HEALTH CLINICS AND CLINICAL SERVICES POLICY 2020

The Vice-Chancellor, as delegate of the Senate of the University of Sydney, adopts the following policy.

Dated: 21 September 2020

Last amended: 27 October 2021

Signatures:

Names: Dr Michael Spence

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1 Name of policy

This is the Health Clinics and Clinical Services Policy 2020.

2 Commencement

This policy commences on 1 October 2020.

3 Policy is binding

Except to the extent that a contrary intention is expressed, this policy binds the University, staff, students and affiliates.

4 Statement of intent

(1) This policy:
   (a) supports the University’s values of courage and creativity, and respect and engagement;
   (b) is the lead document for the Clinical Governance Framework;
   (c) establishes a framework for regulating the governance, management and review of University health clinics and clinical facilities;
   (d) supports the provision and continuous improvement of compassionate, high-quality and safe clinical and research services and activities;
   (e) supports ethical conduct among all involved in the provision of clinical and research services;
   (f) supports the University’s role in providing fair and equitable access to clinical and research services; and
   (g) sets out the University’s requirements for establishing and operating health clinics and clinical facilities.
The University regards the National Safety and Quality and Health Service Standards as important and appropriate guidance on best practice in the provision of health care to consumers, but does not intend to seek formal accreditation under those standards.

5 Application

(1) This policy applies to:
   (a) University staff, students and affiliates;
   (b) any University health clinic;
   (c) any University clinical facility; and
   (d) any other health clinic which is contractually bound to follow this policy or particular clauses within this policy.

(2) This policy does not apply to:
   (a) health clinics that are operated by external entities from premises that are not University lands;
   (b) staff undertaking approved clinical work outside their University employment (regardless of whether they receive a clinical loading as part of their employment);
      
      Note: See Outside Earnings of Academic Staff Policy 2011; Outside Earnings of Academic Staff Procedures 2011; and External Interests Policy 2010 for details of required approvals.
   
   (c) affiliates undertaking clinical work outside their University engagement; and
   (d) the provision of veterinary services.

6 Definitions

In this policy:

affiliate has the meaning given to it in the Staff and Affiliates Code of Conduct 2021. At the date of this policy this is:

- means a person appointed or engaged by the University to perform duties or functions on its behalf, including but not limited to:
  - an honorary title holder engaged under the Honorary Titles Policy 2013;
  - a consultant or contractor to the University; and
  - an office holder in a University entity, a member of any University committee, board or foundation.

An affiliate is not an employee of the University.

child means a person who is under 18 years of age.

clinic includes any activity which provides clinical services to any person.
clinical facility means a physical space used, whether or not exclusively, by a University health clinic to provide clinical services. The same space may also be used for other purposes including, but not limited to, clinical research or clinical education.

Clinical Governance Framework means the University’s integrated system to govern, review, monitor and improve the safety and effectiveness of clinical services, to mitigate risk and provide good clinical outcomes.

Note: See clauses 7(2) and 11.

clinical incident has the meaning given in the National Safety and Quality Health Service (NSQHS) Standards. At the date of this policy this is:

- an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may also be a near miss.

Clinical Governance and Quality Committee means the committee of that name within the Faculty of Medicine and Health established by clause 8.

Clinical Governance Support Office means the organisational unit within the Faculty of Medicine and Health, with the responsibilities set out in clauses 11 and 36.

clinical research means investigation undertaken to gain or advance knowledge, understanding and insight into a range of different health matters, including:

- disease prevention and causation;
- diagnostic methods;
- treatments; and
- effects of and response to illness.

clinical research participants means individuals who have consented to participate in clinical research.

clinical service means providing any or all of:

- health or medical diagnosis;
- health or medical consultation; or
- prevention, monitoring, treatment or alleviation of disease in humans;

and includes other activities related to them, such as clinical research, clinical trials and clinical education.
clinical supervisor means the senior academic staff member within a discipline who:

- holds appropriate professional qualifications and registrations;
- is responsible for the professional learning and support of students to enable competence and professional practice; and
- is responsible for the safety, quality and regulatory compliance of students’ practice.

clinical trial has the meaning provided in the Clinical Trials Policy 2016. At the date of this policy, this is:

any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

Clinical trial inventions include, but are not limited to:

- experimental drugs;
- cells and other biological products;
- vaccines;
- medical devices;
- surgical and other medical treatments and procedures;
- psychotherapeutic and behavioural therapies;
- health related service changes;
- health related preventative care strategies; and
- health related educational interventions.

consumer engagement means the methods and strategies by which consumers are involved in decision making relating to their individual health care and the delivery and evaluation of clinical services generally.

commercial activity has the meaning provided in section 26A of the University of Sydney Act 1989 (as amended). At the date of this policy this is:

(a) any activity engaged in by or on behalf of the University in the exercise of commercial functions of the University; and

(b) any other activity comprising the promotion of, establishment of or participation in any partnership, trust, company or other incorporated body, or joint venture, by or on behalf of the University, that is for the time being declared by the Guidelines [established under s 26B] to be a commercial activity.
commercial functions has the meaning given in section 6(3)(a) of the University of Sydney Act 1989 (as amended). At the date of this policy this is:

[the] commercial functions comprising the commercial exploitation or development, for the University's benefit, of any facility, resource or property of the University or in which the University has a right or interest (including, for example, study, research, knowledge and intellectual property and the practical application of study, research, knowledge and intellectual property), whether alone or with others.

Note: Section 6(3)(b) of the University of Sydney Act 1989 (as amended) states that "the University may develop and provide cultural, sporting, professional, technical and vocational services to the community."

consumer means a person receiving clinical services, and their carers or support persons.

credentialing means a process for formally recognising and recording an individual's qualifications and entitlement to practise, measured against specified criteria.

delegate means any person or entity to whom, or to which, a delegation has been made by Senate.

Note: See University of Sydney (Delegations of Authority) Rule 2020.

Director Clinical Governance means the head of the Clinical Governance and Support Office.

Note: See clauses 11 and 12.

Executive Dean means the Executive Dean and Pro Vice-Chancellor of the Faculty of Medicine and Health.

Executive Dean's Executive Committee means the committee of that name within the Faculty of Medicine and Health, established under Part 3 of the University of Sydney (Governance of Faculties and University Schools) Rule 2016.

health clinic means one or more healthcare professionals who provide clinical services alone or in conjunction with other activities including, but not limited to, clinical research, clinical trials or clinical education.

Note: This refers to clinic categories 1 to 5 as specified in clause 17.

investigational product has the meaning given in the Clinical Trials Policy 2016. At the date of this policy this is:

any medicine, device or other product or intervention being investigated, tested or used as a placebo or reference in a clinical trial.

Independent Medical Assessor means the independent medical expert appointed by the Executive Dean to discharge the responsibilities specified in this policy.

Note: See clauses 9, 10 and 36.
material change means, in relation to any approval given under this policy, any variation which, if known at the time of the original approval, might reasonably have been likely to affect the decision to approve. This includes but is not limited to:

- an increase to the approved budget plus contingency of more than 5% of the approved amount; and
- changes affecting matters required by this policy to be taken into consideration by the relevant decision maker.

