

Submission to the review of PD2010_056

Site authorisation and site specific assessment

To: Research Ethics and Governance Unit, Office for Health and Medical Research

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Re: PD2010_056 Discussion Paper, June 2026

Confidentiality: None of this submission is confidential.

About this submission

I am a Lecturer at Sydney Law School and Deputy Director of Sydney Health Law. I make this submission in my personal capacity. My perspective draws on experience in medical practitioner regulation and research with biomedical scientists on legal pathways for innovative treatments. I do not have direct experience administering hospital research governance.

This submission responds to PD2010_056 on site authorisation and site specific assessment. References to PD2010_055 concern the points at which ethical review and site governance intersect. It addresses the governance of research involving more than one organisation, particularly the movement of data, tissue and researchers between institutions.

I refer to existing legal obligations to clarify the scope of these recommendations and identify any changes to policy or legal authority needed to implement them.¹

Executive summary

The revised directive should make site authorisation proportionate, coordinated and timely. Institutions should be able to reuse reliable assessments and records, progress ethics and governance work in parallel, and reopen only matters affected by a change. Responsibility for coordination should be clear, with transparent timeframes and a means of resolving delay. Institutions should determine how those functions are allocated, supported by central assistance where needed.

Consider a proposed collaboration in which a hospital recruits participants and collects samples, a university laboratory analyses or processes the material, and results or a proposed therapeutic product return to the hospital. These are different activities within one project. The governance problem is to establish who may do each activity, what may pass between the institutions and which assessments each institution can rely on. This hypothetical example assumes that the relevant activities can be lawfully undertaken; the separate question of whether manufacture outside a hospital is permissible under a particular product pathway is addressed below.

Shared assessment should be available across the system. For suitable institutions and programmes, NSW Health should also permit standing authorisation for defined activities, with internal confirmation that each project falls within its scope and satisfies its conditions. Institutional umbrella deeds are one possible means of settling common terms in established collaborations; this optional pathway should neither determine the wider reform nor delay improvements to ordinary SSA. Portable credentials and recognition of

¹ PD2010_056, procedures cls 3.4.3 and 5.1.1; see the discussion of authority and policy amendments in sections 6.3 and 6.5 below.

relevant expertise should similarly reduce repeated access checks, with additional decisions confined to matters outside existing permission.

Implementation should improve and connect existing systems, including carefully verified AI-assisted information exchange, rather than prescribe a single technical architecture. Costing should be transparent, recognise institutional and sponsor contributions, and give credit for work already funded or completed. Targeted NSW assistance should support worthwhile research facing unmet patient or social need and a funding gap. Product-related guidance should identify the relevant pathway accurately and preserve the operation of Commonwealth exclusions. The test of these reforms should be whether they reduce duplicated work and avoidable delay while maintaining clear institutional responsibility.

6.1 Minimum requirements and submission readiness

Question 6.1.1. What elements should be consistently required across all studies, regardless of context?

The statewide minimum should identify:

- the protocol;
- responsible investigators, other project personnel and sponsor where applicable;
- proposed sites and activities (for example, collection at the hospital, analysis at the university laboratory and return of results to the treating team);
- ethics review status, conditions and supporting approval where available;
- service and resource requirements (for example, laboratory time, sample transport and staff to monitor participants);
- funding;
- relevant agreements;
- inventories of data and materials, including their source, custodianship and proposed handling;
- consent arrangements or other lawful authority, identifying where supporting evidence is held;
- role-relevant credentials and applicable material quality requirements, including GMP where required.

Guidance should distinguish information needed to begin review from evidence that must be final before authorisation. The requirements should follow the material, activity and proposed role; the form should not require final HREC approval before useful governance assessment can begin, or impose GMP on materials to which it does not apply.

For research involving an experimental or innovative intervention, the minimum dataset should identify:

- the intervention;
- the responsible team;
- the planned observations;
- the arrangements for recording outcomes and adverse events.

These requirements should be proportionate to the project and may be satisfied by referring to an existing protocol and records plan. The organisation should be able to retrieve its earlier authorisation, conditions and relevant safety or governance correspondence when considering comparable work. The record should identify the custodian of supporting clinical records and the conditions of access. This should support decisions about local capability, resources and oversight; it should not create a second scientific review or require patient-level outcomes to be copied into REGIS.

Guidance should identify the existing process for resolving whether an innovative intervention is research. OHMR should coordinate referral advice with clinical governance

policy owners, keeping non-research clinical care outside the proposed research record requirements.²

Question 6.1.2. How “risk-proportionate SSA” may be interpreted across different study types (e.g. low-risk, high data complexity, high service impact)?

Proportionality should reflect participant risk, information sensitivity, service impact and the complexity of the proposed arrangements. A study with little participant contact may still require detailed privacy or data security review. A study using established methods may place substantial demands on local services. For research with low participant risk and straightforward local arrangements, a short confirmation of those arrangements should ordinarily suffice. Coded data and existing samples should be assessed against these criteria rather than treated as low risk by description alone. Where a PHO supplies access to participants, tissue or data but hosts no research activity, guidance should distinguish the access request route from SSA.

