

AUSTRALIAN AND NEW ZEALAND BOARD OF PERFUSION International Site Approval Policy

SECTION A: FOUNDATIONS AND SCOPE

POLICY PROVISIONS

1. Purpose

- a) This policy describes the requirements for international hospitals and service providers seeking ANZBP international site approval of overseas institutions for limited pathway governance purposes, including support for admission to an ANZBP-recognised academic program, where applicable.
- b) In particular, this Policy supports the partnership between the ANZBP and Monash University by helping to ensure that students entering through an international site pathway are associated with clinical environments that provide a broadly comparable quality of work-integrated learning, including;
 - i) appropriate clinical exposure;
 - ii) sufficient case volume and case mix;
 - iii) appropriate clinical supervision with appropriate supervisors;
 - iv) perfusion practice, equipment and safety systems consistent with applicable ANZCP Standards and Guidelines (or equivalent standards acceptable to the ANZBP);
 - v) support for education, development and progression towards safe independent practice and patient safety standards; and
 - vi) enable the ANZBP to maintain appropriate oversight of pathway governance, patient safety and credentialing integrity.
- c) The purpose of this Policy is also to enable the ANZBP to consider whether an overseas institution appears to maintain standards of perfusion practice, supervision, equipment, governance and patient safety that are broadly comparable to those expected within ANZCP-recognised training environments. Approval under this Policy is therefore limited to determining whether a site demonstrates standards that are sufficiently similar for the specific purpose approved by the ANZBP.
- d) This policy also establishes safeguards to ensure that participation in an ANZBP-recognised academic program does not create an unintended pathway to ANZBP local certification or credentialing without completion of all relevant ANZBP pathway requirements (including OTP requirements, where applicable).
- e) The ANZBP does not regulate, manage, direct or assume oversight of the overseas institution's clinical practice, supervision arrangements, employment practices or local governance systems. Approval under this Policy does not create ANZBP responsibility for the conduct of

the site, the supervision provided at the site, or the clinical practice of persons working within that institution.

- f) International Clinical Site Approval is not equivalent to ANZCP or ANZBP accreditation of a local training site and must not be described as such.

2. Scope

- a) This policy applies to overseas hospitals and service providers seeking ANZBP approval for purposes including, but not limited to;
 - i) ANZBP-supported admission pathways to an ANZBP-recognised academic program
 - ii) Inclusion on an ANZBP approved site list, where maintained by the Board

3. Delineation of International Entry Pathways

- a) ANZBP International Site Approval may support eligibility for admission to an ANZBP-recognised academic program through one of the following international entry pathways:
 - i) International Trainee Perfusionist Pathway: being Monash Entry Pathway 1 International, intended for applicants at approved ANZBP International sites undertaking perfusion training in conjunction with an approved international training environment; and
 - ii) International Clinical Perfusionist Pathway: being Monash Entry Pathway 2 International, intended for qualified or practising perfusionists at approved ANZBP International sites who require formal education in perfusion as part of their professional development or pathway progression.
- b) Unless otherwise expressly stated in this Policy:
 - i) the supervision, trainee progression and case-based training requirements in this Policy apply to Entry Pathway 1 International only;
 - ii) the institutional standards, equipment, governance, safety, approval, renewal, audit and monitoring requirements in this Policy apply to all sites approved under either international entry pathway; and
 - iii) approval of a site under this Policy does not of itself determine an applicant's personal eligibility for certification or credentialling.
- c) Participation in either pathway, including successful completion of an associated academic program, does not confer eligibility to sit the CCP(ANZ) local certification examination.
- d) **Participation in either pathway may ONLY support progression toward OTP(ANZ) only where the applicant subsequently satisfies all other applicable requirements of the OTP Policy.**
- e) Eligibility for ANZBP-supported admission to an ANZBP-recognised academic program does not guarantee admission. Applicants must also meet all applicable entry, eligibility, academic, administrative and enrolment requirements of the relevant university.