Note: See clauses 19, 20

medical lead means the most senior clinician in a clinic or clinical facility, who is accountable and responsible for the standard of medical care provided.

model of care means the document which prescribes the way in which clinic and clinical services are delivered for a particular clinic or clinical facility involved in the delivery of patient care not for research or clinical trial purposes.

near miss has the meaning given in the National Safety and Quality Health Care Standards. At the date of this policy this is:

an incident or potential incident that was averted and did not cause harm but had the potential to do so.


protocol means a document which addresses one or more of the matters set out in clause 12.

reportable conduct means any conduct defined as such in the Children’s Guardian Act 2019 (NSW). At the date of this policy this is:

whether or not any criminal proceeding has commenced or concluded:

- a sexual offence with, towards or in the presence of a child;
- sexual misconduct with, towards or in the presence of a child;
- ill treatment of a child;
- neglect of a child;
- assault against a child;
- offences under s 43(B) or 316A of the Crimes Act 1900 (NSW) (i.e. failing to remove or reduce risk of a child becoming a victim of abuse, or concealing a child abuse offence;
- behaviour that causes significant emotional or psychological harm to a child.

Note: Terms used in this definition are more fully defined in Part 4 Division 2 of the Children’s Guardian Act 2019 (NSW) and “child abuse” is defined in section 43B of the Crimes Act 1900 (NSW)
**Scope of Clinical Practice**

means the extent of clinical practice that a health practitioner is authorised to undertake at a health clinic, based on:

- the health practitioner’s skills, knowledge, performance, credentials and suitability;
- the needs of the health clinic; and
- the capacity of the health clinic to support the health practitioner’s clinical practice.

**Service Delivery Statement**

means the document which prescribes the way in which clinic and clinical services are delivered for a particular clinic or clinical facility involved in the research or clinical trials.

**University Clinical Facility**

means a clinical facility which is:

- operated by or on behalf of the University; and
- in which clinical, research and educational activities are conducted across a range of health and related disciplines.

**University Health Clinic**

means a health clinic or clinical service which is operated with the approval of the University:

- by University staff as part of their University employment;
- by University affiliates as part of their University engagement;
- jointly by the University and a third party (to the extent to which the third party is bound to comply with this policy); or
- using the University’s name or brand.

**Note:** This refers to clinic categories 1 to 3 as specified in clause 18.

**University Executive**

means the University senior management committee, comprised of the Vice-Chancellor, Deputy Vice-Chancellors, Deans of faculties, Vice-Principals and Chair of the Academic Board.

**University Lands**

has the meaning given in the *University of Sydney (Campus Access) Rule 2009*. At the date of this policy, this is:

includes any land or roads occupied or used in connection with the University including the whole or part of any building or structure and any land or roads occupied or used in connection with the whole or part of any building or structure.

**University Resources**

includes, but is not limited to:

- intellectual property;
- premises;
- facilities;
- funds;
- services;
- equipment;
- paid leave;
- staff time; and
- support staff.
vulnerable adult Has the meaning given in the Working with Children and Vulnerable Adults Policy 2021. At the date of this policy this is:

means an individual aged 18 years and above who:

- is or may be unable to take care of themselves; or
- is unable to protect themselves against harm or exploitation by reason of age, illness, trauma or disability, or any other reason.

Note: For further information see the Australian Government Department of Social Services website.

PART 1 – ALL HEALTH CLINICS AND CLINICAL FACILITIES

7 Clinical Governance Framework

(1) The Clinical Governance Framework is part of the University's organisational governance, and operates to develop and maintain a culture grounded in:

(a) quality and safety;
(b) continuous improvement;
(c) effective performance; and
(d) collaboration.

Note: See also the National Model Clinical Governance Framework, published by the Australian Commission on Safety and Quality in Health Care.

(2) The Clinical Governance Framework includes:

(a) this policy, which provides operating principles;
(b) all procedures associated with, and protocols required by, this policy;
(c) the role of the Independent Medical Assessor;
(d) policies and procedures for the protection of children and vulnerable adults; and


(e) University and individual clinic requirements, as documented in relevant protocols, for:

(i) reporting and escalation pathways;

(ii) risk and asset management;

Note: See also Risk Management Policy 2017; Asset Financial Management Procedures 2019

(iii) clinical records management; and

Note: See also Recordkeeping Policy 2017; Privacy Policy 2017; Privacy Procedures 2018.
(iv) secure and appropriate use of information and communications technology resources.


8 Clinical Governance and Quality Committee

(1) There will be within the Faculty of Medicine and Health a Clinical Governance and Quality Committee which will have responsibility for overseeing the operation of University health clinics and clinical facilities.

Note: See subclause 37(9) and the committee’s Terms of Reference.

(2) The committee will consist of the following members:

(a) the Executive Dean, as Chair;

(b) ex officio members:

(i) the Director, Clinical Governance and Support;

(ii) the Independent Medical Assessor; and

(iii) the University’s Chief Information Officer; and

(c) members appointed by the Executive Dean’s Executive Committee for a term of two years each:

(i) a Faculty General Manager, from either the Faculty of Medicine and Health or the Faculty of Science;

(ii) a representative from the University’s Safety Health and Wellbeing unit;

(iii) a person with expertise in medication safety;

(iv) a person with expertise in infection prevention and control;

(v) a registered, practising medical practitioner;

(vi) a registered, practising nurse;

(vii) a person with expertise in clinical trials research;

(viii) a clinic manager;

(ix) two consumer representatives, of whom one must be an Aboriginal or Torres Strait Islander person.

(3) The Executive Dean’s Executive Committee will determine the committee’s Terms of Reference and publish them on the University’s website.

Note: See committee’s Terms of Reference.

(4) The committee must meet at least quarterly and may meet more frequently, as directed by the Chair.

9 Appointment of Independent Medical Assessor

(1) The Executive Dean will appoint the Independent Medical Assessor, who must have the skills and qualifications specified in subclause 9(2).
(2) The Independent Medical Assessor:

(a) must:

(i) be registered as a practising medical practitioner under the Health Practitioner Regulation National Law;

(ii) maintain their registration as a practising medical practitioner while occupying the position; and

(iii) have significant recent experience in a tertiary or quaternary hospital; and

(b) will preferably also have experience as a chief medical adviser or medical administrator.

10 Role of Independent Medical Assessor

The Independent Medical Assessor will:

(a) review all applications for:

(i) establishment of new clinics;

(ii) use of new medical devices or new medical procedures within an existing clinic;

(iii) adoption of new or varied medical models of care; or

(iv) variations to service delivery statements;

(b) after consultation, as appropriate, with the relevant clinical supervisor, medical lead and clinic manager, consider and if appropriate endorse:

(i) proposals for new University health clinics;

(ii) proposals for varying services provided by existing health clinics;

(iii) the model of care document or service delivery statement of category 1, 2 or 3 health clinics;

Note: See clause 18.

(iv) the service delivery statement of a University clinical facility;

(v) the use of new medical devices or experimental or innovative treatments or techniques within an existing clinic;

(c) report to the Executive Dean and any other relevant delegate on the outcome of all applications and proposals reviewed or considered under subclauses 10 (a) and (b); and

(d) advise the Executive Dean on matters relating to clinical governance as required.

11 Clinical Governance and Support Office

(1) The Executive Dean will establish a Clinical Governance and Support Office established within the Faculty of Medicine and Health, with responsibility for providing oversight of, and assistance to, all University health clinics and clinical facilities.
(2) The Clinical Governance and Support Office will:

(a) assist and advise on the operations of clinics and clinical facilities, and provision of clinical services, recognising the inter-relationships between the requirements of proper clinical, research and corporate governance;

(b) work to develop and embed the Clinical Governance Framework;

(c) lead the University’s continuous improvement of clinical safety and quality;

(d) assist management committees, and operations staff to provide and continuously improve safe, quality clinical care;

(e) monitor clinical incident information;

(f) advise on clinical incidents;

(g) advise on protocols, patient management, and requirements for relevant certification or accreditation;

(h) monitor compliance with relevant legislation, guidelines and codes of conduct; and

(i) co-ordinate reviews of University health clinics and clinical facilities.