Institutions should be able to rely on relevant records and assessments already available, with their source, currency and scope clear (who produced them, whether they remain current and which activities they cover). Digital tools may assist in identifying material changes, but their value and reliability would need to be tested with users. The policy objective is to permit justified reliance on unchanged information rather than require its repeated assessment. For example, a hospital considering work with a university laboratory should be able to use a relevant assessment of the laboratory’s capability, while checking whether that assessment covers the proposed method and materials. A different project title should not itself require the same assessment to be repeated; a different manufacturing process or material may require further assessment.

Question 6.1.3. What would help applicants, sponsors, services and Research Offices identify key governance matters earlier in the SSA process?

Early identification of issues would be assisted by clear criteria for when specialist advice or an additional decision is needed. Those criteria could address the people, data, materials and proposed intervention, including unresolved questions of regulatory classification (for example, which regulatory scheme applies to a proposed product). Their practical form should be developed with researchers and governance staff; any automated prompts should remain explainable and open to correction.

Question 6.1.4. What would make the concept of “complete enough for review” clearer without encouraging incomplete or poor-quality submissions?

An application should be ready for review when it provides enough information to assess the proposed activities and local impact. Guidance should distinguish an omission that prevents useful assessment from information that may properly follow later (for example, a final agreement while its proposed terms are being assessed), with an explanation of what remains outstanding. That distinction should be tested with applicants and reviewers. Final approvals and executed agreements should be required at the decision point that depends on them, while other assessment proceeds where useful.

The recipient’s privacy obligations

The university disclosure scenario requires attention to the recipient’s legal status: NSW public universities are HRIP-bound, while the Commonwealth Privacy Act excludes State

² PD2010_056, procedures cls 1.2, 3.3 and 5.1. Clause 1.2 excludes activities other than research and directs those undertaking such activities to consult the PHO about its authorisation process. See also *National Statement on Ethical Conduct in Human Research* (2025), para 5.1.7 and introduction to Section 3, on innovative clinical practice, institutional notification and seeking advice where the appropriate review process is unclear.

or Territory authorities from its definition of “organisation”.³ A controlled entity or separately constituted institute may have different or concurrent obligations, so the form should identify the actual recipient.⁴ Where disclosure relies on HPP 11(1)(f), it should capture the relevant statutory conditions and HREC approval under the Statutory Guidelines on Research, without presenting consent and that provision as the only disclosure grounds.⁵

6.2 Roles responsibilities and capability

Question 6.2.1. How are submission readiness and accountability understood and applied in practice?

Readiness should follow the information standard proposed in section 6.1, with the Principal Investigator accountable for accuracy when others prepare the application. I do not offer a system-wide empirical assessment of current practice.

Question 6.2.2. How can accountability be maintained where preparation, oversight and review functions are distributed across multiple roles?

I support the matrix’s separation of preparation, coordination, specialist assessment, service support and authorisation. Rows combining different judgements should allocate each separately: the PI remains responsible for accuracy, the RGO for coordination, and the Chief Executive or authorised delegate for site authorisation and organisational risk acceptance (see section 6.3).⁶

The consent row, for example, combines preparation of the proposed consent approach with assessment of its ethical suitability, assigning responsibility and accountability to the PI/CPI and a consultative role to the HREC executive officer. It should distinguish the researcher’s proposal, assessment through the applicable ethics review process, and confirmation that the arrangements can lawfully be implemented at the site. Consultation with an executive officer should not appear to substitute for the applicable ethics review decision. The matrix should allocate these tasks without creating an additional substantive consent standard or duplicating ethics review during site authorisation.

The consent row should link to chapters 2.2–2.3 of the *National Statement*, NSW Health’s treatment consent manual and the relevant guardianship, health information and tissue provisions. Distinguishing treatment, research participation and use of information or tissue would make the allocation of tasks clearer, without requiring a new legal opinion for each application.⁷

3 *Privacy Act 1988* (Cth) ss 6C(1), 6C(3)(c); *Health Records and Information Privacy Act 2002* (NSW) s 4(1) (definition of “public sector agency”, para (d)), s 11; *Government Sector Audit Act 1983* (NSW) s 4(1) (definition of “auditable entity”, para (b), expressly including a university or any of its controlled entities). The Information and Privacy Commission NSW’s [NSW Privacy Laws](#) guidance includes universities among the public-sector bodies covered by HRIP.

4 *Privacy Act 1988* (Cth) s 6C, including its exclusions; HRIP Act ss 4, 11. Entity form and the activity concerned must be checked rather than assuming that Commonwealth coverage excludes NSW health-information obligations.

5 HRIP Act, Sch 1 HPP 11(1)(f), s 64; *Statutory Guidelines on Research*, Part 2 cls 1.1–1.6 and 2.1. For the identifiable-data pathway, these address necessity, impracticability of seeking consent, the requirement that the public interest in the research substantially outweigh the public interest in the privacy protection otherwise afforded and HREC approval. The organisation may decline disclosure despite HREC approval. Internal secondary use requires separate attention to HPP 10.

6 Office for Health and Medical Research, *Site Authorisation RACI Matrix* (June 2026), 1–5, 12, 18. The matrix is a consultation draft. Page 12 combines the proposed consent approach and its ethical suitability in one row; page 5 asks users to treat combined judgements separately in practice.

