

Zero Childhood Cancer Program Data Access Committee (“Zero DAC”) Charter			
Date	19/10/2023	Owner	ZERO Program Operations
Due for Revision	01/08/2024	Revision Method	
Approver	ZERO Executive Committee, CCI Head of Legal, CCI Assurance Manager, ZERO Program Director	Approval Date	02/11/2023
1. Purpose and Authority			
1.1	Purpose	The Zero Childhood Cancer Program Data Access Committee (“ZERO DAC”) oversees and authorises internal and external requests to clinical, “omics” and associated data; and human biological samples for research subsequent to the primary purpose for which the data and samples were collected and stored under the custodianship of the Zero Childhood Cancer Program (ZERO) at Children’s Cancer Institute Australia (“CCI”). The ZERO DAC oversees multiple distinct datasets and repositories and is responsible for the decision-making in approving/declining access of personnel, including government, industry, private individuals, organisations or networks of organisations to ZERO data and samples.	
1.2	Authority	The ZERO Data Access Committee is established under the approval of the ZERO Program Executive Committee. The Committee has the authority and power to exercise the responsibilities set out in this Charter and under any separate instruction from the Executive Director of Children’s Cancer Institute from time to time.	
2. Roles and Responsibilities			
2.1	Committee	<p>The role of the Committee includes reviewing applications to access ZERO data and may grant an applicant:</p> <ul style="list-style-type: none">a. direct access to datasets, sent digitally in secure form to data users, or that are stored in secure computing environments (e.g., a data safe haven).b. indirect access to data (i.e. Model-to-data where data users submit algorithms to run on secure data sets that remain hidden).c. access to biological samples that include excess tissue and nucleic acids, cell lines, and PDX models for re-use or secondary use, in accordance with the national standards guided by the National Statement on Ethical Conduct in Human Research, and explicit permissions from the Sydney Children’s Hospital Network (SCHN) Human Research Ethics Committee (HREC) and the Animal Ethics Committee (AEC). <p>The ZERO DAC may, at its absolute discretion, approve, approve with conditions, reconsider with change, or reject any application.</p> <p>All committee members will be required to sign a Deed to officially document that:</p> <ul style="list-style-type: none">a) committee members agree to serve the DAC in line with the Policy and Charter;b) outline that in the event of a breach of policy Committee Members acknowledge that they may be asked to resign;c) and maintain confidentiality.	
2.2	Chairperson	The Role of the Chair	
2.3	Secretariat	<p>Secretariat support for the Committee will be provided by the ZERO Operations Team. The Secretariat will be responsible for:</p> <ul style="list-style-type: none">• Providing a notice of meetings• Preparation and circulation of the meeting agenda and papers• Accurately minuting all decisions of the Committee, in consultation with the Chair. The Secretariat will coordinate the orientation of new members, timely tabling of all correspondence, reports, and other information relevant to the Committee’s activities. The Secretariat will coordinate out of session meetings and or correspondence as determined by the Chair.• Maintaining a registry that records all applications and outcomes	
2.4	Zero DAC Subject Matter Expert	<p>A pool of scientific and clinical tumour experts (referred to here as subject-matter experts/SMEs) will form the Subject Matter Expert Advisory Panel for the ZERO DAC. SMEs on this panel will be approached Ad hoc for complex requests needing specific subject matter advice and expertise before a decision may be made by the DAC. SMEs</p>	

	Advisory Panel	from this panel may be invited at the discretion of the committee to evaluate applications. Co-opted SMEs will have no voting rights on the final decision of the DAC.
3. Committee Membership		
3.1	Composition	<p>The Committee will be comprised of non-voting and voting members.</p> <p><i>Non-voting members:</i></p> <p>ZERO Laboratory Operations Coordinator ZERO Clinical Data Coordinator ZERO Program Coordinator Children's Cancer Institute Tumour Bank Representative</p> <p><i>Voting members (3 members external to CCI and Sydney Children's Hospital):</i></p> <p>ZERO National Study Committee Research Representative ZERO National Study Committee Clinical Representative ZERO National Study Committee Research or Clinical Representative ZERO Research Committee Research Representative ZERO Research Committee Clinical Representative ZERO Research Committee Research or Clinical Representative</p>
	Observers	<p>Observers of the meeting may attend with endorsement by the DAC member majority. Observers will have no voting rights.</p>
	Structure	<p>The ZERO DAC comprises of non-voting members and voting members. Non-voting members make up the administrative and operational core of the DAC, responsible for the liaison and logistical processes of the data/sample request.</p> <p>Voting members make up the review and decision-making core of the DAC, responsible for the review and approval of data/sample applications.</p> <p>The ZERO National Study Committee and ZERO Research Committee Representatives will be nominated by their respective committees.</p>
	Appointment of Chair	<p>A chair under this charter will be appointed by the ZERO Executive Committee. This appointment will be reviewed annually. The Chair must be a full-time employee of Children's Cancer institute.</p> <p>The DAC Chair may appoint a delegate to act as a proxy in their absence.</p>
	Quorum	<p>For key decision making, a simple majority of members (>50%) and the chair (or their proxy) must be in attendance. If a Quorum does not exist, no business decisions may be transacted. Debate may take place; however, voting may not take place, except for voting for adjournment of the meeting. Urgent requests may be assessed via circular resolution.</p> <p>Members should provide out of session comments if they are unable to attend a meeting.</p> <p>If a conflict of opinion is identified and a consensus resolution cannot be achieved, the DAC will notify the applicant and request further information to address any concerns raised. The committee will review additional supporting information for the application and address via an out of session circular resolution, with any arguments raised documented in an email prior to the decision by the DAC.</p> <p>Decisions should be made by consensus. If this cannot be achieved, a subcommittee may be formed by the chair to resolve the dispute. If the dispute cannot be resolved by the subcommittee, then a recommendation to escalate to the National Study Committee will be made.</p>
	Reporting	<p>The ZERO DAC Secretariat is to provide standing reports to ZERO Executive Committee regarding data and sample access requests that includes summary of applicants, number of approved, approved with conditions, reconsider with change, or rejected applications. Details of applicant, outcome and reasons for outcome are to be supplied within the standing reports to the Executive with the meeting papers ahead of scheduled meetings</p>
	Meetings and Attendance	<ul style="list-style-type: none"> • This Committee will meet monthly • The Clinical Data Coordinator to collate data and sample access applications and mail out to Committee Members • Documents requiring review and recommendation to the committee where practical will be submitted to the Secretariat at least 10 days in advance of a scheduled meeting • The agenda, reports, and associated documents will be circulated a minimum of seven days prior to scheduled meetings.