4. Relationship to other Policies

- a) This Policy should be read in conjunction with other relevant ANZBP and ANZCP policies, including but not limited to:
 - i) ANZBP Clinical Supervision Policy;
 - ii) ANZCP Standards and Guidelines;
 - iii) Code of Ethical Standards and Professional Conduct;
 - iv) ANZBP Examination Policy;
 - v) Overseas Trained Perfusionist Policy
- b) The ANZBP may determine the applicable requirement, having regard to the purpose of the relevant policies and the need to uphold patient safety and credentialing integrity.

5. Principles

- a) International Site Approval is guided by the following principles:
 - i) Patient Safety – clinical education and supervision arrangements must not expose patients to unacceptable risk from unsupervised or inadequately supervised practice.
 - ii) Governance Integrity – approval arrangements must support robust oversight of training pathways, admissions support and credentialing boundaries.
 - iii) Accountability – institutions, supervisors, trainees and applicants are accountable for compliance with ANZBP requirements.
 - iv) Professionalism – all persons involved must act in accordance with ANZBP and ANZCP standards.
 - v) Consistency and Fairness – approval requirements and decisions should be applied transparently and consistently.
 - vi) Clarity of Scope – approval must only be interpreted within the limits expressly stated by the ANZBP.

6. Definitions

For the purposes of this Policy:

- a) **ANZBP**: means the Australian and New Zealand Board of Perfusion.
- b) **ANZCP**: means the Australian and New Zealand College of Perfusion
- c) **Approved International Clinical Supervisor**: means a hospital-endorsed and chief perfusionist-endorsed supervisor with at least three years' post-qualification experience, who has received formal approval from the ANZBP under this Policy to provide day-to-day clinical supervision to an International Trainee Perfusionist.
- d) **Approved International Lead Supervisor**: means a hospital-endorsed and chief perfusionist-endorsed supervisor with at least five years' post-qualification experience who has received

formal approval from the ANZBP under this Policy to assume overall responsibility for the trainee's supervision plan, evaluations and liaison with the ANZBP and, where relevant, the university.

- e) **International Clinical Site Applicant:** means a person acting on behalf of an overseas institution and seeking ANZBP International Site Approval for one or more purposes under this Policy.
- f) **International Clinical Site Approval:** means ANZBP approval of an overseas institution or site for a specified and limited purpose, as set out in the ANZBP approval letter.
- g) **ANZBP Approved International Trainee Perfusionist:** means a person located outside Australia or New Zealand who is registered with the ANZBP under an approved international training or academic pathway and is associated with an ANZBP-approved international clinical site.
- h) **ANZBP Approved International Perfusionist:** means a person located outside Australia or New Zealand who is a clinical perfusionist at an ANZBP-approved international clinical site.
- i) **ANZBP-Approved International Clinical Site:** means an overseas clinical perfusion site approved by the ANZBP under this Policy for a specified and limited purpose, having demonstrated standards the ANZBP considers broadly comparable to those expected within ANZCP-recognised training environments. Such approval does not constitute ANZCP accreditation, ANZBP oversight, or ANZBP responsibility or liability for the site's operations, supervision, governance or clinical practice
- j) **Direct Supervision:** means the supervising perfusionist is physically present in the same room as the trainee while the trainee is performing clinical functions.
- k) **Indirect Supervision:** means the supervising perfusionist is on-site, immediately contactable, able to attend within minutes, and not simultaneously responsible for another procedure. The supervisor may be required to be present during initiation, weaning or high-risk events as determined by the lead supervisor and the needs of the trainee.

POSITION AND LIMITATIONS OF APPROVAL

7. Nature of Approval

- a) International Site Approval is limited to the purpose or purposes expressly stated in the ANZBP approval letter.
- b) Approval under this Policy does not:
 - i) confer ANZBP certification or OTP credentialling;
 - ii) waive any OTP pathway requirements;
 - iii) confer eligibility for employment in Australia or New Zealand;
 - iv) create entitlement to ANZBP local certification by virtue of academic program participation alone.

