Policy Statement

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INTELLECTUAL PROPERTY POLICY

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Summary:	This policy sets out how TROG identifies, protects, manages, and uses Intellectual Property (IP) arising from its activities
Applies to:	This policy should be followed by: a) TROG Cancer Research employees b) TROG Board members c) Investigators and collaborators of TROG
Approved by:	TROG Board of Directors
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1. Purpose

TROG Cancer Research ("TROG") undertakes investigator-led cancer clinical trials and research in collaboration with member sites, universities, funders, industry partners, and international cooperative groups. This policy sets out how TROG identifies, protects, manages, and uses Intellectual Property (IP) arising from its activities to:

- support high-quality research and translation for public benefit
- meet obligations under Australian research funding and governance requirements
- ensure appropriate recognition and fair allocation of rights and responsibilities
- enable ethical commercialisation and dissemination of outcomes
- manage conflicts of interest and ensure research integrity.

2. Scope

This policy applies to:

- TROG employees, contractors, consultants, and volunteers
- TROG Board members and committee members (where relevant)
- investigators and collaborators involved in research activities where TROG is the sponsor, coordinating centre, administering institution or provider of central quality assurance activities (including radiation therapy quality assurance (RTQA)).
- all TROG research activities including but not limited to clinical trials, secondary data analysis, registries, translational research, as well as associated research outputs such as datasets, software tools, biological samples and materials derived from those samples.

This policy operates alongside (and does not replace) project-specific agreements, including clinical trial research agreements, collaboration agreements, service agreements, material transfer agreements, and data access agreements.

3. Definitions

For the purposes of this policy:

- **Intellectual Property (IP)** means all statutory and non-statutory rights in inventions, discoveries, methods, processes, know-how, designs, copyright works (including documents,

protocols, manuals, databases, software code), trademarks, and any other protectable or commercialisable outputs, whether registrable or unregistrable

- **Invention:** any invention, idea, discovery, development, improvement or innovation whether or not patentable or capable of registration, and whether or not recorded in any medium
- **Background IP** means IP owned or controlled by a party prior to the commencement of an activity or project, or developed independently of that activity or project, whether before or after its commencement.
- **Project IP / Foreground IP** means IP created, developed or generated in the course of or arising from, a TROG activity or project, by or on behalf of TROG, its investigators, collaborators, or service providers.
- **Clinical Trial Data** includes all trial data collected, generated, managed, and/or curated for a TROG-led or TROG administered clinical trial or research project, including analyses and derived datasets.
- **Confidential Information** includes, but is not limited to any and all non-public information owned, licensed or controlled by TROG in whatever form, including without limitation written, visual or oral form, on electronic media or in the form of samples on the subject of, or containing information whether concerning the field or not; **Commercialisation** includes licensing, assignment, sale, spin-out creation, or other exploitation for value.

4. Policy principles

TROG manages IP in accordance with the following principles:

1. **Public benefit and research translation:** IP should be managed to promote patient benefit, responsible innovation, and impact.
2. **Compliance and accountability:** IP must be managed consistently with legal and ethical obligations, grant conditions, and governance requirements.
3. **Clarity of ownership:** Ownership and rights must be documented early and reflected in appropriate agreements.
4. **Academic freedom and publication:** Results should be published in a timely manner, regardless of whether the findings are positive, negative, neutral or inconclusive; subject to ethical, confidentiality and protection requirements.
5. **Fair recognition:** Contributors should be fairly and appropriately acknowledged, including through inventorship and authorship where applicable, consistent with research integrity and publication standards. Recognition should reflect the nature, significance and extent of the contribution, not simply time spent.

6. **Protection where appropriate:** TROG will protect IP where this supports translation, impact, and value-for-money outcomes.
7. **Responsible commercialisation:** Commercial arrangements must be ethically managed, transparent, and aligned with TROG's mission.

5. Ownership of Intellectual Property

5.1 Background IP

Each party retains ownership of its Background IP. Access rights to Background IP required to deliver a project must be documented in a written agreement (e.g., licence for project purposes).

5.2 TROG IP

TROG's position regarding ownership of IP is as follows:

- IP created by **TROG employees** in the course of their employment is owned by TROG.
- IP created by **contractors or consultants** for TROG will be owned by TROG where the relevant contract includes appropriate IP assignment provisions.

These positions should be documented in employment and commercial arrangements. Departures from above must be approved by the CEO.