7 *National Statement on Ethical Conduct in Human Research* (2025), 9, chs 2.2–2.3; NSW Health, *Consent to Medical and Healthcare Treatment Manual* (2025), ss 4, 7.11; *Guardianship Act 1987* (NSW) pt 5, especially s 45AA(4) (approval of a trial does not itself constitute consent to an individual patient’s participation); HRIP Act sch 1 HPPs 10–11; *Statutory Guidelines on Research; Human Tissue Act 1983* (NSW). The relevant requirements depend on the participant, activity and source of information or tissue.

Responsibility for coordinating an application should be identifiable, including responsibility for following up unresolved matters and delay. A project management function may assist, but its allocation should reflect each institution's arrangements and resources. Coordination should support specialist assessments without adding another approval stage.

Question 6.2.3. What forms of support, guidance or capability development could strengthen consistency across the system?

OHMR should provide practical support in legal, privacy, data and finance matters according to the needs of the participating institutions. Existing specialist expertise, legal counsel and competent assessments should be recognised and used. Institutions facing materially equivalent issues (for example, the same proposed data transfer on the same terms) should be able to rely on common advice, with its scope and currency clear. Central assistance should address gaps and facilitate progress rather than require capable institutions to repeat work through another service.

Advanced research precincts and other institutions with demonstrated capability should be supported to undertake the research they are equipped to manage, including high-risk projects. Specialist questions should reach people with the relevant expertise, alongside appropriate ethical review and community participation. Clinical urgency should inform prioritisation and response periods: avoidable delay can matter ethically where prospective participants face deterioration, although the benefit of an experimental intervention remains uncertain.

Question 6.2.4. What elements of role clarity, training or expectations could be supported at a system level, rather than locally defined?

Common training and worked examples should address:

- submission readiness;
- privacy and data custody issues;
- resource assessment;
- recognising when specialist advice is needed;
- recording decisions.

Shared discussion of difficult cases could help identify divergent interpretations. NSW Health should develop any common training or competency expectations with Research Offices and researchers, recognising that the expertise required will vary with the activity.

6.3 Escalation and decision making

Question 6.3.1. What should trigger escalation, and how this should be understood across roles?

Escalation should be triggered by a need for specialist advice, unresolved legality, risk beyond the decision-maker's authority (for example, a decision reserved to a more senior authorised officer) or an approaching or missed deadline. Each role should know when and to whom it must refer the affected matter.

Question 6.3.2. How could escalation pathways support consistent handling of shared or multisite issues?

A shared issue should have an agreed means of coordination and a recorded outcome on which participating institutions can rely where appropriate. The record described in section 6.5 should identify the scope of the decision and any unresolved differences. Institutions should settle responsibility for coordination; the objective is to resolve a common issue once where possible. For example, where a proposed transfer of samples raises the same

question for the hospital sending them and the laboratory receiving them, a common assessment could address that question for both institutions. Any remaining disagreement should identify its basis (for example, a different proposed use or a condition the receiving laboratory cannot satisfy), so that the researchers know what must change.

Question 6.3.3. How can decision points ensure that accountability for risk acceptance is clear?

The directive should identify each decision-maker and the limits of their authority. Under the optional pathway in section 6.5, standing authorisation would supply authority for defined activities; confirming scope and conditions would not require a fresh discretionary project approval. Only departures requiring additional authority would return for a further decision.

For a local health district, the statutory delegation power is s 40 of the Health Services Act 1997 (NSW).⁸ Under the current directive, authorisation may be delegated to one or more individuals within the PHO according to research activity and risk, but not to its HREC. The express RGO permission is limited to research involving no more than low risk and access requests.⁹ This does not impose a general low-risk ceiling on other lawful internal delegates. Nor does full HREC review, by itself, establish that a project is above low risk.

For the optional standing authorisation pathway, coordinated changes to the directive's application, endorsement and decision requirements would be needed. The revised directive should identify who may grant standing authorisation and who may confirm that a project falls within it, consistently with applicable statutory powers and delegations. Substantive policy amendments require approval by the Secretary or relevant Deputy Secretary through the NSW Health policy approval process (see note 13). Any necessary change to the underlying legal authority should be identified before implementation. An access credential, appointment label or umbrella deed alone would not confer decision-making authority.

Reporting should make significant delays, unresolved issues and departures from authorisation visible to those accountable for the research. Institutions should determine how existing reporting arrangements can serve that purpose before any additional statewide return is considered.

Question 6.3.4. What expectations should guide the timing of issue-specific escalation during SSA, particularly where progress depends on departmental endorsement, specialist input or other decision points? How could these expectations support timely and consistent resolution while allowing flexibility for study complexity and local context?

The revised guidance should support transparent timeframes and clear responsibility for resolving delay. It should distinguish time spent awaiting information from time spent assessing an application, with applicants able to understand the status of an outstanding decision. The appropriate periods and escalation arrangements should be developed with those undertaking the assessments.

⁸ *Health Services Act 1997* (NSW) s 40(1): members of the NSW Health Service; visiting practitioners, councils or committees appointed by the district; bodies appointed by the Minister or Health Secretary under an Act; and persons or bodies of a prescribed class. See also ss 40(1A)–(3), including the exclusions and the Secretary's power to give directions. Statutory health corporations have a different delegation provision: s 61.

⁹ PD2010_056, procedures cl 5.1.1. The clause permits delegation to internal individuals, excludes delegation to the PHO's HREC and expressly permits RGO authorisation of no-more-than-low-risk research and access requests. See also PD2010_056, procedures cls 2 and 5.1, on organisational awareness and written project authorisation. *National Statement on Ethical Conduct in Human Research* (2025), ch 2.1, p 14, includes some clinical trials within low-risk research; PD2010_055 cl 3.1 separately specifies research requiring full HREC review.