8. Academic and Admissions Purposes

- a) Where the ANZBP does not have full oversight of supervision and clinical training standards at an overseas site, the ANZBP may approve the site for academic, admissions or pathway governance purposes only.
- b) In such cases:
 - i) participation in an ANZBP-recognised academic program does not create eligibility for ANZBP local certification;
 - ii) participation in an ANZBP-recognised academic program does not create eligibility for OTP credentialling unless all relevant ANZBP OTP pathway requirements are subsequently met; and
 - iii) any approval given by the ANZBP must not be represented as certification, accreditation or credentialling approval.

9. Visibility of International Applicants

- a) The ANZBP will require completion of an international applicant form or other Board-approved process so that the Board has visibility of the site, supervisors, and applicants entering an ANZBP-recognised academic program through this route.

10. University and Third-Party Correspondence

- a) Eligibility for ANZBP-supported admission to an ANZBP-recognised academic program does not guarantee admission.
- b) Applicants must satisfy all applicable entry, eligibility, academic, administrative and enrolment requirements of the relevant university. In addition, where required by the university, the institution or site may be required to enter into an agreement, affiliation arrangement, placement agreement or other formal documentation with the university, in addition to this ANZBP approval, as a condition of participation in the program.
- c) The ANZBP will also be required to provide a letter to a university or other relevant body for the application process which will enable acceptance into the academic program.
- d) These letters may include, but are not limited to include;
 - i) ANZBP Approved International Trainee Perfusionist:
 - a. The applicant has a clinical perfusion traineeship at an international clinical site approved by the Australian and New Zealand Board of Perfusion (ANZBP) to demonstrate standards comparable to ANZBP accredited training units.
 - b. The applicant has a minimum of three (3) days per week of clinical exposure.
 - c. The approved site has confirmed its ongoing capacity and commitment to maintain those standards for the duration of the applicant's enrolment.

- d. The approved lead supervisor has accepted responsibility that they will support and appropriately supervise the student for the duration of the applicant's enrolment.
- e) The purpose is to ensure that the trainee/student is completely supported throughout enrolment.
- f) Any such correspondence is limited to that purpose and must not be represented more broadly.

SECTION B: APPROVAL REQUIREMENTS

APPLICATION AND ELIGIBILITY REQUIREMENTS

11. Application Process

- a) Overseas institutions/sites seeking approval must submit the ANZBP International Site Approval application (and any associated international applicant documentation required by the ANZBP) via the College portal or other ANZBP-approved process.
- b) The application must include, at minimum:
 - i) institution/site details and key contacts;
 - ii) description of perfusion service and case mix;
 - iii) staffing profile and supervisor credentials;
 - iv) local supervision arrangements;
 - v) equipment/platforms and relevant protocols;
 - vi) evidence of institutional support for participation in the ANZBP-recognised academic pathway (where applicable);
 - vii) confirmation of applicable registration/licensing/regulatory arrangements in the local jurisdiction; and
 - viii) any other information required for ANZBP governance and risk assessment.

12. Documentation

- a) The application must include:
 - i) an official letter from the Head of Department of Perfusion, or equivalent, supporting the application;
 - ii) an official letter from the Head of Surgery, cardiac surgery lead, or equivalent, confirming support for perfusion training at the site;
 - iii) an official letter of support from a hospital executive or authorised institutional representative confirming institutional support for the application and understanding of the ANZBP policy requirements.
- b) The ANZBP may request clarification, further documents, interviews or independent verification before making a decision.

13. Supervisor Approval Requirements

- a) All proposed International Lead Supervisors and International Clinical Supervisors must submit the relevant ANZBP supervisor application form through the College portal or another ANZBP-approved process.
- b) No person may commence supervisory duties under an ANZBP-approved pathway until they have received written ANZBP approval.

