MONTANA BIOSCIENCE ALLIANCE

SB 535 PROCESS GUIDE · NO. 1

FLOWCHART · SPONSORS & MANUFACTURERS

Sponsoring a New Drug Through a Licensed Experimental Treatment Center

The pathway for a drug, biologic, or device sponsor to make a post–Phase I investigational therapy available to eligible patients through a licensed Montana ETC — under SB 535 and ARM 37.106.3301–3325, adopted by MAR Notice 2026-427.2 and effective July 25, 2026.

Status, November 19, 2026: the rules are in force and a private review board has issued the first protocol approval (Parley Neurotech's hearing-loss therapy, August 26, with conditions). But **no ETC has been licensed by DPHHS** and no patient has been treated. Two center license applications were reported pending in September. Step 2 still has no licensed counterparty to contract with — sponsors are engaging centers in formation.

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ELIGIBILITY GATE

Confirm the treatment qualifies

Has the therapy completed phase 1 of a clinical trial and is it not yet FDA-approved for general use?

YES Base condition met. Now satisfy **either** route: **(A)** the product remains under investigation in an FDA-approved clinical trial, **or (B)** it has a demonstrated safety record through documented clinical evidence from a **qualified medical institution** as defined by department rule. Either one qualifies.

NO **Not eligible.** Pre–phase 1 compounds cannot be offered, nor can products already approved by the FDA for general use.

Correction to earlier editions: the statute is an **OR**, not an AND. MCA 50-12-102(1) requires completed phase 1 and no FDA general-use approval, and *either* continued investigation in an FDA-approved trial *or* a demonstrated safety record from a qualified medical institution. Route B — which ARM 37.106.3304 defines by reference to oversight by "a regulatory authority recognized by international standards," or one with substantially equivalent standards — matters most to non-U.S. sponsors. DPHHS said at adoption that it will not list recognized authorities in rule, though its Office of Inspector General can assist with requests; there is no pre-clearance mechanism.

MCA 50-12-102(1) · two alternative qualifying routes · ARM 37.106.3304 (qualified medical institution)

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PARTNERSHIP

Engage a licensed ETC & structure the arrangement

- Identify a **DPHHS-licensed Experimental Treatment Center** — or, in the present market, one in formation. Verify licensure directly with the DPHHS Licensure Bureau before signing; none had been licensed at this writing.

- Negotiate the **supply and administration agreement**: pricing (cash-pay, unregulated), supply chain and GMP logistics, data sharing, liability and insurance.
- Confirm the ETC's medical director — who must hold a **current Montana Board of Medical Examiners license** — supports the clinical fit; align on patient population and exclusion criteria.
- For **devices**: prepare the added dossier — cybersecurity and data-privacy policies, malfunction and recall procedures, and a patient device registry.
- Diligence the **federal overlay**: the FDA has taken no position on the framework and preemption questions remain open. Counsel should price that risk into the agreement.

ARM 37.106 licensing framework · 37.106.3321 (devices) · Goodwin Procter preemption analysis, Aug 2026

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PROTOCOL REVIEW

ETC review board approval

- Submit the **treatment protocol** to the ETC's independent review board — a minimum of **five members** with no personal, financial, employment, or ownership interest in the center, and including a **Montana-licensed physician**, a clinical outcomes researcher, and an ethicist.
- Board examines **safety evidence, dosing, monitoring plan, and patient selection criteria**. It must meet at least monthly; **Montana's rules set no fixed review timeline**, so build schedule slack.
- A board may be **independently contracted or shared among centers**. The one board operating today is the private Montana ETRB ($12,500 review fee). It has published guidance on what counts as Phase 1 evidence (September 29, 2026) and now requires every submission to carry a **continuing evidence-generation plan** that becomes a binding condition of approval (October 28, 2026).

Does the review board approve the protocol?

YES Protocol is authorized for use at centers that have designated that board. Proceed to patient enrollment once a licensed center is in place.

