2026 Regular Session

HOUSE BILL NO. 1223

BY REPRESENTATIVE MCFARLAND

ECONOMIC DEVELOPMENT: Establishes the La. Early-Phase Clinical Trial Acceleration Framework

AN ACT

To enact Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950, to be comprised of R.S. 51:3301 through 3310, relative to creating the Louisiana Early-Phase Clinical Trial Acceleration Framework; to provide for findings and purpose; to provide for definitions; to provide for responsibilities of Louisiana Economic Development; to provide for participation in the framework; to provide for performance benchmarks; to provide for reporting; to provide for confidentiality; to provide for rulemaking; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. Chapter 70 of Title 51 of the Louisiana Revised Statutes of 1950, comprised of R.S. 51:3301 through 3310, is hereby enacted to read as follows:

CHAPTER 70. LOUISIANA EARLY-PHASE CLINICAL TRIAL ACCELERATION FRAMEWORK

§3301. Legislative findings and purpose

The legislature hereby finds and declares all of the following:

(1) Biomedical innovation and clinical research are important drivers of patient access to investigational therapies, improvements in public health, private investment, and economic growth.

(2) Early-phase and first-in-human clinical trials are among the most specialized and capability-intensive forms of clinical research and frequently influence where long-term sponsor relationships, downstream clinical development activity, and related private investment are placed.

(3) Louisiana's competitiveness in biomedical innovation depends not only on the quality of its physicians, hospitals, and research institutions but also on whether the state is responsive, coordinated, and easy for sponsors and contract research organizations to navigate.

(4) Louisiana patients with serious or life-threatening conditions should have improved opportunities to access investigational therapies and related clinical research without unnecessary delay or avoidable travel burdens.

(5) For low-volume, highly specialized, or referral-dependent categories of covered clinical projects, statewide coordination, referral pathways, and cross-institutional collaboration may improve patient access and Louisiana's competitiveness.

(6) Participation in a covered clinical project depends upon factors including patient availability, relevant clinical expertise, and institutional capability, and the purpose of this Chapter is to reduce avoidable process barriers for covered clinical projects for which a research entity is otherwise reasonably capable.

(7) It is therefore the purpose of this Chapter to establish a statewide framework to improve the speed, predictability, and coordination of early-phase clinical trials in Louisiana in order to enhance patient access, attract private investment, and strengthen the state's clinical research ecosystem, all within existing resources.

§3302. Definitions

For the purposes of this Chapter, the following terms have the following meanings:

(1) "Benchmark category" means a project category established by the department or its designee by rule or guidance for purposes of participation

expectations, pilot implementation, process standards, and public reporting for covered clinical projects, including categories reflecting trial phase, therapeutic complexity, participant risk profile, operational intensity, disease prevalence or rarity, required subspecialty expertise, referral-network dependence, participant-sourcing model, and operational setting.

(2) "Complete submission" means a submission containing the materials required by the standardized checklist adopted by the department or its designee for a covered clinical project, together with any research-entity-specific addendum previously posted or incorporated by reference in a participation agreement.

(3) "Contract research organization" means an organization that provides clinical research services to a sponsor or trial manager, including site identification, feasibility assessment, project management, monitoring, regulatory support, data management, or related services associated with the conduct of a clinical trial.

(4) "Covered clinical project" means an industry-sponsored, interventional clinical trial involving a drug, biologic, or medical device regulated by the United States Food and Drug Administration and conducted at a site located in this state, including early-phase, first-in-human, dose-escalation, proof-of-concept, precision-medicine, rare-disease, cell-therapy, gene-therapy, biologic, or medical-device clinical investigations.

(5) "Department" means Louisiana Economic Development.

(6) "External institutional review board" means an institutional review board registered with the appropriate federal authorities and operating in compliance with applicable federal regulations governing human subjects research.

(7) "Participation agreement" means an agreement entered into pursuant to this Chapter establishing expectations for coordination, benchmark performance, reporting, and compliance with applicable provisions of this Chapter.

(8) "Patient-access support" means navigation, scheduling assistance, referral coordination, eligibility pre-screening coordination, travel-support coordination, remote follow-up coordination where permitted, language-access coordination, and

other lawful activities designed to reduce avoidable barriers to participation in a covered clinical project.

(9) "Receipt" means actual electronic or physical delivery to the designated intake contact identified by the research entity pursuant to this Chapter. If delivery occurs after five p.m. local time or on a weekend or legal holiday, receipt shall be deemed to occur on the next business day.

(10) "Repeated failure" means failure to meet the same required benchmark on two or more covered clinical projects within a rolling twelve-month period, or such other threshold as may be established by rule for a specified benchmark category.

(11) "Research entity" means a healthcare provider, hospital, academic institution, research organization, or other entity serving as a trial site or otherwise exercising institutional responsibility for a covered clinical project at a site located in this state.

(12) "Sponsor" means a pharmaceutical company, biotechnology developer, venture-backed therapeutic developer, medical device manufacturer, academic sponsor, or other entity advancing an investigational product, including a contract research organization acting on behalf of such entity.

§3303. State coordination within existing resources

A. The department shall administer a clinical trial acceleration coordination function within existing resources.

B. The department may designate existing personnel or organizational units to carry out responsibilities pursuant to this Chapter.

