HEALTH CLINICS AND CLINICAL SERVICES PROCEDURES 2020

Issued by:	Executive Dean, Faculty of Medicine and Health
Dated:	17 December 2020 (commencing 13 January 2021)
Last amended:	
Signature:	
Name:	Professor Robyn Ward

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1 Purpose and application

(1) These procedures are to give effect to the *Health Clinics and Clinical Services Policy 2020* ("the policy").

(2) These procedures apply to:

- (a) the University, staff, students and affiliates;
- (b) all University health clinics;
- (c) any other health clinic which is contractually bound to follow these procedures, or particular clauses within these procedures.

(3) These procedures do 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 or not they receive a clinical loading as part of their employment);
- (c) affiliates undertaking clinical work outside their University engagement; or
- (d) the provision of veterinary services.

2 Commencement

These procedures commence on 13 January 2021.

3 Interpretation

(1) Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have in the policy.

Note: See clause 6 of the policy.

(2) In these procedures:

Category # Clinic	means a health clinic at the level designated by the number in the description, e.g. Category 2 Clinic, as provided in the clinic classification system established by clause 16 of the policy.
proponent	means the most senior person proposing the establishment or variation of a health clinic
protocol	means a document stating requirements for the conduct of a clinic's or clinical facilities operations, including provision of care consistently with its model of care.

4 Establishing University health clinics (Categories 1-3 Clinics)

(1) Proposals to establish a new University health clinic must be:

(a) submitted by the proponent, who must be the relevant Head of School or higher position;

(b) made in writing using the New Clinic Checklist; and

(c) submitted to the Clinical Governance and Support Office.

(2) The Clinical Governance and Support Office will review the proposal and may:

(a) request further information from the proponent; and

(b) require amendments or improvements to the proposal.

(3) The Clinical Governance and Support Office will evaluate the proposal and provide a copy of the proposal and a written summary of its evaluation to each of:

(a) the Independent Medical Assessor;

(b) the Executive Dean; and

(c) the Clinical Governance and Quality Committee.

(4) Each of the those listed in subclauses 4(3)(a) – (c) will:

(a) review the proposal and evaluation; and

(b) inform the Clinical Governance and Support Office in writing of:

(i) whether or not they endorse the proposal; and

(ii) their reasons for doing so.

(5) The Clinical Governance and Support Office will provide the relevant delegates with:

(a) the proposal and all accompanying documents;

(b) a copy of the evaluation of the proposal;

(c) a copy of the response of each of:

(i) the Independent Medical Assessor; and

(ii) the Executive Dean; and

(d) a recommendation about whether or not the proposal should be approved.

(6) The relevant delegates will inform the Clinical Governance and Support Office of their decision, and the Clinical Governance and Support Office will inform each of the following of the outcome:

(a) the proponent;

(b) the Independent Medical Assessor;

(c) the Executive Dean; and

(d) the Group Secretary in the Office of General Counsel.

(7) The Group Secretary will record the details of the clinic in the University's register of entities.

5 Establishing health clinics operated by external entities (Categories 4-5 Clinics)

(1) Proposals to establish a new University health clinic must be:

(a) submitted by the proponent, who must be the relevant Head of School or higher position;

(b) made in writing using the New Clinics Checklist; and

(c) submitted to each of:

(i) the Clinical Governance and Support Office;

(ii) University Infrastructure.

(2) The proposal must include:

(a) a business case and financial projections;

(b) proposed insurance arrangements;

(c) details of proposed model of care or service delivery statement;

(d) details of the proposed terms of operation as between the University and the relevant third party;

(e) details of the proposed governance structure for the clinic, including who is to be responsible for managing and overseeing clinical governance;

(f) if it is proposed that research may be conducted at the clinic, details of likely research as far as they are known; and

(g) if it is proposed that clinical trials may be conducted at the clinic, details of likely clinical trials as far as they are known.