Extensions should be reasoned and recorded, preferably before the relevant deadline expires. Applicants and assessing services should be able to explain why more time is needed, with the revised timeframe and any conditions visible. A later extension should not erase the record of a missed deadline.

An extension should account for any change in risk, feasibility or the opportunity to participate (for example, deterioration in a prospective participant's condition during the delay). Where delay alters those circumstances, continuation should depend on assessment of the affected activity; the appropriate oversight should be determined by those responsible for it.

Question 6.3.5. What guidance or system supports could enable escalation to operate as a routine governance mechanism, rather than an exception?

Project records should make the owner, escalation route, deadlines and reasons visible. Common guidance and worked examples would support routine use across institutions.

Only the assessment materially affected by missing information, a change or an unresolved issue should pause. Other assessments should continue where they can usefully do so, with that continuing work recorded. The record should identify the reason for a pause, the work affected and what is needed to resume it. Expiry of a timeframe should trigger action and escalation, not automatic approval.

6.4 Parallel ethics and SSA activity

Question 6.4.1. Which SSA activities are most suited to progress early (preparation or review), before final ethics approval is available?

Parallel ethics and governance assessment should be the normal approach wherever sufficient information exists for useful work. Subject to the project's dependencies, activities to consider for early commencement include:

- feasibility discussions;
- identification of supporting services;
- provisional budgets;
- workforce planning;
- review of standard agreement terms.

In the hospital–university example, assessment of laboratory capacity, transport arrangements and proposed costs could proceed while the HREC considers the recruitment and consent documents. A later change to the proposed sample volume might require capacity and cost checks to be revisited. It should not automatically restart assessment of unchanged agreement terms.

Question 6.4.2. Which SSA activities should generally wait until final ethics-approved documents are available?

Standing terms can reduce the work required, but project-specific resources, costs and conditions still need confirmation. Final decisions that depend on the protocol, consent process, recruitment or data arrangements should be reconciled with the approved documents before authorisation.

Question 6.4.3. What would make the parallel ethics and SSA workflow clearer and more predictable for researchers, sponsors and Research Offices? How can roles and responsibilities support consistent decision-making across different sequencing approaches?

The directive and current OHMR guidance already permit parallel ethics and governance activity.¹⁰ The revision should make that permission easier to use by clarifying which decisions depend on final documents and which assessments can proceed provisionally. Institutions should determine how responsibility for reconciling provisional assessments with approved documents is allocated.

Question 6.4.4. What practical safeguards would reduce duplication when ethics review changes study documents or study design?

Changes following ethics review should carry a version history and a short account of their governance implications. Only materially affected assessments should reopen (for example, a change to data access would prompt reconsideration of privacy arrangements, while unrelated assessments could remain valid), retaining completed and continuing work. Commencement remains conditional on the required ethics review and written site authorisation.¹¹

Evaluation should include total elapsed time from site submission to authorisation and the amount of rework, alongside existing governance metrics. OHMR's current metric starts after ethics approval where the site application was submitted in parallel, so that measure alone cannot show the whole effect of earlier submission.¹²

6.5 Multisite research and shared review

Question 6.5.1. For studies conducted at multiple NSW Public Health Organisations, which parts of SSA could reasonably be completed once and shared across sites?

Across participating organisations, assessment of common matters should be undertaken once and relied on where the circumstances are materially equivalent. Repeated assessment should require a recorded reason identifying the difference or unresolved issue. Common matters include:

- a common protocol;
- material- and data transfer terms;
- IP arrangements;
- the data management plan;
- researcher credentials.

Question 6.5.2. Which parts of SSA must remain local to support each Chief Executive or delegate's authorisation decision?

Local assessment should address facilities, workforce, resources and organisational risk, using relevant assessments already completed. In the hypothetical collaboration, the university might assess the laboratory's capacity to perform the proposed work, while the hospital assesses its capacity to administer the intervention and monitor participants. A shared assessment can inform both decisions, but it does not establish that each institution has the staff and facilities needed for its own activities. Under the optional standing authorisation pathway, commitments could be settled for a defined programme

¹⁰ PD2010_056, procedures cls 3.4.3, 3.5; OHMR, [Site authorisation and access request](#).

¹¹ PD2010_056, procedures cls 2, 3.3(viii) and 5.1; PD2010_055, procedures, including cl 2.3 on exemption from ethical review. Sequencing governance work does not displace the applicable ethics pathway or the requirement for written site authorisation.

¹² OHMR, [Ethics and governance metrics](#), FAQ concerning simultaneous site and ethics applications.

or class of activities, with project-level confirmation that they remain sufficient and referrals confined to departures requiring further resources or assessment.

Question 6.5.3. What conditions need to be met for coordinated approaches (e.g. one SSA per LHD) to be appropriate and efficient?

Coordinated approaches should have a clear allocation of responsibilities, an accessible record of common assessments and a means of identifying material differences between sites (for example, whether one site can store the samples at the required temperature and another cannot). These arrangements can improve ordinary SSA without requiring a standing authorisation or an institutional umbrella deed.