12 Clinical safety and quality

(1) Except with the express written permission of the relevant delegates, University Health Clinics and clinical facilities must:

(a) operate consistently with the Clinical Governance Framework, including but not limited to requirements for the protection of children and vulnerable adults; and

(b) develop, keep current and comply with appropriate protocols for managing safety and quality risks in the context of their clinical activities, consistently with the requirements of:

(i) this policy;

(ii) the procedures; and

(iii) the aims and objectives of National Safety and Quality Health Service Standards.

(2) The relevant delegates may only grant permission under subclause 12(1):

(a) after consultation with the Executive Dean, the Director Clinical Governance and the Independent Medical Assessor; and

(b) if they are satisfied that the University health clinic or clinical facility is operating, and will continue to operate, within an identified clinical governance framework with requirements equivalent to those of the Clinical Governance Framework.

Note: An example of such a framework would be that of NSW Health.
(3) Each University health clinic and clinical facility must develop, document and maintain protocols addressing the following matters:
   (a) governance and leadership;
   (b) consumer engagement, rights and responsibilities;
   (c) quality and safety, including environmental safety;
   (d) performance and monitoring; and
   (e) processes used within the health clinic or clinical facility.

(4) Protocols must provide the details, in the form, specified in the procedures.

13 Managing clinical incidents

(1) The focus of clinical incident management and reporting is to promote care quality and continuous improvement.

(2) Upon becoming aware of a clinical incident:
   (a) staff
   (b) affiliates;
   (c) students; and
   (d) any health clinic which is contractually bound to do so;
   must take immediate actions, consistent with their role, qualifications and level of skill and expertise to:
   (e) provide immediate care to the individuals involved;
   (f) make the situation safe;
   (g) prevent an immediate recurrence;
   (h) notify relevant carers or emergency contact persons; and
   (i) notify relevant emergency services and University security, if appropriate.

(3) Staff, affiliates, students and any health clinic contractually bound to do so, must report and record any clinical incident or near miss of which they become aware:
   (a) to the person, and in the manner, required by the applicable protocols; and
   (b) as soon as possible and, in any event, within 24 hours.

(4) Management committees must implement systems, consistent with the applicable protocols to:
   (a) record clinical incidents;
   (b) report data to the Clinical Governance and Support Office for analysis;
   (c) review and analyse, together with the Clinical Governance and Support Office:
      (i) clinical incidents;
      (ii) factors contributing to clinical incidents;
      (iii) outcomes of clinical incidents; and
      (iv) patterns in clinical incidents;
(d) implement quality improvement initiatives and lessons learnt programs; and
(e) report all relevant information and conclusions through the University’s accountability frameworks, as specified in this policy and any associated procedures, and any applicable protocols.

14 Managing medication, poisons and other regulated substances

(1) It is essential that medications, poisons and other regulated substances are managed appropriately, and in compliance with all regulatory and reporting requirements.

(2) Protocols relating to medications, investigational products, poisons and other regulated substances must:

(a) be consistent with all applicable University policies, procedures and safety standards;

(b) specify the manner in which the substance is to be:
   (i) procured;
   (ii) stored;
   (iii) used; and
   (iv) disposed of;

(c) specify the records required for each substance, and the manner in which those records are to be reconciled;

(d) specify the manner in which breaches of management requirements are to be:
   (i) responded to;
   (ii) escalated where required;
   (iii) recorded; and
   (iv) reported;

(e) for medications:
   (i) identify the precise medication and the circumstances in which it is used;
   (ii) specify the appropriate dosage and route of administration;
   (iii) note contraindications;
   (iv) describe appropriate emergency procedures; and
   (v) specify mandatory reporting requirements for adverse events.

Note: See also the Clinical Trials Policy 2016 and the Clinical Trials Procedures 2016.
15 University logo and brand

(1) The University logo and brand may only be used by a health clinic or clinical facility:
   (a) consistently with the Brand Policy 2015; and:
      (i) with the approval of the relevant delegate; or
      (ii) pursuant to an agreement between the University and a third party which has been approved by the relevant delegate.

16 Resources

(1) Each University health clinic and clinical facility must have its own cost centre code in the University’s finance system.

(2) The faculty, University school or centre identified as responsible for a University health clinic or for the provision of a clinical service is also responsible for its funding.
   (a) a faculty, University school or centre can be identified as responsible for any of multidisciplinary, interdisciplinary or trans-disciplinary clinics and clinical services.

(3) Funding may come from University support, external grant funding, commercial activities, or other revenues.
   (a) income from commercial activities includes Medicare or other government payments for services, payments from health insurers or other third parties and payments from consumers.
      Note: Commercial activities may only be undertaken consistently with the Guidelines Concerning Commercial Activities.

(4) Other forms of resourcing may include infrastructure support.

(5) Physical space must be developed consistently with the Building Projects Approval and Management Policy 2014.

(6) Space must be allocated consistently with the Space Management Policy 2012.

PART 2 – HEALTH CLINICS

17 Principles

(1) The University will only provide, or support the provision of, University health clinics if doing so is consistent with its objects and functions under the University of Sydney Act 1989 (NSW) and the University’s strategic goals.
   Note: See Strategic Plan 2016 – 2020

(2) University health clinics should add value to the University’s activities and support its research and education activities.
(3) University health clinics must not engage in activities:
   (a) inconsistent with the University’s vision and values;
   (b) inconsistent with the University’s strategic goals;
   (c) inconsistent with the ethical and clinical practice requirements of relevant professional and accreditation bodies; or
   (d) which could bring the University into disrepute.

(4) University health clinics must be financially sustainable.

(5) A University health clinic must not:
   (a) operate on lands which are not University lands; or
   (b) use an external party’s resources;
without a written agreement between the University and the external party relevant to the operation of the clinic.

(6) University health clinics must:
   (a) only operate with the approval of the relevant delegates, obtained consistently with this policy;
   (b) operate in a safe manner for all, including consumers, clinical research participants, staff and students;
   Note: See Work Health and Safety Procedures 2016 and specific work health and safety performance standards. See also Working with Children and Vulnerable Adults Policy 2021
   (c) except as provided in clause 11, comply with the Clinical Governance Framework;
   (d) operate in an approved clinical facility; and
   (e) only engage in commercial activities approved under the Guidelines Concerning Commercial Activities.

(7) The University will not permit external entities to operate health clinics on University lands or using University resources unless:
   (a) there is a binding written agreement between the University and the external entity; and
   (b) any external entity proposing to establish a new health clinic submits a written proposal to the relevant delegate in the form specified in the procedures.

(8) The University will only operate health clinics jointly with external entities, regardless of physical location or source of staff, if the relationship between the parties is documented in a written agreement that addresses, among other matters:
   (a) the operation of the clinic;
   (b) the ownership of, and responsibility to maintain, patient and clinic records;
   (c) arrangements for closure of the clinic, including preservation and security of records;
(d) the manner in which the requirements of this policy and the Clinical Governance Framework will be met; and

(e) the allocation of responsibility for meeting those requirements.

18 Classification

(1) The University classifies health clinics as specified in this clause.

(2) **Category 1 health clinics:**

(a) are operated by:
   (i) the University; or
   (ii) jointly by the University and a third party;

(b) are located on University lands;

(c) involve either or both of:
   (i) the provision of clinical services by University staff as part of their employment; or
   (ii) the provision of clinical services by University affiliates as part of their University engagement;

(d) may involve supervised students providing clinical services; and

(e) have a risk rating of ‘high’ or ‘very high’ after application of the risk assessment process specified in clause 21(2).