(3) The Clinical Governance and Support Office and University Infrastructure will jointly review the proposal and make a joint recommendation to the relevant delegates as to whether it should be approved.

(a) The Clinical Governance and Support Office and University Infrastructure will consult the Research Integrity Office and Clinical Trials Office if appropriate, before deciding on a recommendation.

(b) If the Clinical Governance and Support Office and University Infrastructure are unable to agree on a joint recommendation, then the recommendation must be that the proposal does not proceed.

(4) The relevant delegates may only approve establishment of a Category 4 or Category 5 health clinic if satisfied that:

(a) the proposal is consistent with the principles set out in clause 15 of the policy;

(b) the proposed model of care, service delivery statement and other terms of operation of the health clinic are:

(i) appropriate; and

(ii) do not represent an unacceptable risk to the University; and

(c) there is or will be a binding written agreement between the University and the other party or parties involved in its operation which addresses the issues specified in subclause 5(3).

(5) Agreements between the University and other parties involved in the operation of Category 4 or Category 5 clinics must:

(a) be in a form approved by the Office of General Counsel;

(b) specify the required insurance arrangements for the health clinic and its operations;

(c) provide that records of privately seen consumers:

(i) are the property of the treating clinician;

(ii) may only be accessible to the treating clinician; and

(iii) must be taken by that clinician at the end of their involvement with the clinic;

and

(d) provide:

(i) that clinical incidents occurring in the clinic must be managed under agreed clinical governance arrangements by the other party or parties, and are not the responsibility of the University; or

(ii) the basis on which responsibility for managing them will be allocated.

6 Establishing clinical facilities

(1) Initial proposals to establish a new University clinical facility must be:

(a) submitted by a proponent, who must be the Head of School or higher;

(b) made in writing using the New Clinics Checklist and

(c) submitted to the Clinical Governance and Support Office.

(2) The Clinical Governance and Support Office will review the proposal and may:

(a) request further information from the proponent; and

(b) require amendments or improvements to the proposal.

(3) The Clinical Governance and Support Office will evaluate the proposal and provide a copy of the proposal and a written summary of its evaluation to each of:

(a) the Independent Medical Assessor;

(b) and the Executive Dean; and

(c) the Clinical Governance and Quality Committee.

(4) Each of the those listed in subclauses 6(3)(a) – (c) will:

(a) review the proposal and evaluation; and

(b) inform the Clinical Governance and Support Office in writing of:

(i) whether or not they endorse the proposal; and

(ii) their reasons for doing so.

(5) If the Clinical Governance and Support Office is satisfied at this point that the proposal would be viable, it will notify the proponent of this conclusion.

(6) The proponent must then lodge a proposal for either or both of building or capital works (as appropriate) with University Infrastructure.

Note: See the *Building Projects Approval and Management Policy 2014* and the *Space Management Policy 2012*.

(a) The proponent is responsible for the conduct of the building and capital work approval process, but may ask for assistance from the Clinical Governance and Support Office if required.

(7) If support and budget for the project is obtained from University Infrastructure, through the applicable building and capital works processes, the Chief University Infrastructure Officer will inform the proponent and the Clinical Governance and Support Office.

(8) The Clinical Governance and Support Office will then provide the relevant delegates with:

(a) the proposal and all accompanying documents;

(b) copies of all relevant approvals and endorsements obtained through the building and capital work approval process;

(c) a copy of the evaluation of the proposal;

(d) a copy of the response of each of:

(i) the Independent Medical Assessor; and

(ii) the Executive Dean; and

(e) a recommendation about whether or not the proposal should be approved.

(9) The relevant delegates will inform the Clinical Governance and Support Office of their decision, and the Clinical Governance and Support Office will inform each of the following of the outcome:

(a) the proponent;

(b) the Independent Medical Assessor;

(c) the Executive Dean; and

(d) the Group Secretary in the Office of General Counsel.

(10) The Group Secretary will record the details of the clinical facility in the University's register of entities.