As an optional alternative for suitable institutions and programmes, the revised directive should permit standing authorisation for defined activities at identified sites. Institutions demonstrating the relevant capability could confirm internally whether registered projects fall within that authorisation, without a fresh SSA application or routine prior approval of the scope check by another governance office. This could operate within one institution or across a collaboration. The present requirement for a separate application at each site, together with the associated project endorsement and authorisation requirements, would need to be revised expressly; this is a proposed alternative pathway, not an interpretation that the current directive already permits it.¹³

For established collaborations, an institutional umbrella deed could settle common terms for document sharing, data and material transfers, facilities and reliance on assessments across projects. Each project would identify the arrangements relied on and any material departure requiring further consideration (for example, a proposed transfer of samples to an organisation outside the agreement). An umbrella deed would be unnecessary where suitable arrangements already exist or work is confined to one institution. Its practical value would resemble agreed terms for a continuing service: the institutions settle recurring questions once, while each project specifies the work and any departure from those terms (for example, the samples to be transferred, the analyses required and the permitted recipients of results). The deed would settle those terms; any standing authorisation would need its own basis, scope and conditions.

Where the optional pathway is adopted, activities falling within the standing authorisation should be able to proceed once their inclusion is recorded and the applicable conditions, including any required ethical approval, are satisfied. An activity requiring additional authorisation should be referred separately and should not hold up authorised work unless that work depends on the outstanding decision.

An umbrella deed should identify what institutions and authorised officers may undertake and rely upon. Reliance on a specialist assessment should not automatically import the other institution's unrelated procedural restrictions; differences should be resolved against the activities and responsibilities within the collaboration's agreed scope.

Institutions adopting standing authorisation should identify who has the expertise and lawful authority to confirm that a project falls within its scope and satisfies its conditions (for example, the proposed activity and site are covered, and the required expertise is available). The allocation of that function should be settled by the institution. Confirmation should be written and recorded; registration alone would not confer authorisation. Within

¹³ NSW Health, PD2010_056, mandatory requirements and procedures cls 3.4.2–3.4.3, 3.5 and 5.1. Clause 3.4.3 requires a separate application for each site, including sites controlled by the same PHO. The institutional pathway proposed here would require coordinated policy amendments and confirmation of the legal authority for standing authorisation and internal scope decisions. See also NSW Health, NSW Health Policies and Other Policy Documents, PD2025_031 (17 July 2025), s 3.5, p 16, on approval of substantive policy amendments by the Secretary or relevant Deputy Secretary.

the proposed model, confirmation would not require a fresh discretionary approval, while decisions reserved to other authorities would remain with them.

Sonja van Wichelen's analysis of international material transfer agreements draws attention to their role in sustaining reciprocity, recognition and participation in research.¹⁴ Umbrella deeds should preserve commitments concerning permitted and onward uses, access to findings and recognition of contributions, including commitments associated with the material's source (for example, a restriction on passing donated samples to another laboratory or using them in a different study). Terms governing information derived from materials should also be explicit (for example, whether a laboratory may retain sequence data after returning or destroying the samples).

Institutions should qualify for standing authorisation only if they demonstrate the relevant capability. Any high-risk activities must be expressly covered, and those granting the authorisation or confirming a project's scope must act within their lawful authority. Scope confirmations, changes and exceptions should be subject to proportionate audit and periodic review. Institutions should not have to adopt this pathway to benefit from the wider reforms.

Question 6.5.4. How could shared issues, such as agreements, data arrangements or common study documents, be communicated consistently across participating sites?

For shared matters, the existing project record should identify:

- the responsible reviewer;
- the outcome;
- the relevant version;
- affected sites;
- conditions of reliance (for example, that the same protocol version and data access restrictions apply).

Participating institutions should be able to identify the shared conclusion, its scope and any disagreement requiring resolution. Material changes (for example, adding a laboratory that will receive identifiable information) should prompt reconsideration of the affected issue and communication with institutions relying on the earlier outcome. The choice of record or coordination arrangement should follow local needs and the systems already available.

Shared governance review should be coordinated with the separate acceptance and routing arrangements under PD2010_055, National Mutual Acceptance and the NSW Early Phase Clinical Trials HREC Scheme.¹⁵ Changes to those arrangements would need to proceed through their respective processes.

¹⁴ Sonja van Wichelen, 'After Biosovereignty: The Material Transfer Agreement as Technology of Relations' (2023) 53(4) *Social Studies of Science* 599, 608–614. Her analysis concerns the Indonesian and international context of material transfers, reciprocity, recognition and scientific exchange; the institutional-authorisation proposal in this submission is my own.

¹⁵ OHMR, [Which HREC to consult at your study phase](#), 'NMA exemption for adult early phase clinical trials in NSW', 'Paediatric early phase clinical trials in NSW' and 'Age group within the scope'. Adult EPCTs at NSW PHO sites are excluded from NMA and routed to Bellberry. Paediatric EPCTs with a NSW PHO lead site are routed to SCHN. For multicentre paediatric EPCTs, the guide preserves acceptance of approval by an HREC hosted in a specialist paediatric tertiary hospital outside NSW. It also specifies mixed-age criteria; routing should follow those criteria rather than an unqualified adult/paediatric shorthand.

6.6 SSA form and system design

Question 6.6.1. How well does the current SSA form and system workflow support applicants, reviewers, services and decision-makers to provide and locate the information needed for site authorisation?