(3) **Category 2 health clinics:**

(a) are operated by:
   (i) the University; or
   (ii) jointly by the University and a third party;

(b) are located on University lands;

(c) involve either or both of:
   (i) the provision of clinical services by University staff as part of their employment; or
   (ii) the provision of clinical services by University affiliates as part of their University engagement;

(d) may involve supervised students providing clinical services; and

(e) have a risk rating of “medium” or “low” after application of the risk assessment process specified in clause 20(2).

(4) **Category 3 health clinics**

(a) are operated by:
   (i) the University; or
   (ii) jointly by the University and a third party;

(b) are not located on University lands;
(c) may involve either or both of:
   (i) the provision of clinical services by University staff as part of their employment; or
   (ii) the provision of clinical services by University affiliates as part of their University engagement; and

(d) may involve supervised students providing clinical services.

(5) **Category 4 health clinics:**
   (a) are operated by external entities;
   (b) are located on University lands; and
   (c) involve either or both of:
      (i) the provision of clinical services by University staff as part of their employment; or
      (ii) the provision of clinical services by University affiliates as part of their University engagement.

(6) **Category 5 health clinics:**
   (a) are operated by external entities;
   (b) are located on University lands; but
   (c) do not involve the provision of clinical services by University staff or affiliates as part of their University employment or engagement.

**19 Establishing new University health clinics**

(1) New University health clinics may only be established with the approval of the relevant delegates.

   **Note:** See *University of Sydney (Delegations of Authority) Rule 2020*.

(2) Employing new staff to operate an existing health clinic does not, of itself, constitute establishing a new health clinic.

(3) Any faculty, University school or centre proposing to establish a new University health clinic must submit a written proposal to the Clinical Governance and Support Office.

(4) The proposal must include:
   (a) the identity of the faculty, University school or centre which will be responsible for the proposed clinic;
   (b) a draft model of care document;
   (c) detailed descriptions of the scope of practices to be provided;
   (d) a draft of the proposed model of care or service delivery statement;
   (e) the physical location of the proposed clinic;
   (f) an initial risk assessment for the proposed clinic;
   (g) if the proposal would involve child related work, details of how requirements of the *Working with Children Policy 2021* will be met, including obtaining relevant approvals and conducting required risk assessments;
(h) a copy of any approval already given for the clinical facilities in which the clinic will operate, or if approval is being sought, sufficient information to evidence that approval should be given;

(i) an approval from the relevant clinical facility for the proposed health clinic to operate within it;

(j) a business case for the establishment of the clinic, including provision of necessary facilities and equipment;

(k) an indicative annual budget for operating the clinic for an initial period of three years;

(l) details of the strategic, research and or education benefits of the proposed clinic and how these will be maintained on an ongoing basis; and

(m) all other information required by the procedures.

(5) The Clinical Governance and Support Office will:

(a) review the proposal;

(b) if necessary, work with the proponent to amend and improve it; and

(c) make a recommendation to the relevant delegates and any required endorsers about whether it should be approved.

(6) The relevant delegates may only approve the establishment of a new University health clinic:

(a) after endorsement by each of:
   (i) the Independent Medical Assessor;
   (ii) the Executive Dean; and
   (iii) the Clinical Governance and Quality Committee;

and

(b) if they are satisfied that:
   (i) the proposal provides all the required information;
   (ii) the clinic would be consistent with this policy, particularly the principles set out in clause 17;
   (iii) the clinical facilities from which the clinical services are to be provided are appropriate;
   (iv) the risks posed are within the University's Risk Appetite and Tolerance Statement; and
   (v) the clinic is likely to be financially sustainable.

(7) New clinics must be:

(a) approved for an initial period of three years, except as varied by the relevant delegates; and

(b) be reviewed after the initial period, as provided in clause 25.
20 Varying clinical services provided by existing health clinics

(1) Any material change to the clinical services approved at the time a health clinic was originally established or first approved under this policy:

(a) constitutes a redefinition of its model of care or service delivery statement; and

(b) must be approved by the relevant delegates.

(2) Material change includes, but is not limited to:

(a) introducing new procedures or devices;

(b) introducing new research programs or trials;

(c) providing clinical services not already approved;

(d) modifying approved clinical services;

(e) adding new vulnerable client groups such as children or vulnerable adults;

(f) altering arrangements by which clinical services are provided; or

(g) any variation which has potential to impact the performance or safety of the care or services delivered at the clinic.

(3) Approvals for variations to clinical trials or research do not constitute approval under this clause. If the variation affects participants or consumers, approval under this clause is an additional requirement.

(4) A health clinic wanting to implement a material change must submit a written proposal to the Clinical Governance and Support Office.

(5) The proposal must include:

(a) a detailed description of the proposed change;

(b) the reasons for the change;

(c) an initial risk assessment of the change consistent with clause 21 and the procedures;

(d) details of the strategic, educational or research benefits of the change;

(e) details of the anticipated financial impacts of the change;

(f) evidence of consultation with consumers and other stakeholders, and details of the outcomes of those consultations; and

(g) any other information required by the procedures.

(6) The change:

(a) must be approved by the relevant delegates, after consultation with the Independent Medical Assessor and Executive Dean;

(b) if children are involved, must also be approved by the relevant delegate under clause 9 of the Working with Children and Vulnerable Adults Policy 2021; and

(c) must not be implemented until approved.

(7) A health clinic wanting to cease providing one or more of its clinical services must follow the process specified in the procedures.
The relevant delegates may direct the cessation of one or more clinical services provided by a health clinic at any time if satisfied that:

(a) the clinic has failed to meet the clinical governance and safety standards required for the provision of the service, including those related to the protection of children or vulnerable adults;

(b) the clinic has failed to meet objectives of providing the service;

(c) the clinical service is found on review to be financially unsustainable; or

(d) a review has recommended cessation of the clinical service.

21 Risk assessment for health clinics

(1) The Executive Dean may specify in procedures the process to be undertaken when assessing the risks to the University posed by the operation of a health clinic.

Note: See Risk Management Policy 2017

(2) Where the operation of a health clinic involves or might involve working with children or vulnerable adults, risk assessments must specifically address the risks posed to such individuals.

Note: See the Working with Children and Vulnerable Adults Policy 2021.

(3) The risk assessment process must:

(a) take into account:

(i) the nature and complexity of the clinical services to be provided;

(ii) the arrangements for provision of those services;

(iii) the type and vulnerability of the likely consumers of the services;

(iv) the degree of participation and supervision of students in provision of the services;

(v) the terms of any agreements or other arrangements with third parties; and

(vi) any other matters specified in procedures;

and then

(b) rate the risk as very high, high, medium or low, using the risk matrix in Schedule One.

22 Governance

(1) All University health clinics must develop, document and maintain (as appropriate) a model of care or service delivery statement for the services delivered at each site at which they operate.