(11) Other parties must not be

(a) involved in the operation of a University clinical facility; or

(b) provide clinical services from a University clinical facility

without a formal written agreement with the University.

(12) Such agreements must:

(a) be in a form approved by the Office of General Counsel;

(b) specify the required insurance arrangements for the parties;

(c) provide that records of privately seen consumers:

(i) are the property of the treating clinician;

(ii) may only be accessible to the treating clinician; and

(iii) must be taken by that clinician at the end of their involvement with the clinical facility;

and

(d) provide appropriately for the management of, and responsibility for, clinical incidents occurring at the facility.

7 Business case documents

(1) Any business case required by the policy must be documented in writing.

(2) Business cases must:

(a) identify all relevant local government and other approval authorities;

(b) specify appropriate communication pathways with each of these authorities;

(c) specify all clinical practices and activities proposed to be conducted;

(d) identify positions responsible for the provision of all clinical services at the site;

(e) describe the governance and management systems which will apply at the facility, and the allocation of responsibilities between the University and any external party;

(f) specify the process by which the protocols required by clause 10 of the policy and clause will be developed and maintained for each clinic or clinical service to be provided, and who will be responsible for them;

(g) provide full details, and where appropriate copies, of all registrations, accreditations, and compliance confirmations necessary for any proposed external party to be involved in the clinical facility.

(3) Business cases must be provided using the template available from the clinical governance website.

8 Model of care and service delivery statements

(1) Models of care and service delivery statements must:

(a) be focussed on the patient or participant, and take into account their cultural norms and practices;

(b) support a culture of safety and quality in service delivery;

(c) be flexible and equitable in their operation;

(d) meet the strategic intent of the clinic or clinical facility;

(e) provide standardised performance and evaluation measures; and

(f) provide a comprehensive list of all procedures or interactions conducted in the clinic or clinical facility and the steps involved in each.

(2) No change may be made to the model of care or statement of service delivery document approved at the time a clinic or clinical facility is established otherwise than as provided in this clause.

(a) The Clinic Manager or the relevant medical lead must provide a copy of the proposed amendments to the Clinical Governance and Support Office.

(b) The Clinical Governance and Support Office will review the proposed amendments and decide if they are:

(i) minor variation, with low risk;

(ii) moderate variation with low risk, or minor variation with medium risk;

(iii) significant variation, or variation with high risk; or

(iv) complete change, introduction of new practice, device or location, or very high risk.

(c) The Clinical Governance and Support Office, after consulting the Independent Medical Assessor, may approve minor variations with low risk.

(d) For moderate variations with low risk or minor variations with medium risk:

(i) the Clinical Governance and Support Office will provide a copy of the proposed variation to the Independent Medical Assessor;

(ii) each of the Clinical Governance and Support Office and the Independent Medical Assessor will evaluate the proposed variation and provide a recommendation to the Executive Dean;

(iii) the Executive Dean, after considering the recommendations, will determine whether or not to approve the variation.

(e) For significant variations, or those with high risk:

(i) the Clinical Governance and Support Office will provide a copy of the proposed variation to the Independent Medical Assessor and the Executive Dean;

(ii) each of the Clinical Governance and Support Office, the Independent Medical Assessor and the Executive Dean will evaluate the proposed variation and provide a recommendation to the Clinical Governance and Quality Committee;

(iii) the Clinical Governance and Quality Committee will consider the proposed variation and the recommendations and decide whether or not to endorse the proposal;

(iv) if the Clinical Governance and Quality Committee decides to endorse the proposed variation, the Executive Dean will decide whether or not to approve it;

(v) if the Clinical Governance and Quality Committee decides not to endorse the proposed variation, the proposed variation may only be approved by the relevant delegates;

(vi) complete changes, introductions of new practices devices or locations, or proposed amendments which are high risk must proceed as for the establishment of a new University health clinic.