- c) The ANZBP may maintain an internal or published list of approved supervisors.
- d) Where required, the ANZBP may mandate the completion of an endorsed supervision course to ensure that the student is supported with appropriate clinical supervision during their work-integrated learning.
- e) Non-Approved Supervisors
 - i) A person who has not received formal approval from the ANZBP as an Approved International Clinical Supervisor or Approved International Lead Supervisor must not provide direct clinical supervision under an ANZBP-approved pathway.
 - ii) Such persons may, however, provide educational support, teaching, mentoring or observational guidance outside the formal clinical supervision framework.
 - iii) Any such support does not constitute ANZBP-recognised clinical supervision and must not be counted toward supervision requirements under this Policy.

14. Fees

- a) An application fee and renewal fee, as determined by the ANZBP from time to time, may apply.
- b) The applicable fees and payment process will be published by the ANZBP or otherwise advised to the applicant or institution at the time of application or renewal.
- c) Fees are non-refundable once assessment has commenced, except at the ANZBP's discretion.
- d) Payment of a fee does not guarantee approval, renewal or continued inclusion on any approved site list.

INSTITUTIONAL ELIGIBILITY AND TRAINING ENVIRONMENT

15. Established Service Requirement

- a) The institution must be an established perfusion service with at least 24 months' experience in cardiac surgery, unless otherwise approved by the ANZBP in exceptional circumstances.

16. Case Volume Requirements

- a) To be approved as a primary training site, the institution should ordinarily demonstrate:
 - i) For each trainee:
 - a. a minimum of 200 cardiopulmonary bypass cases per year for adult units; or
 - b. a minimum of 150 cardiopulmonary bypass cases per year for paediatric units.
 - ii) Where these minimum volumes cannot be achieved at a single institution, training may only proceed through an ANZBP approved site shared trainee arrangement, subject to ANZBP approval.

17. Departmental Capacity

- a) The institution must have a perfusion department with sufficient staffing, resources and organisational capacity to maintain safe clinical service delivery and support education and supervision.
- b) The institution must have a staffing and rostering model that allows for supervision and education without compromising service delivery or patient safety.

18. Training Environment

- a) The institution must demonstrate that training arrangements are planned across the duration of training to ensure exposure to appropriate case volume, case mix and progression of complexity in keeping with trainee capability and experience.
- b) The ANZBP recommends that international trainees have access to a minimum of three clinical sessions per week, unless otherwise approved.
- c) The institution should, where applicable:
 - i) provide reasonable study time during the working week;
 - ii) provide a suitable environment and allocated time for course examinations and assessments; and
 - iii) support concurrent education requirements, including attendance at required workshops or academic activities.

WORK-INTEGRATED LEARNING ARRANGEMENTS

19. Employment

- a) The trainee's employment must be satisfactory to complete the entirety of their training.
- b) The trainee's employment must be satisfactory to complete training within three years, with the ANZBP acknowledging that extensions may be considered in exceptional circumstances.
- c) The ANZBP recommends full-time employment with a minimum of three (3) days per week of clinical exposure.

20. Arrangements

- a) The institution should:
 - i) provide a reasonable amount of study time during the working week for trainees
 - ii) provide a suitable environment and appropriately allocated time for all course examinations and assessments
 - iii) support the trainee's concurrent education, including prioritising leave for attendance to conferences (where required to present) and university workshops.
- b) Training arrangements should be planned across the entirety of training to ensure appropriate case complexity scaled to the trainee competency and experience level.

EQUIPMENT, PROTOCOLS AND SAFETY SYSTEMS

21. Equipment and Standards

- a) The institution must utilise maintained and in-service perfusion equipment, consumables and technology that meet the minimum safety standards detailed in the ANZCP Standards and Guidelines, or other standards acceptable to the ANZBP.

22. Required Systems and Documentation

- a) The institution must have:
 - i) documented and current protocols and policies relevant to perfusion practice;
 - ii) emergency procedure manuals relevant to perfusion practice;
 - iii) processes for equipment maintenance, incident reporting and escalation; and
 - iv) orientation and competency processes for staff using perfusion equipment.

23. Safety and Governance Concerns

- a) The institution must disclose any significant patient safety, regulatory or governance issues relevant to the perfusion service.
- b) The ANZBP may impose conditions, request further information, defer a decision, or refuse approval or renewal where such concerns are not adequately addressed.