Note: See Agency for Clinical Innovation guidance on models of care
(2) Models of care or service delivery statement documents must include at least the following information:

(a) the name of the health clinic or clinical facility;
(b) a summary of the services provided;
(c) details of location, including whether spaces are exclusive or shared;
(d) details of staffing including:
   (i) full time equivalent numbers, and specialty;
   (ii) student allocations and supervision;
   (iii) working with children check clearances or national criminal record checks (where appropriate);
   
   Note: See Working with Children and Vulnerable Adults Policy 2021.
   (iv) mandatory training and credentialing requirements; and
   (v) vaccination requirements;
(e) scope of activities undertaken and clinic types operating, including:
   (i) inclusion and exclusion criteria; and
   (ii) consent processes;
(f) governance arrangements:
   (i) structure;
   (ii) roles and responsibilities;
   (iii) reporting requirements including those related to reportable conduct or other reports required by the Working with Children and Vulnerable Adults Policy 2021;
   (iv) performance metrics; and
   (v) processes for escalating concerns
(g) identified risks and corresponding mitigation strategies;
(h) funding mechanisms, including:
   (i) arrangements for Medicare billing, payments from health insurers or other third parties and payments from consumers;
   (ii) billing processes;
   (iii) referral criteria; and
   (iv) out-of-pocket charges;
(i) data and records collection methodology and storage requirements;
(j) training, education and associated teaching requirements;
(k) consumer engagement processes; and
(l) consultation processes for practitioners, clinicians, consumers and others involved in development and maintenance of the model of care or service delivery statement document.

(3) The Executive Dean may specify in procedures required formats for models of care or service delivery statements.
Category 1 or Category 2 health clinics must have:

(a) written documentation of the model of care or service delivery statement, approved by the relevant delegates after endorsement by the Independent Medical Assessor and Executive Dean;

Note: See also clauses 9, 18 and 19

(b) a management committee constituted as provided in clause 23;

(c) if operated jointly with a third party, a clinical advisory committee:
   (i) constituted in a manner approved by the relevant delegates; and
   (ii) including at least one member, with expertise in the relevant disciplines of the clinic's operations, who is external to the University; and

(d) other governance arrangements as determined to be appropriate by the Vice-Chancellor or their nominee.

Category 3 health clinics must have:

(a) written documentation of the model of care approved by the relevant delegates after endorsement by the Independent Medical Assessor and the Executive Dean;

Note: See also clauses 9, 18 and 19.

(b) a management committee constituted as provided in clause 23;

(c) a clinical advisory committee:
   (i) constituted in a manner approved by the relevant delegates; and
   (ii) which includes at least one member, with expertise in the relevant disciplines of the clinic's operations, who represents the University; and

(d) other governance arrangements as determined to be appropriate by the relevant delegates.

23 Management

(1) All University health clinics must have clearly defined processes for:
   (a) monitoring operations; and
   (b) reporting and escalating issues for resolution.

(2) All University health clinics must be managed in a manner:
   (a) proportionate to the nature and complexity of the clinical services provided and other activities undertaken;
   (b) consistent with relevant legislation, industry guidelines and codes of conduct;
   (c) consistent with this policy and its associated procedures; and
   (d) consistent any other requirements necessary for the purpose of attaining relevant accreditation or certification.
(3) **Category 1, 2 and 3 health clinics** must have a management committee including:

(a) a member with clinical expertise in each discipline in relation to which the clinic provides clinical services; and

(b) at least one member with expertise in the provision of clinical services of the kind provided by the clinic.

(4) If several University health clinics which are required to have a management committee operate from a single clinical facility they may, with the approval of the relevant delegates, have a single joint management committee.

(5) Health clinics which are not operated jointly with third parties may, with the approval of the relevant delegates, use a clinical facility or precinct management committee as their management committee for the purposes of this policy, with clearly defined monitoring, reporting and escalation pathways.

(6) The relevant delegates may permit a health clinic to have multiple committees discharging the roles and responsibilities of a management committee, if satisfied that this is appropriate for the nature and complexity of clinical services and other activities.

**Note:** For example, a management committee, an operations committee and a clinical committee.

### 24 Reporting

(1) All health clinics must make reports required under the *Working with Children and Vulnerable Adults Policy 2021* as soon as they become aware of reportable matters.

(2) **Category 1, 2 and 3 University health clinics** must provide written reports as specified in this clause to the Clinical Governance and Support Office, which will prepare and distribute reports, including trend analyses of key performance criteria, to:

(a) all participating faculties, University schools, centres and other University organisational units;

(b) the Clinical Governance and Quality Committee; and

(c) the University Executive Audit Committee.

(3) Management committees must establish and implement arrangements for the regular collection and recording of the data necessary for required reports.

(4) All reports must comply with the requirements of the *Privacy Policy 2017* and the *Privacy Procedures 2018*.

(5) **Category 1, 2 and 3 clinics** must provide annual reports on:

(a) asset audits; and

(b) clinical trial activities.

(6) **Category 1 clinics** must provide:

(a) operational reports monthly;

(b) quality and safety reports quarterly; and

(c) corporate reports quarterly.
(7) **Category 2 and 3 clinics** must provide:
   (a) operational reports quarterly;
   (b) quality and safety reports quarterly; and
   (c) corporate reports annually.

(8) **Operational reports** must include, for the period since the last update report:
   (a) occasions of service provided to consumers;
   (b) revenue received;
   (c) relevant workforce reports, including current liability for sick leave and annual leave;
   (d) a summary of key financial and operational data, as specified in the procedures;
   (e) details of reported clinical incidents and near misses;
   (f) issues for escalation, including quality and safety issues;
   (g) details of audits conducted in relation to:
      (i) asset management;
      (ii) environment;
      (iii) work health and safety; and
      (iv) quality and safety processes;
   and
   (h) any other information required by the Clinical Governance and Support Office.

(9) **Quality and safety reports** must include:
   (a) audit results relating to:
      (i) infection control measures;
      (ii) management of medication, poisons and other regulated substances,
      (iii) regulatory compliance; and
      (iv) compliance with protocols;
   (b) progress reports on any improvement plans being implemented;
   (c) clinical incident investigation and trend reports;
   (d) consumer engagement reports; and
   (e) any other information required by the Clinical Governance and Support Office.

(10) **Corporate reports** must include:
   (a) staff numbers, including full time equivalent, and vacancies;
   (b) budget status, including variances;
   (c) work health and safety and workers’ compensation reports;
   (d) details of mandatory training completed;
   (e) status reports for clinical trials and other research activities; and
(f) any other information required by the Clinical Governance and Support Office.

(11) The Clinical Governance and Quality Committee must provide quarterly reports to the University Executive Audit Committee, summarising the information received from clinics identifying and commenting on:
   (a) relevant trends;
   (b) any matters of concern;
   (c) matters escalated for consideration;
   (d) service review reports; and
   (e) any identified risks requiring further consideration.

(12) The reporting framework is summarised diagrammatically in Schedule Two.

25 Review

(1) The relevant delegates must review each University health clinic every three years.

(2) The Clinical Governance and Support Office is responsible for co-ordinating reviews of University health clinics.

(3) In conducting such reviews, the relevant delegate must consider:
   (a) the performance criteria agreed at the time of establishment, and recorded in the record of approval;
   (b) the strategic, research and educational benefits realised by the clinic;
   (c) the clinic’s record in meeting clinical and safety standards required by the model of care or service delivery standards documents;
   (d) the clinic’s record in meeting clinical accreditation requirements, including:
      (i) any applicable professional body accreditation requirements and
      (ii) National Safety and Quality and Health Service Standards, if applicable;
   (e) the clinic’s risk rating;
   (f) financial sustainability; and
   (g) any other matters specified in the procedures.

(4) The relevant delegates may:
   (a) require a review of a clinic at any time; or
   (b) defer a scheduled review;
      regardless of the usual review cycle.

(5) The relevant delegates may specify an alternative review cycle for a clinic.
26 Closure

(1) University health clinics may be closed at the direction of the relevant delegates.