Note: See clause 17 of the policy, and clauses 4 and 5 of these procedures

9 Risk assessment

(1) The proponent must:

(a) complete the initial risk assessment:

(i) in the required form Risk Assessment template; and

(ii) attaching all required supporting documents;

and

(b) submit it to the Clinical Governance and Support Office.

(2) The Clinical Governance and Support Office must review the initial risk assessment and categorise the risks to the University posed by the proposal as one of:

(a) low;

(b) medium;

(c) high; or

(d) very high.

(3) The Clinical Governance and Support Office may require the proponent to submit further information to assist with its risk assessment.

(4) If a proposal is assessed as very high or high risk, the Clinical Governance and Support Office will:

(a) provide advice to the proponent about risks; and

(b) where possible, assist them to develop a plan to mitigate those risks.

(5) The Clinical Governance and Support Office may permit a proponent to submit a revised risk assessment application and supporting documents for reassessment.

(6) The Clinical governance and Support Office will consider the initial or revised risk assessment (as appropriate) and:

(a) determine a final risk rating; and

(b) make a recommendation about whether or not the University should approve the proposal.

(7) The Clinical Governance and Support Office must provide to the proponent:

(a) the final risk rating;

(b) an explanation of the basis for the rating; and

(c) the recommendation about whether or not the University should approve the proposal.

(8) The Clinical Governance and Support Office must also provide copies of the final risk assessment, reasons and recommendation to:

(a) any person or committee whose endorsement is required for the proposal to proceed; and

(b) the relevant delegates.

10 Protocols

(1) The Clinic Manager, in consultation with the relevant medical leads, is responsible for developing and maintaining all required protocols.

(2) Protocols, including any proposed amendments to existing protocols, must be:

(a) submitted to the Clinical Governance and Support Office in writing at least two months before they are scheduled to be implemented;

(b) approved by the Clinical Governance and Support Office before they are implemented; and

(c) recorded by each of the clinic or clinical facility and the Clinical Governance and Support Officer in a manner which identifies changes made and when they were made.

(3) In exceptional circumstances, the Clinical Governance and Support Office, after consultation with the Independent Medical Assessor, may permit a proposed amendment to a protocol to be implemented on an interim basis before it is finally approved.

(4) **Governance and leadership protocols** must specify:

(a) local governance, reporting and escalation pathways;

(b) the model of care or service delivery statement for each site;

(c) how consumer confidential information, including health care and service records, is managed;

(d) how clinical incidents and near misses are managed and reported;

(e) how feedback is managed, including responding to complaints;

(f) the process for credentialing staff, students, clinicians and visitors;

(g) supervision requirements for staff, students, clinicians and visitors;

(h) processes for obtaining and maintaining necessary accreditations where required;

(i) the requirements for records of education and training of staff and students, including professional development, to maintain best practice service delivery;

(j) the requirements for recording health screening and vaccination information for staff, students, clinicians and visitors; and

(k) business continuity plans for emergencies, disasters or similar events.

(5) **Consumer engagement** protocols must specify:

(a) the process by which consumers are to be informed about and involved in:

(i) their care; and

(ii) where relevant, the design of clinics or clinical facilities; and

(b) the processes by which feedback is to be obtained from and provided to consumers.

(6) **Safe environment** protocols must specify processes for:

(a) managing assets, including:

(i) maintaining facilities and equipment;

(ii) appropriate disposal of equipment; and

(iii) cleaning requirements and schedules;

(b) identifying, assessing and managing risk;

(c) infection control processes;

(d) managing clinical waste and other biohazardous substances; and

(e) medication and regulated substance management processes;

Note: See also *Work Health and Safety Policy 2016*; *Work Health and Safety Procedures 2016*; *Risk Management Policy 2017*

(7) **Performance and monitoring** protocols must specify:

(a) metrics for clinical and operational performance;

(b) audit requirements; and

(c) reporting mechanisms.

(8) **Process protocols** must:

(a) define the process used within the health clinic or facility to:

(i) deliver care;

(ii) acquire information; or

(iii) deliver educational experiences.