I do not offer an operational evaluation of the current form or REGIS workflow. NSW Health should assess existing functions against the information needs identified in questions 6.6.3–6.6.4, retaining what works and addressing gaps or duplication.

Question 6.6.2. Based on your experience, what parts of the current form or workflow support efficient preparation and review?

I do not have an experience-based assessment of which current features work best; the recommendations below concern design requirements.

Question 6.6.3. What would improve visibility of current documents, version control, review status and communication between roles?

Participants in the authorisation process should be able to identify the current documents, their approval status and outstanding decisions. Relevant completed assessments should remain available for reliance. NSW Health should develop these information requirements with users, without assuming that a new record or platform is necessary.

NSW Health should prioritise improving and connecting existing systems while allowing participating institutions to use compatible shared systems where those better support their collaboration. Common requirements should address reliable information exchange, lawful access and an auditable record, without prescribing a single technical architecture.

Where institutions exchange records, their source, currency and scope should remain clear, together with any changes material to reliance. The choice between linking, importing or otherwise sharing information should follow technical assessment and user needs.

Automated checks may help identify omissions or inconsistencies, but their usefulness should be tested with applicants and reviewers. Users should be able to understand and challenge a flag. Software rules should remain subordinate to the governing requirements and should not introduce additional substantive conditions by default.

AI-assisted tools may improve communication between institutional systems by matching fields, reconciling terminology and identifying equivalent records (for example, recognising that differently labelled fields refer to the same approval). Their use should preserve the meaning, provenance, permissions and conditions attached to source information. Automated interpretation should not itself expand an authorisation or alter its conditions.

Any use of AI for information exchange should have accountable arrangements for validating fidelity to source records and resolving discrepancies. The appropriate technical assurance and allocation of responsibility should be determined with information governance specialists and users, proportionately to the consequences of error. Checking an output against a source record does not establish where either record was processed or retained. Any proposed exchange should also demonstrate compliance with the applicable access and data handling conditions (for example, a requirement that identifiable records remain within an approved environment). Where that cannot be demonstrated, the affected AI use should not proceed until a compliant arrangement is established.

Question 6.6.4. What practical enhancements or alternative approaches could make the SSA form and/or the system easy to use and intuitive?

The following matters should inform the design of the form, with the detail and presentation tested with users:

- Health information: the data custodian, proposed collection, use and disclosure, applicable legal bases, recipient and privacy regimes. The form should distinguish consent from other lawful grounds and identify any approval still required.
- Human tissue: its source and status, the applicable consent or authorisation requirements, and the basis on which any proposed payment is lawful under s 32 of the Human Tissue Act 1983 (NSW), including any exception relied on.
- Therapeutic goods: distinguish the applicable product regime and any exclusion or exemption before asking about a supply pathway. Where CTN or CTA is required, identify the pathway and sponsor. Existing sponsor assessments or relevant regulatory advice should be referenced rather than reproduced. Fields for inapplicable requirements should be suppressed. GMO dealings require a separate assessment under the gene technology scheme (see the discussion under “Commonwealth product classification and supply pathways”).
- **Documents and readiness:** current versions, approval status, resources, service support, structured explanations of outstanding information, responsible officers, maximum timeframes, pauses and extensions. The record should show both completed and continuing work and retain the reasons for changes to deadlines.

For later research use of data or samples, the record should identify the scope of consent or other authority, restrictions and outstanding approvals. Unresolved permission should be visible to users.

REGIS or an interoperable system should link the project to the authorisation, agreements and assessments relied on. For standing authorisation, it should support registration and scope confirmation without reproducing the full SSA form, linking any umbrella deed used.

The research record proposed in section 6.1 should identify where clinical observations are held, their custodian and access arrangements, without copying patient-level information into the authorisation form.

6.7 Research passport

Question 6.7.1. What checks, approvals or evidence are commonly repeated across sites or organisations?

I have not assessed how frequently particular checks are repeated across NSW institutions. Candidates for reusable evidence include:

- identity;
- qualifications;
- relevant training;
- professional registration;
- insurance and indemnity;
- police or working-with-children checks where required.

Question 6.7.2. What information would a NSW Public Health Organisation need before relying on checks or assurances completed elsewhere?

The UK model described in the Discussion Paper offers a starting point: checks validated by one organisation and carried in a portable record. A receiving PHO needs the identity of the validating organisation, the evidence checked, currency dates and the scope of activities for which the checks are relevant.

Where an institution has granted standing permission to participate in defined research activities, the passport should be capable of recording it. A researcher with current

credentials and permission covering the proposed role should be able to join a qualifying project through recorded confirmation, without a fresh application for the same authority. Recognition of specialist expertise should support rapid confirmation for the relevant task. Reusable credentials and recognition of expertise should remain useful whether or not standing permission is available.

Question 6.7.3. Which access decisions would still need to remain local, even where some checks or assurances had already been completed?

Institutions should retain decisions about local induction, supervision, access and activities outside existing permission (for example, permission to use a particular laboratory). Where standing permission covers the proposed role (for example, analysis of specified coded data within an approved computing environment), a simple recorded confirmation may suffice. The means of confirmation should be settled locally, with physical attendance distinguished from authority to participate in a project.

Host and employing organisations should record their responsibilities and arrangements for communicating concerns. Employer notification should serve a defined purpose without becoming another project approval step.