(2) University health clinics may be closed if:
   (a) the clinic has ceased activity;
   (b) the clinic has failed to meet clinical and safety standards required by model of care or service delivery standard documents, including those relating to the protection of children or vulnerable adults;
   (c) the clinic has failed to meet any relevant professional accreditation requirements, or lost any required accreditation;
   (d) the clinic has failed to meet a requirement imposed by a regulator;
   (e) there are significant unmanaged risks associated with the clinic;
   (f) the clinic has failed to meet objectives recorded in its model of care or service delivery standard documents;
   (g) the clinic is found on review to be financially unsustainable; or
   (h) a review has recommended closure.

(3) The process for changing or closing clinics must be managed in the manner specified in the procedures, except that the relevant delegates may direct immediate closure if satisfied that there is evidence of a serious breach of policy, regulatory or other requirements.

27 Transitional provisions

(1) University health clinics already established at the date of commencement of this policy must achieve compliance with the requirements of this policy within:
   (a) two years of the date of commencement of the policy; or
   (b) any other date determined on a case-by-case basis by the relevant delegates.

(2) A clinic which fails to achieve compliance within the time required by subclause 26(1) will be reviewed as provided in clause 24, regardless of whether or not a review would otherwise be required.

PART 3 – CLINICAL FACILITIES

28 Principles

(1) The University will only provide clinical facilities if doing so is consistent with its objects and functions under the University of Sydney Act 1989 (NSW) and the University’s strategic goals.

Note: See Strategic Plan 2016 – 2020
(2) University clinical facilities should:
(a) add value to the University’s activities;
(b) support its research and education activities;
(c) provide a substantial benefit to community stakeholders; and
(d) generate revenue or profits for the University’s benefit.

(3) University clinical facilities must not engage in activities:
(a) inconsistent with the University’s vision and values;
(b) inconsistent with the University’s strategic goals;
(c) inconsistent with the ethical and clinical practice requirements of relevant professional and accreditation bodies; or
(d) which could bring the University into disrepute.

(4) University clinical facilities must be financially sustainable.

(5) A University clinical facility must not:
(a) operate on lands which are not University lands; or
(b) use an external party’s resources;

without a written agreement between the University and the external party relevant to the operation of the clinical facility.

(6) University clinical facilities must:
(a) only operate with the approval of the relevant delegates, obtained consistently with this policy and, where required, with the Working with Children and Vulnerable Adults Policy 2021;
(b) operate in a safe manner for all, including consumers, clinical research participants, staff and students;
(c) Note: See Work Health and Safety Procedures 2016 and specific work health and safety performance standards. See also Working with Children and Vulnerable Adults Policy 2021 comply with the Clinical Governance Framework; and
(d) only engage in commercial activities approved under the Guidelines Concerning Commercial Activities.

29 Establishing new clinical facilities

(1) New University clinical facilities may only be established with the approval of the relevant delegates.

Note: See University of Sydney (Delegations of Authority) Rule 2020

(2) Any faculty, University school or centre proposing to establish a clinical facility must submit a written proposal to the Clinical Governance and Support Office.

(3) The proposal must include:
(a) the identity of the faculty, University school or centre which will be responsible for the proposed clinical facility;
(b) a detailed role description of the clinical services to be provided;
(c) detailed descriptions of:
   (i) all intended uses of the premises; and
   (ii) the scope of practices to be provided;

(d) a draft of the proposed model of care;

(e) the physical location of the proposed clinical facility;

(f) an initial risk assessment for the proposed clinical facility, including any risk assessment required by the Working with Children and Vulnerable Adults Policy 2021 if the facility may be involved in providing services to such individuals;

(g) a business case for the establishment of the clinical facility, including provision of necessary facilities and equipment;

(h) an indicative annual budget for operating the clinical facility for an initial period of three years;

(i) details of the strategic, research and or education benefits of the proposed clinical facility and how these will be maintained on an ongoing basis; and

(j) all other information required by the procedures.

The Clinical Governance and Support Office will:

(a) review the proposal;

(b) if necessary, work with the proponent to amend and improve it;

(c) if relevant, liaise with relevant delegates in relation to any approval required under the Working with Children and Vulnerable Adults Policy 2021; and

(d) make a recommendation to the relevant delegates and any required endorsers about whether the final proposal should be approved.

The relevant delegates may only approve the establishment of a clinical facility:

(a) after endorsement by each of:
   (i) the Independent Medical Assessor;
   (ii) the Executive Dean; and
   (iii) the Clinical Governance and Quality Committee;

(b) after any required approval relating to the provision of services to children has been obtained; and

Note: See the Working with Children and Vulnerable Adults Policy 2021.

(c) if they are satisfied that:
   (i) the proposal provides all the required information;
   (ii) the clinical facility would be consistent with this policy, particularly the principles set out in clause 27;
   (iii) the risks posed are within the University’s Risk Appetite and Tolerance Statement; and
   (iv) the clinical facility is likely to be financially sustainable.
New clinical facilities must be:

(a) approved for an initial period of five years except as varied by the relevant delegates; and
(b) be reviewed after the initial period, as provided in clause 33.

30 Risk assessment for clinical facilities

(1) The risk assessment process for new or varied University clinical facilities will be undertaken by the University Infrastructure professional services unit.

(2) The risk assessment must:

(a) be consistent with all policies, procedures and other process requirements for undertaking capital works and managing infrastructure at the University, including but not limited to:
   (i) Space Management Policy 2012;
   (ii) Building Projects Approval and Management Policy 2014;

(b) take into account:
   (i) all intended uses for the premises;
   (ii) the operating plan for the premises;
   (iii) the nature and complexity of the clinical services to be provided;
   (iv) the arrangements for provision of those services;
   (v) the type and vulnerability of the likely consumers of the services;
   (vi) the degree of participation and supervision of students in provision of the services;
   (vii) the terms of any agreements or other arrangements with third parties; and
   (viii) any other matters specified in the procedures;

and then

(c) rate the risk as very high, high, medium or low, using the risk matrix in Schedule One.

31 Governance

(1) Governance arrangements for University clinical facilities must be proportionate to the nature and complexity of the uses to which they are put.

(2) Each clinical facility must have:

(a) a written statement of the terms and conditions upon which it operates and upon which access is provided to users (whether individuals or user groups);
(b) a management committee, constituted as provided in clause 29; and
(c) other governance arrangements as determined to be appropriate by the relevant delegates.
32 Management

(1) Clinical facilities must have:
   (a) an operations manager, with experience and qualifications appropriate to the size and complexity of the facility;
   (b) administrative and operational staff, appropriate to the size and complexity of the clinical services and other activities undertaken there; and
   (c) a management committee, including:
      (i) a member representing each clinic or other user (whether a group or an individual clinician) of the facility; and
      (ii) the clinical facility operations manager; and
      (iii) at least one additional member with expertise in clinic operations.

(2) The relevant delegates may permit a clinical facility to have multiple committees discharging the roles and responsibilities of a management committee, if satisfied that this is appropriate for the nature and complexity of clinical services and other activities.

Note: For example, a management committee, an operations committee and a clinical committee.

33 Reporting

(1) Clinical facility management committees must provide:
   (a) operational reports to the Clinical Governance and Support Office quarterly, or at a frequency determined by the Clinical Governance and Support Office; and
   (b) corporate reports quarterly to:
      (i) the Vice-Chancellor or their nominee;
      (ii) the Vice-Principal (Operations); and
      (iii) the Clinical Governance and Quality Committee.

(2) Clinical facility management committees must establish and implement arrangements for the regular collection and recording of the data necessary for required reports.

