Summary of changes to the NSW Health Research Handbook

Section 2

Addition to final bullet point: We have expanded the text to include the roles of consumers and the community.

The revised point now reads: “Consumers and the community, including research participants, can contribute in a meaningful way to research through their engagement and involvement to ensure that outcomes are relevant and of value.”

Section 4.1.1

New Sentence Added: Clarification regarding TransCelerate training. “TransCelerate training is specifically designed for site staff conducting externally sponsored trials. Staff involved in investigator-led or collaborative group trials should also ensure they receive training covering the GCP responsibilities of the Trial Sponsor.”

Section 6

Language Change: Adjusted wording to align with updated terminology from the NHMRC. The phrase "NHMRC Consumer and Community Involvement" is now consistently applied.

New References:NHMRC Statement on Sex, Gender, Variations of Sex Characteristics and Sexual Orientation in Health and Medical Research – A new sentence was added referencing this statement.

James Lind Alliance Priority Setting Partnership (PSP) – A reference to the PSP has been added.

Section 10.1.2

Addition of Missing References: The section now includes missing references to REDCap to ensure proper acknowledgment of this tool's role in data collection and management.

Section 10.4

Data Retention Clarification: We have refined the wording to clearly define the data retention requirements for clinical and non-clinical research. The revised text is as follows: “For Clinical Trials, data must be retained for a minimum of 15 years for adult studies after the last attendance or official contact, or until the patient reaches or would have reached the age of 25 years for paediatric studies, whichever is longer.

For areas such as gene therapy, research data must be retained permanently.

For clinical and non-clinical research, data must be retained for a minimum of 15 years after the date of publication, completion of the research, or termination of the study.”

Section 12

CTN/CTA Scheme Update: A clarification was added regarding therapeutic goods and their inclusion in the Australian Register of Therapeutic Goods (ARTG):

“Therapeutic goods that are included in the ARTG but are to be used in a manner not covered by the existing entry in the ARTG, also require a CTN/CTA.”

Section 16.3

New Reference Added: We have included a reference to CT: IQ’s Joint Position Statement.

Section 18.1

New Sentence Added: An additional line has been included to emphasize the role of risk assessments in determining safety reporting requirements:

“Based on a risk assessment, the sponsor should determine the most appropriate safety reporting requirements for a trial.”

Refined the wordings/language of the section to improve clarity.