		<ul style="list-style-type: none"> Accurate minutes will be recorded. These minutes will be circulated to Committee Members for ratification at the next scheduled meeting <p>Urgent requests out of session may be assessed via circular resolution.</p>
4. Application & Review process		
4.1	DAC review Process	<p>DAC review is separated into 3 stages:</p> <p>Stage 1: Verifying applicant's institution credentials, eligibility, application completeness and relevant supporting documents.</p> <p>Stage 2: Reviewing and assessing project scope for adherence to data restrictions, permitted use of the data consent, ethics approval.</p> <p>Stage 3: Where required, referral of the access request to the DAC Subject Matter Expert Advisory Panel for further review and assessment of project feasibility and potential collaborations.</p>
5. Governance		
5.1	External Complaints	<p>Complaints may be received verbally via telephone or face to face, however the Committee recognises that complaints may also be received by other communication mediums such as email, letter or SMS.</p> <p>Making a Complaint To make a complaint, contact the Committee Chair on 02 7209 6763. The Committee Chair will then escalate the complain to the Complaints Officer (the Institutes Risk & Assurance Manager) who will manage the complaints process.</p> <p>Complaints will go through the following process:</p> <ol style="list-style-type: none"> 1. Receiving of the Complaint; 2. Assessment; 3. Investigation; and 4. Resolution. <p>Complaints Management Within two (2) business days of the receipt of a complaint, the Complaints Officer will acknowledge the receipt in writing to the complainant unless the complainant has indicated that they do not require further contact. If the complaint was received verbally, a description of the Institute's understanding of the complaint will be included in the acknowledgement.</p> <p>In handling a complaint, the Institute must respect the complainant's reasonable concerns about confidentiality. Personal information that can identify a complainant will not be disclosed to any person who does not need to know for the purpose of the assessment or investigation of the matter. All records relating to the complaint will be kept secure and only accessible by the Complaints Officer and other employees with a need to have access.</p> <p>If a complaint is made by a person who is a whistleblower under the terms of the Institute Whistleblower Policy, the provisions of that policy prevail, including the right to anonymity.</p>
	Data Incidents and Mishandling	<p>Internal Data Incidents All Internal ("Children's Cancer Institute Australia") Data Incidents must be handled in accordance with the CCI Data Breach Response Policy and Data Breach Response Plan.</p> <p>External Data Incidents If a person, Data User (an authorised user of the data/sample asset) or third party becomes aware of a data incident that impacts ZERO Program data, they must immediately notify a Member of the Committee (via Zero phone +612 7209 6763) If you do not receive a response within 10 minutes, please phone the Risk & Assurance Manager of 0448559287. This must then be immediately escalated and assessed by the Institute Data Governance and Cyber Steering Group (DGCSG).</p> <p>Four key steps in responding to a Data Breach Regardless of the type of Data Breach, there are four critical steps that are always required. These are:</p> <ol style="list-style-type: none"> 1. Contain - Action must be taken to immediately limit or stop the breach. For example, stop the unauthorised practice, recover the records, or shut down the system that was breached.

		<p>2. Assess - The Institute's DGCSG will evaluate all relevant information to determine what type of breach has occurred and the necessary steps to mitigate any further harm.</p> <p>3. Notify - This could involve notifying affected individuals, Third Parties, and the public. The DGCSG will determine if and when notification is necessary.</p> <p>4. Review - A thorough investigation into the cause of the Data Breach and recommendations for change for continuous improvement.</p>
	Conflicts of Interest	<p>Each member must declare any potential conflicts of interest prior to review of relevant access requests, or any other matters considered.</p> <p>All conflicts – actual (e.g. direct conflict with role in an external organisation, close personal relationships, party to the data application), potential or perceived, must be disclosed.</p> <p>The Chair of the Committee should determine the most appropriate course of action given the situation at the table, including:</p> <ul style="list-style-type: none"> • Member refraining from participating in any discussion about related matters • Member removing themselves from the room • Member abstaining from voting on any matter related to the conflict