

Policy Memorandum No. 47

Subject: Intellectual Property

Departments Affected: All

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INTELLECTUAL PROPERTY POLICY

Background and Purpose

The SWOG Cancer Research Network (SWOG) is a global cancer research community funded predominantly by the National Cancer Institute (NCI) and part of the NCI's National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP). SWOG designs and conducts multidisciplinary clinical trials to prevent, detect, and treat cancer.

In conducting clinical trials, SWOG and its participating institutions generate valuable intellectual property (IP), proprietary methods, clinical trial data, and biological specimens. Because SWOG operates through a network of independent academic and clinical institutions rather than as a single corporate employer, this policy establishes principles for ownership, stewardship, access, permitted use, protection, and governance of those assets. For purposes of this policy, intellectual property governance is a multi-layered framework under which ownership of patentable inventions generally remains with the inventing investigator's member institution under the Bayh-Dole Act, or, in the case of a commercial entity, with that entity, subject to federal rights and applicable NCI and CTEP requirements, including CTEP IP Option to Collaborator rights (explained below). Separately, SWOG maintains custodial and stewardship responsibilities for SWOG protocols, clinical trial data and biospecimens collected under SWOG protocols. This policy is intended to support and ensure compliance with federal law, NIH award terms, NCI and CTEP requirements, protocol-specific obligations, informed consent and IRB requirements, privacy protections, and contractual commitments, while protecting investigator rights, trial participant interests, scientific integrity, and collaborations that advance cancer care.

Defined Terms

For purposes of this policy, the following terms have the meanings set forth below unless the context or a more specific legally controlling agreement provides otherwise.

- **Agent-Treated Specimens** means biospecimens collected from clinical trial participants who received an investigational proprietary agent supplied through an applicable NCI/CTEP agreement, including a CRADA or CTEP CTA, or through a Clinical Trial Agreement held directly by SWOG.
- **Biospecimens** means human biological materials collected, processed, stored, shared/transferred, and/or analyzed, in connection with a SWOG study, including tissue, blood, fluids, nucleic acids, derivatives, and associated annotations (clinical trial data).
- **CRADA** means a Cooperative Research and Development Agreement, typically used by NCI/CTEP to support broader co-development of an investigational agent or technology with an outside collaborator, which may include preclinical and clinical research, regulatory responsibilities, intellectual property provisions, data rights, confidentiality, publication review, and provision of a proprietary agent or technology.
- **CTA** means a Clinical Trial Agreement. A **CTEP CTA** is an NCI/CTEP agreement with an outside collaborator that provides an investigational agent or other proprietary technology for clinical testing under NCI/CTEP-sponsored or supported research, without necessarily involving the broader co-development structure of a CRADA. A **SWOG CTA** is a Clinical Trial Agreement held directly by SWOG or a SWOG-related contracting entity with an outside collaborator for a SWOG-supported clinical trial, including terms governing agent supply, funding, study conduct, confidentiality, publication, data, biospecimens, intellectual property, and other trial-specific obligations.

- **Clinical Trial Data** means clinical, genomic, DICOM imaging, scanned tissue slide images, outcomes, safety, statistical, correlative science, and other study data generated, collected, analyzed, or maintained in connection with a SWOG protocol.
- **Collaborator** means any industry sponsor that provides investigational agents, funding, and other support for a SWOG study under an applicable CRADA or CTA agreement.
- **Confidential Information** means non-public information disclosed or generated in connection with a SWOG study, including SWOG Protocols, proprietary agent information, unpublished results, trade secrets, regulatory information, operational information, participant-related information, and information designated as confidential under an applicable agreement.
- **CTEP IP Option** means the NCI Cancer Therapy Evaluation Program Intellectual Property Option to Collaborator, or any successor or related mechanism, that governs defined Collaborator rights in certain inventions arising from studies involving Collaborator-provided agents.
- **Data Use Agreement or DUA** means a written agreement governing access to, use of, disclosure of, protection of, and retention of data.
- **Intellectual Property or IP** means inventions, discoveries, patent rights, copyrights, trade secrets, proprietary methods, know-how, data rights, and other legally protectable research outputs, but does not by itself alter institutional ownership, SWOG stewardship, federal rights, or collaborator rights established by applicable law or agreement.
- **Investigator** means the approved party conducting research that uses SWOG assets governed by this policy.
- **Material Use Agreement or MUA** means a written agreement governing the transfer, receipt, handling, permitted use, storage, return, destruction, and custody of biospecimens.
- **Member Institution** means an institution, site, university, hospital, cancer center, or other organization credentialed through the NCI and approved by SWOG to participate in SWOG research through NCI supported NCTN or NCORP networks.
- **Subject Invention** means an invention conceived or first actually reduced to practice in the performance of supported research and subject to the Bayh-Dole Act, NIH award terms including the CTEP IP Option, or other applicable federal requirements.
- **SWOG Protocols** means SWOG-developed and administered study protocols, concepts, study designs, statistical plans, correlative science plans, operational procedures, manuals, forms, methods, and related study documents.