Question 6.7.4. What practical risks could arise if researcher access checks were standardised or mutually recognised across NSW Public Health Organisations?

Risks to consider include reliance on expired or incomplete checks, uncertainty about permitted activities and mistaken assumptions about another institution's responsibilities. Clear evidence of currency and scope, together with arrangements for communicating changes, could reduce those risks; their relative importance should be assessed with participating institutions.

Suspension of reliance on a credential should be proportionate to the concern and its implications for the proposed activities. Unrelated permissions should remain effective where safe and lawful. Institutions should settle arrangements for notification, correction and review that allow others relying on the credential to understand any change in its status.

Question 6.7.5. How do the access requirements differ between university researchers, students, sponsor staff, contract research organisation staff, external data analysts and NSW Health employees working across sites?

The evidence required should follow the proposed role and activity, including supervision, clinical responsibilities and the scope of access to information or facilities. Employment category alone is an insufficient basis for treating all researchers alike (for example, two university researchers may need different permissions if one analyses data and the other treats participants). Detailed requirements for the groups identified in the question should be developed with host institutions, employers and sponsors, with a view to recognising equivalent evidence where appropriate.

Appointment, access and sponsorship

OHMR should provide guidance on the appointment and access arrangements available to external researchers, including the circumstances in which a contingent-worker arrangement is appropriate. The guidance should distinguish systems access, supervision, indemnity, employment status and authority to perform the proposed activities. It should also explain how the sponsor is identified and accepts responsibility for a student- or university-led study.

6.8 Clinical trial start up costings

Question 6.8.1. Should NSW Health consider a more standardised approach to costings for clinical trials and other research projects? Please outline any benefits, risks or implementation considerations.

For trial conduct and service start-up costs, a common costing method and schedule could provide a starting point that can be adjusted with reasons (for example, where a project requires additional specialist support), with documented adjustments for the work actually required. This proposal concerns the costs agreed between the site and sponsor, which PD2025_017 distinguishes from ethics and governance review fees. Those review fees are already prescribed under PD2025_017 and IB2025_014 and should be separately identified in the budget. The Finance Reform Project identified in the Discussion Paper is the appropriate setting to test the proposed costing method, including whether an activity has already been covered by another charge.¹⁶

The schedule should define the activities and assumptions covered, allow documented adjustments for complexity and identify when rates will be reviewed. It should address the treatment of non-commercial research and guard against both under-recovery and duplicate charges for common work. Implementation should test whether the schedule reduces negotiation time without shifting unfunded service costs onto sites.

Charges should identify the additional work required and give credit for contributions and expenditure already covering that work (for example, laboratory support already funded by the university under a shared arrangement).

Costing should recognise contributions of funding, staff or facilities from participating institutions and sponsors. For established collaborations, an umbrella deed could settle allocation, although contributions should not depend on that form of agreement. Budgets should show the support available and any funding gap (for example, where university funding covers laboratory analysis but not the hospital staff needed for follow-up visits).

NSW Health should facilitate worthwhile research and consider targeted support where there is a demonstrable social or patient need and insufficient funding from other sources. Decisions should consider scientific quality, the importance of the research question, patient need, feasibility and the resources required. Support may take the form of funding, shared services or other institutional contributions. For experimental interventions, anticipated benefit should be assessed without assuming that participation will benefit an individual patient.

Question 6.8.2. Do you have any other comments or suggestions regarding research costings?

Tissue-related charges require a separate check under s 32 of the Human Tissue Act 1983 (NSW). The section prohibits specified contracts or arrangements for valuable consideration, subject to exceptions. These include qualifying sales or supplies of processed or treated tissue under s 32(2), necessary removal expense reimbursement under s 32(3), and arrangements approved by the Minister under s 32(4).¹⁷ Calling a charge

¹⁶ NSW Health, [Fee Schedule for Research Ethics and Governance Review of Clinical Trial Research](#), PD2025_017 (6 May 2025), ss 2–3, 4.4 and 6; NSW Health, [Fees for Research Ethics and Governance Review of Clinical Trial Research](#), IB2025_014 (6 May 2025), tables 3–4.

¹⁷ *Human Tissue Act 1983* (NSW) s 32 ("Trading in tissue prohibited," Part 6): s 32(1) prohibits a contract or arrangement for valuable consideration for the sale or supply of tissue; s 32(2) excepts processed or treated tissue supplied for therapeutic, medical or scientific purposes; s 32(3) excepts reimbursement of expenses necessarily incurred in the removal of tissue; s 32(5) renders an offending arrangement void (s 32(4) allows Ministerial approval in special circumstances). Section 31A concerns authority to use tissue removed for post-mortem examination for other purposes. GL2023_008 distinguishes consent requirements and limits on waiver according to the tissue's source and status.

“cost recovery” does not establish that an exception applies. The costing record should identify what is supplied, what each charge covers and the legal basis relied on. If NSW Health adopts a cost recovery ceiling, that should be stated as a policy choice in addition to the statutory requirements.

Commonwealth product classification and supply pathways

Classification and access to advice

Guidance should distinguish whether goods fall within Commonwealth therapeutic goods regulation, their classification within that framework, and the supply pathway required for the proposed activity. OHMR should facilitate timely access to specialist advice and referral to the TGA where needed, through existing support arrangements. Participating organisations should be able to rely on advice addressing materially identical products and circumstances, reconsidering it where a relevant fact or the law changes. This should resolve uncertainty early without creating another approval body or requiring a fresh classification opinion at every site.