5.3 Collaborator and multi-party IP

Where IP is developed jointly with other parties (e.g., universities, hospitals, industry partners), ownership will be determined and recorded in a written agreement. In general:

- each party will own the IP it creates; and/or
- jointly created IP will be jointly owned in proportions reflecting contribution, unless otherwise agreed.

5.4 Investigator and site-generated IP

IP created by investigators or sites may be owned by their employing institution unless agreed otherwise. TROG will ensure appropriate project agreements include:

- rights needed to conduct the project and use relevant outputs
- publication pathways and acknowledgements
- access rights for ongoing trial conduct and regulatory requirements
- any commercialisation pathways (if applicable).

6. Clinical Trial Data, study documents and research outputs

6.1 Trial documents and coordination materials

TROG owns copyright in TROG-developed study documents and operational materials, including their design, structure, format and content, and including where applicable:

- protocols and amendments
- case report forms and participant materials
- monitoring tools and trial coordination procedures
- training materials
- statistical analysis plans and reporting templates.

Where templates or materials incorporate third-party content, TROG will ensure appropriate permissions are in place.

6.2 Custodianship and governance of Clinical Trial Data

TROG is the custodian of Clinical Trial Data for TROG-sponsored studies unless a written agreement states otherwise. Data must be governed in accordance with:

- ethics approvals and participant consent
- privacy and data protection requirements
- TROG policies on data access, secondary use and publication
- contractual obligations to funders, collaborators and sponsors.

6.3 Secondary use, sharing and access to data

Requests for access to Clinical Trial Data (including secondary analyses) must follow TROG's data access procedures and may require:

- ethics/HREC confirmation (as applicable)
- a data access agreement
- appropriate confidentiality and de-identification safeguards
- publication and acknowledgement conditions.
- review and decision-making within reasonable timeframes, subject to the complexity of the request and any ethical, legal, governance or operational requirements.

7. Disclosure, protection and confidentiality

7.1 Duty to disclose potentially protectable IP

All TROG personnel and project participants must promptly notify TROG if they believe a project has produced potentially protectable IP, including inventions, software tools, or novel methods.

Notification should occur **before** any public disclosure (including abstracts, posters, conference presentations, manuscripts, websites, preprints, or stakeholder communications).

7.2 Confidentiality obligations

All TROG personnel must protect Confidential Information and comply with confidentiality requirements in:

- employment and contractor agreements
- trial and collaboration agreements
- sponsor agreements
- ethics and governance approvals.

7.3 Protection measures

TROG may seek appropriate protection where justified, including:

- patenting or provisional filings
- copyright notices and access controls
- trade secret management and confidentiality controls
- trademark registration for TROG programs or initiatives.

Protection decisions will consider: public benefit, translation potential, time sensitivity, cost, freedom-to-operate, and funder requirements.

8. Publication and dissemination

8.1 Publication commitment

TROG supports dissemination of research outcomes through peer-reviewed publication and scientific presentation, consistent with research integrity obligations.

8.2 Publication approvals and timing

Publications and presentations arising from TROG projects must comply with:

- ethics and consent requirements
- confidentiality obligations
- trial agreements (including industry partner review rights where applicable)
- TROG publication policy and authorship processes (where applicable)
- IP protection requirements (including delaying disclosure briefly to enable filings).

Where partner review is required, it must be limited to ensuring protection of Confidential Information and protectable IP, and must not unreasonably delay publication.

8.3 Acknowledgement of funding

All outputs must acknowledge relevant funding sources in accordance with applicable funding agreements, including NHMRC and MRFF where relevant.

9. Commercialisation and revenue sharing

9.1 Commercialisation pathways

Where commercialisation is appropriate, TROG may pursue:

- licensing to a third party
- collaborative development with an industry partner
- assignment or sale of IP
- other appropriate commercialisation or translation pathways approved by the Board.

Commercialisation must be consistent with TROG's charitable purpose and any constraints in funding or collaboration agreements. Commercialisation of IP must be approved by the Board or CEO in accordance with this Policy.

9.2 Revenue use

Net revenue derived from IP commercialisation will be used to advance TROG's mission (including reinvestment in research, infrastructure and sustainability), subject to:

- contractual obligations
- Board-approved financial delegations and governance processes
- any required distribution arrangements with co-owners or inventors (where agreed).