Governing Frameworks and Agreements

All intellectual property, data, biospecimens, protocols, confidential information, and research outputs created, developed, used, transferred, or derived from SWOG-conducted clinical trials and research protocols are governed by the following primary frameworks, as applicable. In interpreting applicable terms, the more specific or legally controlling requirement shall govern, including federal law, NIH award terms, NCI or CTEP requirements and policies, protocol-specific language, CRADAs, CTAs, DUAs, MUAs, informed consent, and applicable institutional agreements.

- **CTEP IP Option to Collaborator:** For clinical studies utilizing investigational agents supplied through NCI CTEP, including studies under a CTEP-sponsored IND, NCI-supported studies using Collaborator-provided agents, and secondary research using data or biospecimens generated from

such studies, IP rights and Collaborator options are governed by the NCI CTEP Intellectual Property Option to Collaborator required to be present in both CRADA and CTA agreements. These terms may grant Collaborators defined non-exclusive license rights or time-limited options to negotiate exclusive or co-exclusive licenses for certain inventions, subject to institutional ownership rights and rights of the U.S. Government.

- **Industry Agreements:** Where research is supported by direct industry partnerships, excluding all federal funding, through SWOG Clinical Trials Partnerships or a successor SWOG entity, the applicable intellectual property, data, specimen, confidentiality, publication, disclosure, regulatory, and commercialization rights will be governed by SWOG held CTAs with industry partners.

Inventorship and the Bayh-Dole Act

SWOG is a network organization and is not itself the legal inventor of patentable discoveries. Patentable inventions generated within the network are conceived or first actually reduced to practice by SWOG investigators, clinicians, researchers, or other personnel employed by their respective member institutions. The inventing member institution is responsible for determining inventorship and ownership under applicable law, institutional policy, funding terms, and agreements, and for coordinating with SWOG, NCI CTEP, Collaborators, and other affected parties as required.

- **Protection of Investigator Rights:** SWOG's primary objective regarding patentable IP is to protect investigator inventorship rights and member institutions' proprietary interests, subject to applicable federal rights, funding terms, and agreements.
- **Federal Compliance and Invention Reporting:** Protection of investigator and institutional rights shall be maintained in accordance with SWOG's obligations and member institutions' obligations under the **Bayh-Dole Act (35 U.S.C. § 200 et seq.)**, NIH award terms, and implementing regulations. Member institutions must require covered personnel to disclose subject inventions promptly, review and report federally funded subject inventions through iEdison when applicable, elect title within required timelines, file patent applications when title is elected, include required federal support clauses, provide confirmatory licenses to the U.S. Government, submit utilization reports, and otherwise preserve federal rights. Failure to satisfy Bayh-Dole or NIH invention-reporting obligations may result in loss of patent rights, funding remedies, or other corrective actions.
- **Coordination with CTEP and Collaborator Rights:** When a subject invention may fall within the scope of a CTEP IP Option included in a CRADA, CTA, MUA, DUA, or other agreement, the investigator and member institution must notify and coordinate with the NCI, SWOG and the appropriate institutional technology transfer office before public disclosure, patent filing, licensing, data transfer, or commercialization activity. Collaborator rights must be acknowledged and are limited to those expressly granted by the applicable agreement and remain subject to federal rights and institutional ownership determinations.

SWOG Protocols and Proprietary Information

SWOG Protocols, including study designs, statistical plans, concepts, objectives, correlative science plans, operational procedures, and methodologies developed by SWOG committees and SWOG's Network Operations Center, constitute the **intellectual and proprietary information of SWOG**, subject to applicable NCI, NIH, and contractual requirements.

- Unauthorized distribution, reproduction, disclosure, publication, commercialization, or use of SWOG protocols, study concepts, statistical plans, proprietary methods, confidential collaborator information, or unpublished study results outside the scope of authorized network activities is prohibited.

- Access to proprietary protocol information is granted solely to facilitate the safe, compliant, and accurate execution of the clinical trial and related approved research activities.
- Manuscripts, abstracts, presentations, public disclosures, and other publications must be reviewed under applicable SWOG, NCI and CTEP requirements and procedures to identify confidential information, patentable inventions, proprietary agent information, privacy concerns, and publication obligations, while avoiding unreasonable delays inconsistent with academic and NIH expectations.