NO Revise per board findings — safety data, monitoring plan, or eligibility criteria — and resubmit.

ARM 37.106.3316 · five-member board, conflict-free, monthly meetings, protocol approval authority · Montana ETRB guidance

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PATIENT PATHWAY

Enrollment, consent & pre-treatment workup

- CHANGED Patient is evaluated; the file documents that the patient **evaluated other FDA-approved treatment options**. "Attempted" was struck at adoption — alternatives must be considered, not tried or failed.
- **Written informed consent** executed — disclosing the treatment, its trial phase, experimental status (not FDA-approved), and **all costs** (cash-pay; insurance is not established).
- CHANGED Consent must also carry the **full text of 50-12-110, MCA (immunity from suit)** and the center's **patient grievance policy** — both added at adoption.
- Pre-treatment screening plus a full **history and physical within 30 days** before treatment initiation, documented in the patient file.
- Complete patient file assembled: consent, protocol, screening, H&P, treatment plan, outcome tracking.

ARM 37.106.3312 · consent content, alternatives standard, H&P ≤ 30 days, patient file

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ADMINISTRATION

Deliver treatment under center oversight

Has the review board determined the treatment is safe for delivery outside the center?

YES **Off-site administration permitted** under the center's safeguards — the rural-access provision, adopted as proposed, with access for rural Montanans expressly considered.

NO Administer **at the licensed center**, with the medical director serving as safety officer and the hospital transfer agreement in place for emergencies.

⟲ **Continuous safety loop:** monitor outcomes per protocol · report **serious adverse events — death, life-threatening events, hospitalization, or significant incapacity — simultaneously to the review board and DPHHS within five days** · board may suspend or modify the protocol at any time.

ARM 37.106.3325 (off-site standard) · 37.106.3317 (5-day dual AE reporting) · transfer agreements

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ONGOING OBLIGATIONS

Revenue, reporting & the road to full approval

- Treatment revenue flows to the sponsor and center per agreement. Separately, **SB 535 §2 requires the center to allocate 2% of its net annual profits** to support access to experimental treatments and health care — a **statutory duty, not a licensing rule**. DPHHS declined to define or implement it in rulemaking, so allocation and enforcement mechanics are unsettled and should be addressed in the commercial agreement.
- Outcomes feed the center's **annual quality and adverse-event report to DPHHS, due February 1** via the electronic licensing system (moved from January 31 at adoption; a late filing may reduce the center's license to provisional), and the review board's **annual public report, which must include aggregate treatment outcome data**.
- Real-world clinical experience and revenue **fund the continuing FDA pathway**. A therapy that qualified under Route A must remain under investigation in an FDA-approved trial to stay eligible.

Disclosure exposure: aggregate outcome data becomes public through the review board's annual report. Sponsors should plan for outcomes generated under SB 535 to be visible to regulators, investors, and the press, and should consider how that interacts with the ongoing FDA program.

SB 535 §2 (2% allocation, statutory) · ARM 37.106.3322 (Feb 1 report) · 37.106.3316(6) (public outcome data)

The Sponsor's Bottom Line

Six gates separate a post–Phase I asset from paying patients in Montana: eligibility, an ETC partnership, board approval, documented consent, supervised administration, and disciplined public reporting. Clear them, and revenue and real-world evidence begin while the FDA process continues — a pathway available in no other U.S. state. One sponsor has now cleared the review-board gate. The binding constraint is still upstream: no center is licensed yet.

Prepared by the Montana BioScience Alliance. Current as of November 19, 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 draft-rule summaries still circulating in published client alerts. Treatments offered under SB 535 are investigational, cash-pay at unregulated prices, and not FDA-approved. No Experimental Treatment Center has been licensed and no patient has been treated under this law as of this printing; one protocol has been approved, with conditions, by a private review board, which is not FDA approval. Federal preemption questions are unresolved and the FDA has taken no public position. Verify current requirements with DPHHS and qualified counsel.