MONTANA BIOSCIENCE ALLIANCE
SB 535 PROCESS GUIDE · NO. 2

FLOWCHART · OPERATORS & FOUNDERS

Establishing a Licensed Experimental Treatment Center

The path from concept to a DPHHS-licensed, operating ETC under SB 535 and the 25 implementing rules, ARM 37.106.3301–3325, adopted by MAR Notice 2026-427.2 and effective July 25, 2026.

Status, August 21, 2026: the rules are in force and the licensing pathway is open, but **DPHHS has licensed no center to date** and no patient has been treated. Every step below is untested in practice — the first operators through will set the precedent.

1

FOUNDATION

Entity, site & feasibility

- Form the **Montana business entity**; secure the physical site (clinical space; GMP/manufacturing access if handling product — e.g., the planned Innovation Corridor Gateway).
- Define the **clinical focus**: modalities (drugs, biologics, devices), target sponsor pipeline, patient population.
- Decide **inpatient or outpatient** licensure. A patient admitted to or residing at the facility for **24 hours or more** makes the center inpatient, with the heavier requirement set that follows.
- Line up capital, malpractice/liability insurance, and counsel familiar with the ARM 37.106 rule set. Budget the statutory fees: **$10,000 application, $5,000 annual renewal**.
- Compile the **safety-history disclosure**: prior facility and staff safety records must be fully disclosed in licensing.

SB 535 §1 · fees · ARM 37.106.3301 et seq. · licensing scope, inpatient definition & disclosure duty

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LEADERSHIP

Appoint the two required officers

Administrator

- Oversees daily operations and promotes and protects patient health, safety and welfare
- Manages staff credentialing plus **written orientation and training procedures** for all staff
- Owns records, policies, and regulatory licensure compliance
- May serve multiple centers under common ownership; available daily in person or remotely

Medical Director

- Physician holding a **current license in good standing with the Montana Board of Medical Examiners** — Montana licensure is required from day one
- CHANGED No internal-medicine residency requirement; **relevant specialty licensure now qualifies**
- CHANGED The one-year Montana-licensure tenure requirement was struck at adoption
- Serves as the center's **safety officer**; infection-control duties may be delegated to qualified practitioners
- May serve multiple centers only where each is **owned and operated by the same legal entity**

Correction to earlier editions of this guide: Montana licensure was **not** removed at adoption. What DPHHS struck (responses to comments 6 and 86) was the *one-year* tenure requirement and the internal-medicine residency — the Montana Board of Medical Examiners license itself is retained in ARM 37.106.3308(1). Plan hiring timelines accordingly.

ARM 37.106.3307 (administrator) · 37.106.3308 (medical director) · definitions at 37.106.3304

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OVERSIGHT

Seat the independent review board

MT-Licensed Physician	Clinical Outcomes Researcher	Ethicist	Member 4	Member 5
Required seat	Required seat	Required seat	Conflict-free	Minimum raised from 4 → 5 at adoption to prevent deadlocks

- **No personal, financial, employment, or ownership interest** in the center being reviewed — screened and documented for every member.
- Meets **at least monthly**. Duties: **approve every treatment protocol** before any patient is treated, examine safety and outcomes, and receive serious adverse-event reports.
- Publishes an **annual public report** that must include **aggregate treatment outcome data**.

ARM 37.106.3316 · five-member minimum, required disciplines, COI bar, annual public reporting

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INFRASTRUCTURE

Policies, records & the hospital lifeline

- **Informed-consent documents** disclosing the treatment, its trial phase, experimental status, and all patient costs — and, CHANGED as added at adoption, the **full text of 50-12-110, MCA (immunity from suit)** and the center's **patient grievance policy**.
- **Patient-file system**: consent, protocol, pre-treatment screening, full history and physical **within 30 days** of treatment start, outcomes tracking.

- CHANGED Documentation that the patient **evaluated** other FDA-approved treatment options. "Attempted" was deliberately removed at adoption to match the statute — patients need not have tried or failed alternatives, only considered them.
- **Adverse-event procedures**: serious AEs — death, life-threatening events, hospitalization, or significant incapacity — reported to the department **and** the review board simultaneously within five days.
- **Hospital transfer agreement** executed for emergencies — a licensing prerequisite.
- If devices are in scope: **cybersecurity plan, malfunction protocols, and a patient registry** for connected devices.
- Off-site administration protocols, if the review board may find a treatment safe for delivery outside the center.

ARM 37.106.3312 (patient records, consent, alternatives) · 37.106.3317 (adverse events) · transfer agreements · devices

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LICENSURE

Apply to DPHHS

- Submit the **ETC license application** under ARM 37.106.3301–3325 with the **$10,000 fee**: governance roster, review-board composition and COI screening, policies, transfer agreement, safety-history disclosures.
- Respond to DPHHS completeness review and any inspection or follow-up requests.

Does DPHHS grant the license?

YES **Licensed ETC** — the center may accept sponsors and enroll patients. Proceed to launch. Renew annually at $5,000.

NO Cure the deficiencies identified — personnel qualifications, board composition, policies, disclosures — and reapply.

No precedent yet. As of August 21, 2026 DPHHS has issued no ETC license and published no licensee roster, applicant count, or processing-time guidance. Treat review duration, inspection posture, and the practical evidentiary bar as unknowns, and confirm current forms and mechanics directly with the department before filing.

MAR Notice 2026-427.2 · rules effective July 25, 2026; licensing open, no licenses issued to date

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OPERATIONS

Launch & stay in good standing

- Onboard sponsors; the review board approves each protocol before any patient is treated (see companion flowchart, Guide No. 1).
- Administer at the center, or **off-site where the review board determines the treatment is safe for delivery outside the center** — the rural-access provision, adopted as proposed.
- File the **annual quality and adverse-event report by February 1** through the electronic licensing system. CHANGED The proposed January 31 deadline moved to February 1 at adoption; a late report may reduce the license to **provisional**, and continued noncompliance invites further licensing action.
- The review board publishes its annual public report, including aggregate outcome data.
- Direct **2% of net annual profits** to support access to experimental treatments and health care. This is a **statutory duty under SB 535 §2, not a licensing rule** — DPHHS expressly declined to implement it in rulemaking, so collection and calculation mechanics are unsettled. Get counsel's view early.
- Maintain license: current transfer agreement, credentialed staff, conflict-free board, timely dual AE reporting.

⟲ **Compliance loop:** every new protocol → board approval → consent & H&P → treatment → outcomes & dual AE reporting → annual public reporting. This loop is the license.

ARM 37.106.3322 (reports) · 37.106.3325 (off-site) · SB 535 §2 (2% access allocation, statutory)

The Operator's Bottom Line

An ETC is six building blocks: an entity, two officers — one of whom must hold a Montana medical license — a five-member conflict-free board, a paper-tight safeguard infrastructure, a DPHHS license, and a live compliance loop. The rules took effect July 25, 2026 and no one has been licensed yet. The window is open and entirely unclaimed.

Prepared by the Montana BioScience Alliance. Current as of August 21, 2026. Summarizes SB 535 (2025, Ch. 621) and ARM 37.106.3301–3325 as adopted by MAR Notice 2026-427.2, effective July 25, 2026, for orientation purposes only — not legal or medical advice. Thirteen of the twenty-five rules were modified between the April 2026 proposal and adoption; items marked "changed" above differ from the draft-rule summaries still circulating in published client alerts. No Experimental Treatment Center has been licensed and no patient has been treated under this law as of this printing. Application mechanics, fees, forms, and rule text should be verified directly with DPHHS and qualified counsel before filing.