(b) specify the following:

(i) the purpose of the protocol;

(ii) the intended audience;

(iii) definitions of relevant terms;

(iv) expected outcomes of the process, including complications;

(v) staff and resources required;

(vi) from whom referrals will be accepted;

(vii) consent requirements;

(viii) criteria for including or excluding a participant from the process;

(ix) equipment required to handle the process safely;

(x) all steps to be followed during the interaction;

(xi) requirements for information to be entered into relevant patient management systems;

(xii) recordkeeping requirements, including for consent records, clinical record, medication records and research records;

(xiii) billing processes including cost centres, distributions between cost centres, fees charged, Medicare codes and billing mechanism;

(xiv) infection control guidelines;

(xv) medication management requirements;

(xvi) clinical incident management requirements;

(xvii) work health and safety requirements;

(xviii) risk mitigation requirements;

(xix) education notes and reference documents;

(xx) related policy and protocol references

(xxi) review and version control information;

(xxii) author details;

(xxiii) record number, as recorded in the University's recordkeeping system.

(9) Copies of all approved protocols must be:

(a) available at the relevant clinic or clinical facilities at all times;

(b) recorded in the University's recordkeeping system.

Note: See *Recordkeeping Policy 2017.*

11 Varying clinical services provided by existing health clinics

(1) Proposals to vary clinical services must be:

(a) submitted to the Clinical Governance and Support Office;

(b) made using the form Clinic Variation or New Device Checklist;

(c) accompanied by the following documents:

(i) a revised model of care or service delivery statement, marked up to show differences from the currently applicable document;

(ii) a draft process protocol for each new or amended process, marked up to show differences from currently applicable documents;

(iii) an initial risk assessment for the variation;

Note: See clause 10.

(iv) copies of all clinical trial and research ethics approvals.

(2) The variation to the model of care or service delivery statement must be approved in the manner specified in clause 8(2) of these procedures.

(3) If the variation involves ceasing to deliver a particular clinical service, then the requirements of clause 14 of these procedures must also be met.

12 Reporting requirements

(1) Reports required by the policy must be provided in the forms and formats specified by the Clinical Governance and Support Office and available from the clinical governance website.

(2) The Clinical Governance and Support Office will specify dates by which periodic reports are to be provided to it, and:

(a) publish these dates on the University committee dates website;

(b) inform the Executive Dean, Heads of School or Heads of Discipline; and

(c) as appropriate, assist the clinics or clinical facilities with external and internal communications relating to the reports.

13 Reviews

(1) Routine periodic reviews required by the policy will be instigated with the approval of the Executive Dean, on the recommendation of the Clinical Governance Support Office.

(a) The Executive Dean will determine written terms of reference for the review after consultation with the Clinical Governance and Quality Committee.

(b) The terms of reference must:

(i) address all criteria required by the policy and any others considered appropriate by the Executive Dean; and

(ii) specify the reporting pathway for the outcome of the review.

(c) The Executive Dean will appoint a reviewer to conduct the periodic review. This may be:

(i) the Clinical Governance and Support Office;

(ii) a team of University staff or affiliates; or

(iii) an appropriately qualified external agency or group.

(2) If the relevant delegates require a review outside the usual periodic schedule, they will:

(a) determine the terms of reference for the review, and:

(i) notify the Clinical Governance and Quality Committee of the terms of reference; and

(ii) specify a reporting pathway for the outcomes of the review which includes, at a minimum, the Executive Dean and the Clinical Governance and Quality Committee; and

(b) appoint a reviewer to undertake the review, who may be:

(i) the Clinical Governance and Support Office;

(ii) a team of University staff or affiliates; or

(iii) an appropriately qualified external agency or group.