Preserving the hospital exclusion

Qualifying autologous human cell and tissue products are excluded under s 6 and sch 2 item 4A of the Therapeutic Goods (Excluded Goods) Determination 2018. The exclusion is not limited to minimal manipulation or homologous use. Its original explanatory statement relied on practitioner–patient consultation and management of risks by practitioners in the hospital setting. The revised guidance should respect that allocation of responsibility and should not introduce additional approval, reporting or recordkeeping requirements solely because a product is excluded.¹⁸

For hospital–university collaborations, guidance should explain the limits of the exclusion accurately. Item 4A permits contracted off-site storage or testing; a contract does not extend that exception to off-site manufacture generally. Where the status of manufacturing premises is uncertain, OHMR should facilitate clarification with the relevant hospital and Commonwealth authorities. A university affiliation or physical proximity to a hospital should not be treated as resolving that question.

Clinical trial supply pathways

Guidance should distinguish products covered by an exclusion from unapproved therapeutic goods requiring a supply pathway. For the latter, it should identify whether CTN or CTA is required.¹⁹ Because CTN is a notification pathway, the site authorisation record should show the sponsor’s pathway assessment and any steps still required before commencement, drawing on existing sponsor, investigator or HREC records.

Where CTN submission follows local approval, site authorisation may record completion of that notification as a condition to be satisfied before commencement. The record should then be completed with evidence that the notification or approval relied on covers the goods and proposed sites before the affected supply and trial activities begin. A Class 4

¹⁸ *Therapeutic Goods (Excluded Goods) Determination 2018* (Cth) s 6, sch 2 item 4A. The exclusion requires the same patient, the relevant practitioner’s professional supervision, manufacture in the relevant hospital subject to the contracted storage or testing exception, and no direct-to-consumer advertising. See [Explanatory Statement, Therapeutic Goods \(Human Cells, Tissues and Organs\) Determination 2018](#), 2–3: the original exclusion relied on practitioner control, practitioner–patient consultation and management of risks within the hospital setting, regardless of the level of manipulation or processing. See also TGA, [Manufacturing excluded autologous human cell and tissue products](#), especially “Clinical care of a registered medical or dental practitioner” and “All steps in manufacture must occur in the hospital, except storage and testing”.

¹⁹ *Therapeutic Goods Act 1989* (Cth) ss 19(1)(b), 32CK(1)(e), 41HB(1)(e); *Therapeutic Goods Regulations 1990* (Cth) regs 12(2)–(3), 12AD, sch 5A item 3; *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) reg 7.1(2), sch 4 pt 2 item 2.3. The applicable provisions depend on the type of goods. See TGA, [Australian clinical trial handbook](#), on the respective scheme requirements and responsibilities.

biological proposed for CTN should be referred for specialist confirmation that the notification exemption is available under the operative conditions; CTN and CTA should not appear as interchangeable options in the form.²⁰ For GMO work, the record should identify the dealings to be undertaken at the site and the basis of any licence, notifiable low risk dealing (NLRD) classification or exemption, with advice from the institutional biosafety committee where needed.²¹ Unresolved eligibility should prevent commencement of the affected activity, while unrelated governance preparation may continue.

Further assistance

I would welcome the opportunity to discuss the legal and governance conditions for these proposals, including how their effects on review times, duplication and local accountability could be evaluated.

Thank you for the opportunity to contribute.

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²⁰ *Therapeutic Goods Regulations 1990* (Cth) sch 5A item 3, especially col 3(h), which restricts the CTN exemption for Class 4 biologicals. The sponsor should identify the basis on which the operative conditions are satisfied and resolve any uncertainty with TGA before relying on CTN. See also TGA, [Australian clinical trial handbook](#), 'Choosing between the CTN and CTA schemes' and 'The CTN scheme'. The applicable goods classification and conditions, rather than the trial's phase alone, determine whether the notification exemption is available.

²¹ Office of the Gene Technology Regulator, [Types of GMO dealings](#), describing the applicable classifications and approval processes. For example, introduction of qualifying genetically modified human somatic cells does not require an OGTR licence: the cells must be incapable of secreting or producing infectious agents as a result of the modification and, if generated using viral vectors, testing must not detect viruses likely to recombine with the modified nucleic acid, with the vector no longer present. OGTR, [Guidance for Conducting Human Clinical Trials Involving GMOs](#) (September 2022) 1, describes dealings with qualifying cells as exempt. See *Gene Technology Regulations 2001* (Cth) reg 6 and sch 2; sch 3 cl 3.1(1)(n) states the somatic-cell exception to the exclusion from NLRD classification and is not itself the exemption provision. Exempt dealings must not involve intentional environmental release. The production process in Australia must separately be appropriately authorised. On the 2011 reforms and CAR-T therapies, see Gabrielle M O'Sullivan et al, '20 Years of Legislation — How Australia Has Responded to the Challenge of Regulating Genetically Modified Organisms in the Clinic' (2022) 9 *Frontiers in Medicine* 883434, 4–7; Gabrielle O'Sullivan, Joshua G Philips and John EJ Rasko, 'Clinical Gene Technology in Australia: Building on Solid Foundations' (2022) 217(2) *Medical Journal of Australia* 65, 67 (box 2).