(3) Operational reports must include, for the period since the last such report:
   (a) occasions of service provided to consumers;
   (b) a summary of clinical incidents, including:
      (i) their severity;
      (ii) how they were managed;
      (iii) the clinics involved;
(c) Numbers of each of the following using the facility:
   (i) clinics;
   (ii) staff and affiliates providing clinical services;
   (iii) consumers;
   (iv) research participants;
   (v) students;
(d) details of users of the facility, including equipment used and period of time for which the facility was used by each user;
(e) details of activities and outcomes relating to:
   (i) quality improvement;
   (ii) risk management;
   (iii) performance against performance metrics and action plans;
   (iv) feedback and complaints; and
(f) any other information required by the Clinics and Governance & Support office.

(4) **Corporate reports** must include:
   (a) a summary of the information provided in operational reports;
   (b) a financial statement, in the form specified in the procedures; and
   (c) any other information required by the procedures.

(5) The **Clinical Governance and Quality Committee** must provide quarterly reports to the University Executive Audit Committee, summarising the information received from clinical facilities identifying and commenting on:
   (a) relevant trends;
   (b) any matters of concern;
   (c) matters escalated for consideration;
   (d) service review reports; and
   (e) any identified risks requiring further consideration.

(6) The reporting framework is summarised diagrammatically in Schedule Two.

### 34 Review

(1) The Executive Dean, in consultation with the Independent Medical Assessor, must arrange for each clinical facility to be inspected annually by a person qualified to assess the adequacy of the facilities for the purposes of the clinical services provided in them.

(2) The person conducting the inspection must provide a written report addressing matters including, but not limited to:
   (a) whether the facilities and equipment are being correctly used and maintained;
   (b) the degree to which the facility is appropriate for the uses to which it is put;
(c) whether the facility is safe for continued use;
(d) recommendations for required or desirable improvements to the facility;
(e) the likely costs of such improvements; and
(f) any other matter required by the procedures.

(3) Copies of the report must be provided to:
(a) the Vice-Principal (Operations);
(b) the Vice-Chancellor or their nominee;
(c) the Clinical Governance and Quality Committee; and
(d) anyone else nominated by the Executive Dean of the Faculty of Medicine and Health.

(4) Each clinical facility must be formally reviewed every three years after the initial five-year period of operation.

(5) The Clinical Governance and Support Office is responsible for co-ordinating inspections and reviews of University clinical facilities.

35 Closure

(1) Clinical facilities may be closed at the direction of the relevant delegates.

(2) Clinical facilities may be closed if:
(a) the clinical facility is not considered safe for continued use;
(b) the clinical facility has failed:
   (i) to meet a requirement imposed by a regulator; or
   (ii) to comply with this policy; or
(c) a review has recommended closure.

(3) The process for changing or closing clinical facilities must be managed in the manner specified in the procedures, except that the relevant delegates may direct immediate closure if satisfied that there is evidence of a serious breach of policy, regulatory or other requirements.

36 Transitional provisions

University clinical facilities already established at the date of commencement of this policy must achieve compliance with the requirements of this policy within:

(a) two years of the date of commencement of the policy; or
(b) any other date determined on a case by case basis by the relevant delegates.
PART 4 – ROLES AND RESPONSIBILITIES

37 Roles and Responsibilities

(1) All clinic and clinical facility staff are responsible for:

(a) familiarising themselves with the requirements of:

(i) this policy;
(ii) the procedures;
(iii) protocols applicable to their role and work;
(iv) legislative and regulatory requirements; and
(v) professional accreditation requirements relevant to their practice or the clinic in which they work;

and

(b) complying with their legislative, regulatory, professional and policy obligations.

(2) Clinic management committees are responsible for:

(a) managing the clinic consistently with its objectives, legal and regulatory requirements and University rules, policies and procedures;

(b) establishing and implementing systems demonstrating compliance with the Clinical Governance Framework, this policy, the procedures and all applicable protocols;

(c) managing and continuously improving the safety and care of consumers, and ensuring the safety of all persons involved in their clinics;

(d) reviewing and reporting on performance as required by this policy, the procedures and all applicable protocols;

(e) establishing and maintaining systems to collect and record data necessary for reports;

(f) recording accurate financial information and providing financial reports as required;

(g) providing other reports and plans as required by the procedures;

(h) monitoring the management of any staff directly attached to the clinic.

(i) monitoring the management of fixed assets and equipment attached to the clinic;

(j) monitoring the management of quality and accreditation processes required to ensure clinic continuation; and

(k) reporting on and appropriately escalating any issues of concern as they relate to clinical safety and quality.

(3) Clinical advisory committees are responsible for:

(a) providing advice on a clinic’s strategy, operations and direction;

(b) providing advice on continuously improving the safety and care of consumers, and the safety of all persons involved in the clinic;
(c) providing advice on protocols, patient management, and other requirements to ensure compliance with the Clinical Governance Framework and any relevant certification or accreditation; suggest facility operations committee

(d) reporting and appropriately escalating any issues of concern as they relate to clinical safety and quality;

(e) establishing and maintaining systems to collect and record data necessary for reports;

(f) monitoring compliance with relevant legislation, guidelines and codes of conduct.

(4) Clinical facility operations managers are responsible for:

(a) supporting and servicing the needs of clinics and other users, including provision of appropriate resources;

(b) managing and continuously improving the safety and care of consumers;

(c) establishing appropriate measures to protect the safety of all persons attending their clinical facility;

(d) managing staff directly attached to the clinical facility;

(e) complying with the Clinical Governance Framework; and

(f) reporting and appropriately escalating any issues of concern as they relate to clinical safety and quality.

(5) Clinical facility management committees are responsible for:

(a) managing the operations of the clinical facility in a safe manner, in compliance with legal and regulatory requirements and University rules, policies, procedures and applicable protocols;

(b) establishing and implementing systems for compliance with the Clinical Governance Framework, the procedures and all applicable protocols;

(c) reviewing and reporting on performance as required by this policy, the procedures and all applicable protocols;

(d) providing other reports and plans as required;

(e) managing any staff directly attached to the clinical facility; and

(f) appropriately escalating any issues of concern as they relate to clinical safety and quality.

(6) The Clinical Governance and Support Office is responsible for:

(a) developing and embedding the Clinical Governance Framework, to ensure consistent high-quality clinical care and service provision which supports clinical education and research;

(b) leading the University’s continuous improvement of clinical safety and quality;

(c) advising the relevant delegates about applications from University health clinics for exemption from the Clinical Governance Framework;

(d) considering, and where appropriate endorsing, models of care and service delivery statements proposed for Category 1, 2 or 3 health care clinics;

(e) assisting management committees, c and operations staff to provide and continuously improve safe, quality clinical care;
(f) monitoring clinical incident information, consistently with this policy, the procedures and all applicable protocols;

(g) advising on clinical incidents, consistently with this policy, the procedures and all applicable protocols;

(h) providing advice on protocols, patient management, and other requirements to ensure compliance with any relevant certification or accreditation;

(i) monitoring compliance with relevant legislation, guidelines and codes of conduct; and

(j) co-ordinating reviews of University health clinics and clinical facilities.

(7) The Executive Dean is responsible for:

(a) determining procedures for risk assessment under clause 20;

(b) chairing the Clinical Governance and Quality Committee;

(c) directing the implementation of the Clinical Governance Framework through the development of the procedures and protocols as required by clause 11;

(d) arranging the review of clinical facilities under clause 32;

(e) receiving, considering and, where appropriate, acting upon, advice from the Independent Medical Assessor and Clinical Governance and Quality Committee;

(f) receiving, considering and, where appropriate acting upon, reports from staff of the Clinics Support and Governance Office.