(3) The Clinical Governance and Support Office will:

(a) provide support to reviewers in the conduct of a review; and

(b) record all relevant documentation for the review, consistently with the *Recordkeeping Policy 2017;*

(c) monitor compliance with the requirements of the review's terms of reference;

(d) provide support for the clinic or clinical facility the subject of the review in implementing its recommendations; and

(e) provide post review briefings and "lessons learnt" information as required.

14 Ceasing delivery of a clinical service

(1) The Clinic Manager must inform the Clinical Governance and Support Office at least six months in advance of any intention to cease delivery of a particular clinical service, unless this is not possible as a result of legal or regulatory requirements or directions.

(2) The Clinical Governance and Support Office will then work with the clinic to ascertain requirements, and implement plans, for:

(a) identifying consumers and other stakeholders who will need to be informed;

(b) identifying consumers who will need to be referred elsewhere;

(c) hand over or liquidation of assets, including equipment or premises, if necessary;

(d) necessary cleaning, infection control, and substance management;

(e) appropriate transfer or disposal of equipment that is no longer needed; and

(f) required notifications to government and regulatory authorities.

(3) The Clinic Manager and Clinical Governance and Support Office will identify and notify affected stakeholders of the plans as soon as practicable.

15 Closing University health clinics or clinical facilities

(1) Unless the closure is directed by the relevant delegates, the Clinic Manager must inform the Clinical Governance and Support Office at least six months in advance of any intention to close a University health clinic or clinical facility, unless this is not possible as a result of legal or regulatory requirements or directions.

(2) If closure is directed by the relevant delegates, they must inform the Clinical Governance and Support Office as soon as possible.

(3) The Clinical Governance and Support Office will then work with the Clinic Manager to ascertain requirements, and implement plans, for:

(a) identifying consumers and other stakeholders who will need to be informed;

(b) identifying consumers who will need to be referred elsewhere;

(c) hand over or liquidation of assets, including equipment or premises;

(d) necessary cleaning, infection control, and substance management;

(e) appropriate transfer or disposal of equipment that is no longer needed; and

(f) required notifications to government and regulatory authorities.

(4) The Clinic Manager and Clinical Governance and Support Office will identify and notify affected stakeholders of the plans as soon as practicable.

(5) The Clinical Governance and Support Office and the Clinic Manager will work with:

(a) Human Resources, to manage the workforce implications of the closure;

(b) University Infrastructure, to manage the site and premises implications of the closure; and

(c) the relevant faculty or portfolio, to manage the research or teaching implications of the closure.

NOTES

Health Clinics and Clinical Services Procedures 2020

Date adopted: 17 December 2020

Date commenced: 13 January 2021

Administrator: Executive Dean, Faculty of Medicine and Health

Review date: 17 December 2025

Rescinded documents: None

Related documents:

Therapeutic Goods Act 1989 (Cth)

Poisons Standard 2020 (Cth)

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 – Academic Functions) Rule 2016

University of Sydney (Delegations of Authority – Administrative Functions) Rule 2016

Guidelines Concerning Commercial Activities

Building Projects Approval and Management Policy 2014

Code of Conduct – Staff and Affiliates

Clinical Trials Policy 2016

Health Clinics and Clinical Services Policy 2020

Privacy Policy 2013

Recordkeeping Policy 2017

Risk Management Policy 2017

Space Management Policy 2012

Student Placement and Project Policy 2015

Work Health and Safety Policy 2016

Healthcare Records Management Procedure 2020

Space Management Procedures 2012

Work Health and Safety Procedures 2016

National Model Clinical Governance Framework. Sydney ACSQHC; 2017 www.safetyandquality.gov.au

Australian Commission on Safety and Quality in Health Care: National Clinical Trials Governance Framework. Sydney ACSQHC; 2019 www.safetyandquality.gov.au

National Model Clinical Governance Framework

National Safety and Quality Health Service (NSWQHS) Standards

Australian Open Disclosure Framework

NSW Health PD 2013_043 Medication Handling in NSW Public Health Facilities

AMENDMENT HISTORY

Provision	Amendment	Commencing