PART C: SUPERVISION AND TRAINING

SUPERVISION STANDARDS

24. General Supervision Requirement

- a) International Trainee Perfusionists must be supervised in the clinical setting by ANZBP-approved supervisors in accordance with this Policy and the ANZBP Clinical Supervision Policy.
- b) Supervisors take ultimate responsibility for the trainee in the clinical setting and must ensure that risk management systems are in place to maintain patient and trainee safety.

25. Direct and Indirect Supervision

- a) A trainee must have direct supervision for at least the first 125 cases, with the supervisor physically present for the conduct of cardiopulmonary bypass or ECLS.
- b) After the first 125 cases, indirect supervision may be used only where the International Lead Supervisor deems the trainee competent for that level of oversight and the ANZBP has no objection.
- c) Under indirect supervision, the supervisor must remain on-site, immediately available, and not simultaneously responsible for another case or procedure.

26. Approved International Lead Supervisor

- a) An Approved International Lead Supervisor is responsible for the trainee's overarching supervision, education and training progression.
- b) Unless otherwise approved by the ANZBP, the minimum requirements for an Approved International Lead Supervisor are:
 - i) at least five (5) years' post-qualification experience;
 - ii) current certification, where applicable in the local jurisdiction;
 - iii) demonstrated capacity to oversee supervision, case allocation, evaluations and communication with the ANZBP;
 - iv) the ability to assume responsibility for the supervision framework and trainee progression.
- c) The Approved International Lead Supervisor must complete trainee evaluations at intervals determined by the ANZBP, at least every 20 cases.
- d) The International Lead Supervisor is encouraged to establish a documented training plan with the trainee at the start of each year, setting out expectations, goals and responsibilities.

27. Approved International Clinical Supervisor

- a) An Approved International Clinical Supervisor is responsible for day-to-day clinical supervision and may be assigned on a case-by-case basis, having regard to case complexity, trainee capability and supervisor experience.
- b) Unless otherwise approved by the ANZBP, the minimum requirements for an Approved International Clinical Supervisor are:
 - i) at least two (2) years' post-qualification experience;
 - ii) current certification, where applicable in the local jurisdiction; and
 - iii) the ability to assume full responsibility for the case and take over from the trainee if required.

28. Supervisor Development

- a) The ANZBP may require, recommend or endorse supervisor education or supervision training as a condition of approval or continued approval.

29. Supervisor Approval and Renewal

- a) Approval of an International Lead Supervisor or International Clinical Supervisor is subject to ongoing compliance with this Policy and any other ANZBP requirements.
- b) Supervisor approval must be reviewed and renewed at two-year intervals or as determined by the ANZBP, and ordinarily in conjunction with renewal of the relevant International Site Approval, unless otherwise specified by the Board.
- c) The ANZBP may require updated information or supporting documentation for renewal, including but not limited to:
 - i) confirmation of the supervisor's current role and responsibilities;
 - ii) confirmation of continued institutional endorsement;
 - iii) evidence of current certification, where applicable;
 - iv) confirmation of continued involvement in relevant perfusion practice;
 - v) evidence of supervision activity, evaluations or training undertaken; and
 - vi) any other information reasonably requested by the ANZBP.
- d) The ANZBP may decline to renew, suspend, or withdraw supervisor approval where it is not satisfied that the supervisor continues to meet the requirements of this Policy or where concerns arise regarding supervision quality, compliance, professionalism, governance, or patient safety.
- e) If supervisor approval lapses, is not renewed, or is withdrawn, that person must not continue to act as an Approved International Lead Supervisor or Approved International Clinical Supervisor under an ANZBP-approved pathway.

SECTION D: GOVERNANCE AND REVIEW

GOVERNANCE

30. Compliance

- a) The institution, supervisors and applicants remain responsible for compliance with all applicable local laws, licensing, registration, employment and regulatory requirements in the relevant jurisdiction. ANZBP approval does not replace or satisfy those obligations.
- b) The ANZBP may require an institution, supervisor, applicant or associated party to provide further information, clarification, documentation or evidence at any time for the purposes of assessing, monitoring, reviewing or renewing approval under this Policy.