Custody of Patient Specimens and Clinical Trial Data

Patient biospecimens, including tissue, blood, fluids, nucleic acids, and other biological materials, together with clinical, laboratory, genomic, DICOM imaging, scanned tissue slide images, outcomes, and other study data collected during SWOG trials are vital resources dedicated to public health advancement. These resources are governed separately as distinct from patentable inventions: member institutions may own certain inventions, but SWOG maintains custodial and stewardship responsibilities for data and specimens collected under SWOG protocols, subject to NCI, NIH, consent, and contractual requirements.

- **Legal Custody and Stewardship:** All clinical trial data and patient specimens collected under SWOG protocols are under the **primary legal custody and stewardship of SWOG**. SWOG's custodial role includes preserving scientific value, participant protections, specimen integrity, data quality, access controls, confidentiality, and compliance with applicable federal requirements.
- **Participant Ownership and Withdrawal Rights:** Biospecimens are contributed by trial participants subject to the informed consent, IRB approval, protocol requirements and applicable law. SWOG's role is custodial and stewardship-based and does not override participant rights. Participants retain the right to withdraw consent for future use of their identifiable biospecimens or to request withdrawal of specimens from banking or future research use to the extent permitted by applicable law, the informed consent, and practical limitations, including where specimens or data have already been de-identified, distributed, analyzed, exhausted, or incorporated into completed research.
- **Access, Utilization, and Sharing:** Any use, transfer, secondary analysis, data sharing, or biospecimen distribution must be reviewed and approved through the applicable SWOG and/or NCI required process before release or use. Approval will be consistent with informed consent, IRB determinations, participant privacy protections, HIPAA and other applicable privacy laws, NIH Data Management and Sharing Policy obligations, genomic data sharing requirements where applicable, DUAs, MUAs, award terms, Collaborator agreements, and protocol-specific restrictions. De-identified or controlled-access data sharing and biospecimen access will be provided through approved repositories, review committees, NCTN Navigator or other applicable NCI processes, and access agreements as required.
- **NIH Data Management and Sharing:** For NIH-funded research that generates scientific data, investigators and member institutions must comply with any applicable NIH-approved Data Management and Sharing Plan, including requirements regarding what data will be preserved and shared, when sharing will occur, where data will be deposited, who may access the data, what limitations apply, and how compliance will be monitored. Any limitation on sharing must be justified and documented in accordance with applicable NIH, NCI, consent, privacy, intellectual property, and contractual requirements.

SWOG Contracting and Its Role in Supporting This Policy

SWOG contracting is the operational mechanism that translates the intellectual property, data, specimen, confidentiality, publication, data sharing, and collaboration principles described in this policy into enforceable obligations among SWOG, member institutions, investigators, NCI components, and industry collaborators. Because SWOG conducts research through a distributed network rather than through a

single employer-employee structure, contracting provides the legal structure needed to align responsibilities before a trial begins, during study conduct and after study completion.

For federally supported studies, SWOG contracting works alongside NCI and CTEP requirements, including the CTEP IP Option, CRADAs, CTAs, NIH award terms, NCI policies, data management and sharing requirements, biospecimen access requirements, publication requirements, invention-reporting obligations, and institutional commitments. These agreements clarify when industry collaborators may receive defined patent or licensing options, when member institutions retain invention ownership under Bayh-Dole principles, how federal rights are preserved, and how SWOG maintains its custodial role over clinical trial data, protocols, and patient biospecimens.

For non-federal industry-supported studies, SWOG contracting also establishes the terms for intellectual property, financial support, study governance, confidentiality, publication, regulatory responsibilities, access to investigational agents or proprietary materials, data delivery, specimen use, and permitted secondary research. Where SWOG Clinical Trials Partnerships or other SWOG-related contracting structures are used, those agreements support efficient trial development while preserving the scientific mission of SWOG and avoiding conflicts with NCI-sponsored trials.

Contracting supports this policy by ensuring that investigator inventorship and institutional ownership rights are respected; Bayh-Dole reporting and NIH award obligations are addressed; Collaborator rights are preserved and limited to those expressly granted by applicable agreements; SWOG protocols and methodologies remain protected proprietary information; clinical trial data and specimens are accessed only for approved uses; confidentiality obligations apply to sensitive study information; publication and patent-review procedures are coordinated; data management and sharing obligations are documented; commercialization, disclosure, licensing, and secondary research activities are coordinated with applicable federal, institutional, network, consent, privacy, and contractual requirements.

SWOG, investigators, and member institutions are responsible for escalating potential conflicts, suspected unauthorized disclosures, unapproved data or specimen use, failure to disclose inventions, failure to comply with NIH or Bayh-Dole reporting requirements, breach of confidentiality, or failure to follow applicable agreements. Corrective action may include suspension of access to data, specimens, protocols, or study materials; referral to the relevant institution or oversight body; contract remedies; additional training; reporting to NCI, NIH, or other authorities when required; or other action appropriate to the nature and severity of the noncompliance.