourable experience in the clinical trial setting and with the hospital.
- **On Services:** No impact on services.
- **On Industrial Relations:** Under the proposed change the positions of Clinical Trial Coordinator (3.2 FTE) (HM1) and Research Data Support Officer (AO4) (0.8 FTE) will be deleted from the structure. These positions are currently filled where the incumbents (4.0 FTE) will be considered 'Affected' in accordance with NSLHD procedure '*Restructuring in Northern Sydney Local Health District*' (**TAB B**). Affected staff are staff members whose positions have been deleted, altered, or relocated as a result of organisational change and who will become excess if they are not placed in a position within the new structure. Subsequently, given the industrial impact, the Northern Sydney Local Health District (the District) will consult with the Health Services Union in line with the relevant industrial awards.

1.2.4 Likely impact on budget and funding

The additional cost of the restructure, including the appointment of an additional new Clinical Trial Coordinator position (A05), has been reviewed by the District Research Finance Business Manager. The funding cost centre is in surplus.

1.2.5 Likely impact on employees

Incumbents in the positions of Clinical Trial Coordinator (3.2FTE) (HM1) and Research Data Support Officer (AO4) (0.8 FTE) will be impacted by the proposed change and will be declared as Affected staff in accordance with NSLHD procedure '*Restructuring in Northern Sydney Local Health District*'

1.2.6 Current and proposed FTE establishment;

- Current FTE establishment: 4.75 FTE
- Proposed FTE establishment: 4.75 FTE

1.2.7 Current and proposed position descriptions

Current Position Descriptions

- Clinical Trial Coordinator (HM1) – (**TAB C**)
- Research Data Support Officer (AO4) – (**TAB D**)

Proposed Position Descriptions

- Clinical Trial Coordinator (HM2) – (**TAB E**)
- Research Data Support Officer (AO5) – (**TAB F**)

1.2.8 Current and proposed organisational charts

- Current organisational chart (**TAB G**)
- Proposed organisational chart (**TAB H**)

1.2.9 Proposed method of filling positions in the new structure;

New positions will be filled via an Expression of Interest (EOI) process internal to the ECRU. Positions will be filled via a merit-based selection process in accordance with NSW Health

Stage 2 – Consultation and Communication Strategy

Consultation will occur in accordance with NSLHD procedure *Restructuring in Northern Sydney Local Health District* and in line with the relevant industrial awards

2.1 Notification to employees

All employees impacted by the proposed changes will be advised in writing of the proposed changes and are invited to provide feedback during a 2-week consultation period in accordance with the District's procedure *Restructuring in Northern Sydney Local Health District*.

2.2 Notification to Union/Industrial Bodies and other relevant parties

A draft restructure consultation paper which includes the new organisational structure will be provided for consultation. The consultation paper will be sent to the following stakeholders as detailed below:

- All staff within the Endocrinology Clinical Research Unit, Department of Endocrinology
- NSW Health Services Union (HSU)

Stage 3 – Implementation

It is anticipated that the proposed restructure will be implemented in April 2023 following the consultation with staff and industrial bodies.

Stage 4 – Review and evaluation methodology and timeframes including success indicators;

The restructure will be reviewed after 3 months following implementation to ensure there is no negative impact to staff or service delivery. The review will assess the efficiency of the team, staff satisfaction with the change and continued delivery of services.

4.1 Final audit of overall plan by management accountant.

The plan has been reviewed by Selin Armutcu, NSLHD District Business Manager, Research Finance, to ensure accuracy of content.