APPROVAL AND REVIEW

31. Approval Decisions

- a) The ANZBP may make one of the following decisions:
 - i) **Approved:** site approved for the specified purpose(s);
 - ii) **Approved with Conditions:** site approved subject to stated conditions, limitations, or timeframes;
 - iii) **Deferred Pending Further Information:** decision deferred until requested information is provided;
 - iv) **Not Approved:** application declined;
 - v) **Suspended:** existing approval suspended pending review/remediation;
 - vi) **Withdrawn:** existing approval removed.
- b) Approval is limited strictly to the scope stated in the ANZBP approval letter and must not be interpreted more broadly.
- c) The ANZBP retains discretion to approve, conditionally approve, defer, decline, suspend or withdraw approval where, in the ANZBP's opinion, patient safety, governance integrity, policy compliance, or credentialing standards cannot be adequately assured.

32. Renewal

- a) International Site Approval must be renewed every three (3) years, unless otherwise specified by the ANZBP.
- b) Approved sites should submit renewal applications before the expiry date specified by the ANZBP. The ANZBP may remove or suspend a site from any approved site list where renewal is not completed by the due date.
- c) Renewal requires submission of a renewal application, payment of the applicable renewal fee, and any updated information or supporting documentation requested by the ANZBP.
- d) Approval may be withdrawn or not renewed if the institution no longer meets the requirements of this Policy.

AUDIT AND MONITORING

33. Monitoring

- a) The ANZBP may monitor an approved site through one or more of the following:
 - i) Student Feedback
 - ii) Supervisor Reports
 - iii) Academic Program Educators
 - iv) Review of compliance with this Policy
 - v) Review of verification of continued institutional support

34. Audit

- a) The ANZBP reserves the right to audit any institution approved under this Policy.
- b) Supporting documents and information may be requested as part of an audit, review or monitoring process.

35. Review of Approval Status

- a) Any concern regarding supervision, governance, patient safety, training quality, institutional support or policy compliance may lead to a review of approval status.
- b) Following review, the ANZBP may maintain approval, impose or vary conditions, suspend approval, decline renewal, or withdraw approval.

CERTIFICATION AND CREDENTIALING BOUNDARIES

36. Certification

- a) Overseas-trained perfusionists who participate in an ANZBP-recognised academic program are not eligible:
 - i) for ANZBP local certification CCP (ANZ).
- b) Where the ANZBP does not oversee supervision at an overseas site, participation in an academic program and/or overseas clinical practice does not of itself satisfy ANZBP clinical supervision or training requirements for local certification.
- c) Participation in an ANZBP-recognised academic program, or association with an approved international clinical site, does not of itself create eligibility for OTP(ANZ) unless all relevant OTP pathway requirements are subsequently met.

POLICY REVIEW AND ADMINISTRATION

37. Policy Review

- a) This Policy will be reviewed periodically, and ordinarily at least once every two years, by the ANZBP to ensure its continuing relevance, effectiveness and alignment with contemporary professional standards and governance requirements.
- b) Any amendments to this Policy will be approved and communicated in accordance with ANZBP governance processes.

38. Administrative Authority

- a) The ANZBP retains authority to interpret and apply this Policy, and to make decisions necessary for the administration of International Site Approval, provided such decisions are consistent with the purpose of the Policy, procedural fairness and patient safety.
- b) The ANZBP reserves the right, at any time, to suspend, discontinue, withdraw or terminate this approval process, or any approval granted under this Policy, where it is no longer satisfied that the relevant standards of supervision, clinical exposure, governance, equipment, institutional support or patient safety are being maintained, or where the requirements of this Policy are otherwise no longer met.
 - i) In such circumstances, the ANZBP may determine that no further progression toward OTP (ANZ) may occur through that site or arrangement unless otherwise approved by the ANZBP.