(8) The Independent Medical Assessor is responsible for:

(a) after consultation with the relevant management committees, considering and if appropriate endorsing:
   (i) proposals for new University health clinics;
   (ii) proposals for varying services provided by existing health clinics; and
   (iii) the models of care and statements of service delivery of category 1, 2 or 3 health clinics;

(b) reporting to the Clinical Governance and Quality Committee;

(c) advising the relevant delegates about applications from University health clinics for exemption from the Clinical Governance Framework;

(d) advising the Executive Dean about processes to be undertaken when assessing risks to the University posed by the operation of a health clinic; and

(e) considering, and where appropriate endorsing, models of care and service delivery statements proposed for Category 1, 2 or 3 health clinics.

(9) The relevant delegates are jointly responsible for:

(a) approving the establishment, governance arrangements, and reporting arrangements of clinics and clinical facilities;

(b) overseeing the review, variation to or closure of clinics and clinical facilities;

(c) approving exceptions to the naming requirements of this policy;
(d) providing copies of reports and reviews to the Group Secretary as required;
(e) determining the *Health Clinics and Clinical Services Policy*.

(10) The **Clinical Governance and Quality Committee** is responsible for:

(a) monitoring, and receiving reports on, the operations of clinics and clinical facilities, as required by this policy, the procedures and any applicable protocols;
(b) providing a forum for discussion of obstacles and issues that pose a risk to the strategic intent or standard of clinical care offered by University health clinics or clinical facilities;
(c) reporting to the University Executive Audit Committee about the operations of clinics and clinical facilities, particularly in relation to the occurrence and management of clinical incidents;
(d) where appropriate, escalating matters for consideration to the University Executive Audit Committee;
(e) advising the relevant delegates in relation to the governance, management and strategic operation of clinics and clinical facilities.

(11) The **University Executive Audit Committee** is responsible for:

(a) monitoring the operations of clinics and clinical facilities, through the Clinical Governance and Quality Committee;
(b) receiving reports on the operations of clinics and clinical facilities, as required by the Clinical Governance Framework, this policy, the procedures and applicable protocols; and
(c) reporting to the Vice Chancellor and the Senate Strategy and Risk Committee on issues of concern in relation to the operations of clinics and clinical facilities, particularly the occurrence and management of clinical incidents; and
(d) where appropriate, escalating matters for consideration to either or both of the Vice-Chancellor and the Senate Strategy and Risk Committee.
### SCHEDULE ONE

#### RISK MATRIX

<table>
<thead>
<tr>
<th>Potential Consequences</th>
<th>Class 1</th>
<th>Class 2</th>
<th>Class 3</th>
<th>Class 1b/1c</th>
<th>Class 3c</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor injuries or physical discomfort, short-term psychological impact (isolated or one-off event)</td>
<td>Minor</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
<tr>
<td>Injury or illness requiring medical treatment and/or short-term impairment (less than 2 weeks)</td>
<td>Minor</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
<tr>
<td>Injury or illness requiring hospital admission and/or temporary impairment (less than 6 months)</td>
<td>Minor</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
<tr>
<td>Injury or illness requiring medical treatment, psychological impact, requiring support,</td>
<td>Minor</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
<tr>
<td>Injury or illness (physical or psychological) resulting in long-term or permanent impairment (more than 6 months)</td>
<td>Minor</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
<tr>
<td>Injury or illness resulting in long-term or permanent impairment to multiple people.</td>
<td>Minor</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Almost Certain</th>
<th>Likely</th>
<th>Possible</th>
<th>Unlikely</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected to occur regularly under normal circumstances</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Expected to occur at same time</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>May occur at same time</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Not likely to occur in normal circumstances</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Could happen, but probably never will</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
<td>Medium</td>
<td>Low</td>
</tr>
</tbody>
</table>
SCHEDULE TWO

SUMMARY OF REPORTING FRAMEWORK as at 20 August 2020

20 October 2020
NOTES

Health Clinics and Clinical Services Policy 2020

Date adopted: 21 September 2020
Date commenced: 1 October 2020
Administrator: Executive Dean, Faculty of Medicine and Health
Review date: 1 October 2025
Rescinded documents: None
Related documents:

- Therapeutic Goods Act 1989 (Cth)
- Poisons Standard 2020 (Cth)
- Child Protection (Working with Children) Act 2012 (NSW)
- Children’s Guardian Act 2019 (NSW)
- Government Information (Public Access) Act 2009 (NSW)
- Health Records and Information Privacy Act 2002 (NSW)
- Human Tissue Act 1983 (NSW)
- Poisons & Therapeutic Goods Act 1966 (NSW)
- Poisons & Therapeutic Goods Regulations 2008 (NSW)
- Privacy and Personal Information Protection Act 1998 (NSW)
- University of Sydney (Campus Access) Rule 2009
- University of Sydney (Delegations of Authority) Rule 2020
- Guidelines Concerning Commercial Activities
- Building Projects Approval and Management Policy 2014
- Children in University Workplaces and Premises Policy
- Clinical Trials Policy 2016
- Code of Conduct – Staff and Affiliates
- Privacy Policy 2013
- Working with Children and Vulnerable Adults Policy 2021
AMENDMENT HISTORY

<table>
<thead>
<tr>
<th>Provision</th>
<th>Amendment</th>
<th>Commencing</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Definitions of ‘affiliate’, ‘delegate’ and ‘reportable conduct’ amended.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>6</td>
<td>Definitions of ‘child’, ‘clinic’, ‘material change’, ‘near miss’ and ‘vulnerable adult’ added.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>7(2)</td>
<td>Sub-clause amended to add 7(2)(d) and Note</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>12(a)</td>
<td>Sub-clause amended</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>12(a)(b)(iii)</td>
<td>Link to National Safety and Quality Health Service Standards added</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>Section</td>
<td>Change Description</td>
<td>Date</td>
</tr>
<tr>
<td>---------</td>
<td>--------------------</td>
<td>------------</td>
</tr>
<tr>
<td>12(3)(b)</td>
<td>Sub-clause amended to include ‘rights and responsibilities’.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>12(6)(b)</td>
<td>Note amended to include link to ‘Working With Children and Vulnerable Adults Policy 2021’.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>19(1)</td>
<td>Note updated to include link to ‘University of Sydney (Delegations of Authority) Rule 2020’.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>19(4)(g)</td>
<td>New sub-clause added</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(1)</td>
<td>‘variation’ replaced by ‘material change’.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(2)</td>
<td>‘variation’ replaced by ‘material change’ and ‘but is not limited to’ added.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(2)</td>
<td>Addition of sub-clauses (e), (f) and (g)</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(4)</td>
<td>‘vary the clinical services it provides’ replaced by ‘implement a material change’</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(5)</td>
<td>‘variation’ replaced by ‘material change’</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(6)</td>
<td>amended</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>20(8)</td>
<td>amended</td>
<td>27 October 2021</td>
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<tr>
<td>21(2)</td>
<td>New sub-clause and Note added.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>22(d)(iii)</td>
<td>New sub-clause and Note added.</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>22(f)(iii)</td>
<td>amended</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>24(1)</td>
<td>New clause added</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>26(2)(b)</td>
<td>Addition of ‘including those relating to the protection of children or vulnerable adults added</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>28(6)(a)</td>
<td>amended</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>28(6)(b)</td>
<td>Note amended</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>29(1)</td>
<td>Note amended to include updated link to Delegations of Authority Rule</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>29(1)(f)</td>
<td>amended</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>29(4)(c)</td>
<td>New sub-clause added</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>29(5)(b)</td>
<td>Note added</td>
<td>27 October 2021</td>
</tr>
<tr>
<td>30(1)</td>
<td>Professional services unit added</td>
<td>27 October 2021</td>
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</tbody>
</table>