9.3 Inventor recognition and benefit sharing

TROG will recognise inventors and contributors and may implement benefit-sharing arrangements where appropriate, taking into account:

- the nature of the contribution
- co-ownership and institutional arrangements
- applicable laws and agreements
- administrative burden and public benefit.

Any benefit-sharing approach must be documented and approved through TROG governance processes.

10. Conflicts of interest

All persons covered by this policy must declare actual, potential or perceived conflicts of interest relating to intellectual property, commercial relationships, consultancy or advisory roles, equity or ownership interests, or personal benefit.

Conflicts must be managed in accordance with TROG's Conflict of Interest Policy and may require:

- management plans
- recusal from decisions

- independent oversight or review
- disclosure in publications and presentations.

11. Third-party IP and open-source software

11.1 Third-party IP

Before using third-party materials (including tools, datasets, software, images, or instruments), all persons covered by this policy must ensure appropriate permissions and licensing are in place.

11.2 Software IP ownership

Unless otherwise agreed in writing, software, source code, scripts, algorithms, databases, workflows, applications, tools, machine learning and/or artificial intelligence models and related documentation developed in the course of TROG activities or projects shold part of TROG Project IP and all commercial arrangements should be drafted accordingly.

11.3 Open-source software

Use of open-source software must comply with relevant licence terms. Where TROG develops software, TROG will determine an appropriate distribution model (e.g., open-source vs proprietary), considering:

- funder expectations
- sustainability and maintenance obligations
- interoperability and security considerations
- commercialisation potential.

12. Grant and funding compliance (NHMRC/MRFF and other funders)

Where TROG is an administering institution or otherwise responsible for grant management, TROG will manage IP and outputs in line with:

- the relevant grant agreement and funding rules
- obligations for proper use of funds, reporting, and governance
- requirements for appropriate management of research outputs, dissemination and impact
- any conditions relating to collaboration, exploitation, or benefit sharing.

Project leaders must ensure IP arrangements are identified early and recorded in project documentation.

13. Roles and responsibilities

13.1 Board

The Board provides oversight of IP governance and approves (or delegates approval for):

- significant commercialisation decisions and material IP transactions
- IP-related risk settings and major disputes.

13.2 Chief Executive Officer (CEO)

The CEO is responsible for:

- implementing this policy
- ensuring appropriate agreements are in place for projects
- approving IP protection or commercialisation actions within delegated authority
- escalating material risks or transactions for governance approval.

13.3 Project Leaders / Chief Investigators (CIs)

CIs and project leaders are responsible for:

- identifying potential IP early
- ensuring project agreements reflect the intended IP arrangements
- ensuring compliance with confidentiality and publication requirements
- notifying TROG of protectable IP before public disclosure.

13.4 Staff, contractors and collaborators

All personnel must:

- comply with this policy and related procedures
- protect Confidential Information
- participate in disclosure processes when relevant
- avoid unauthorised use of TROG materials or data.

14. Records and documentation

TROG will maintain appropriate records relating to IP, including:

- invention disclosures and determinations
- agreements governing ownership, licensing and publication
- commercialisation decisions and approvals
- conflict of interest declarations and management plans
- data access requests and approvals (where applicable).

15. Breaches and enforcement

Breaches of this policy may result in corrective action, including:

- requirement to remediate harm (e.g., retraction, corrective disclosures, access restrictions)

- disciplinary action for employees (where applicable)
- contract remedies for contractors or collaborators
- reporting to funders or regulators where required.

16. Related documents

This policy should be read alongside:

- TROG Conflict of Interest Policy
- TROG Publication Policy
- TROG Data Access / Secondary Data Access Guidelines
- TROG Privacy and Data Governance Policies
- Research Integrity and Code of Conduct documents
- Clinical trial agreements and collaboration templates.

17. Review

This policy will be reviewed at least every **two (2) years**, or earlier if required due to:

- changes to NHMRC/MRFF requirements or Australian law
- material changes to TROG's operating model
- audit findings or incidents.

Appendix A **(optional): IP Disclosure Form (template headings)**

1. Project title and identifier (trial number / grant ID)
2. Description of the invention / method / output
3. Contributors and affiliations
4. Date and circumstances of creation
5. Prior disclosures (if any)
6. Publications planned / deadlines
7. Supporting documentation
8. Recommendation (protect / publish / open-source / other)
9. Conflicts of interest declared