C. The department may enter into cooperative endeavor agreements, memoranda of understanding, or other lawful agreements with public or private entities to support implementation of this Chapter, provided that nothing in this Chapter shall be construed to require the creation of new positions or the expenditure of state funds unless separately appropriated.

D. The department may coordinate with state agencies, public and private postsecondary institutions, healthcare providers, research organizations, sponsors, contract research organizations, and site-selection teams to support the implementation of this Chapter.

E. Nothing in this Chapter shall be construed to transfer ownership of research programs, clinical operations, faculty governance, medical judgment, licensure standards, or hospital credentialing authority from any research entity to the department or its designee.

F. Nothing in this Chapter shall be construed to require department approval of a protocol, contract, local operational determination, or site activation decision, or to transfer clinical decision-making authority from a research entity to the department or its designee.

§3304. Participation and participation agreements

A. Participation in the framework established by this Chapter shall be mandatory for any research entity with respect to any covered clinical project conducted at a site located in this state. Nothing in this Chapter shall be construed to require participation with respect to research activities that are not covered clinical projects.

B. A research entity shall enter into a participation agreement with the department or its designee for purposes of coordination, contact designation, benchmark-category implementation, reporting, and escalation pursuant to this Chapter.

C. A participation agreement shall establish expectations for all of the following:

(1) Benchmark categories or project types for research entities.

(2) Primary contacts and internal routing procedures for intake, contracts, budgets, institutional review board reliance, ancillary reviews, and escalation.

(3) Institution-specific addenda, if any, that supplement the standardized checklist; provided that any such addenda shall be limited to nonduplicative

materials reasonably necessary to address a specific legal requirement or documented institutional responsibility.

(4) Local review categories that remain applicable when an external institutional review board is used.

(5) Provision of information reasonably necessary to support performance evaluation and fair distinction between institution-controlled time and sponsor-controlled time.

(6) Escalation contacts and internal accountability procedures applicable when a covered clinical project becomes stalled or repeatedly misses benchmark expectations.

(7) Any category-specific limitations, capacity constraints, or participation conditions the research entity elects to disclose.

D. A participation agreement shall not waive or reduce any duty imposed by this Chapter except as expressly authorized by rule or guidance for a specified benchmark category.

§3305. Process acceleration and coordination

A. The department or its designee shall publish standardized completeness checklists and intake procedures for covered clinical projects within benchmark categories.

B. The department or its designee may publish model clinical trial agreement provisions, budget assumptions, and bounded redline guidance for benchmark categories, recognizing that deviations may be necessary because of applicable law, patient-safety requirements, payer or billing requirements, insurance requirements, sponsor-specific regulatory obligations, or other circumstances designated by rule or participation agreement.

C. The department or its designee may coordinate directly with sponsors, contract research organizations, and site-selection teams regarding feasibility, site identification, benchmark implementation, and covered clinical project issue resolution.

D. The department or its designee may maintain a sponsor-facing, contract-research-organization-facing, and site-selection-team-facing coordination function with authority to coordinate across research entities for covered clinical projects, obtain feasibility and routing responses, elevate stalled matters for executive review, and present this state's verified capabilities in a uniform market-facing manner, all within existing resources.

E. The department or its designee may coordinate feasibility responses among research entities and may provide sponsors, contract research organizations, or site-selection teams with a consolidated statewide feasibility response based on information provided or confirmed by research entities.

F. The department or its designee may maintain, subject to applicable confidentiality protections and participation agreements, a registry of research investigators, sites, benchmark categories, and verified operational capabilities for use in sponsor, contract research organization, and site-selection coordination. The registry may include, to the extent practicable, therapeutic area or subspecialty focus, trial phase experience, active covered clinical project categories, institutional affiliation, and other information relevant to sponsor or contract research organization feasibility assessment and statewide gap identification. Any verified capabilities presented pursuant to this Subsection shall be based on criteria established by the department or its designee, including demonstrated operational capacity, staffing, and prior experience appropriate to the applicable benchmark category.

G. The department or its designee may facilitate lawful referral, navigation, and patient-access support activities in coordination with research entities and community providers.

H. Compliance with this Chapter shall be a condition for inclusion in any department-coordinated feasibility response, site-identification effort, sponsor-facing coordination, or presentation of verified capabilities conducted by the department or its designee.

I. For benchmark categories designated by rule or guidance as rare-disease, precision-medicine, pediatric specialty, bone marrow transplant, cellular therapy, cell-therapy, gene-therapy, or other low-volume or highly specialized categories, research entities shall cooperate in department-coordinated feasibility review, de-identified prescreening, referral pathways, and specialist-access planning, subject to applicable privacy law, patient consent requirements, institutional credentialing requirements, and clinical appropriateness.

§3306. Activation standards for covered clinical projects

A. For each covered clinical project, a research entity shall do all of the following, unless modified by rule or guidance for a specified benchmark category:

(1) Acknowledgment of receipt by the designated intake contact or its designee of a sponsor, contract research organization, or site-selection feasibility inquiry within two business days, provided that acknowledgment of receipt shall not constitute acceptance of feasibility or commitment to participate in the study.

(2) Completeness confirmation or a single consolidated deficiency notice not later than five business days after receipt of a submission. A submission shall be deemed complete on the sixth business day if no such notice is issued.

(3) No serial deficiency notices for items that were reasonably available to be identified in the initial completeness review, except for sponsor-requested changes, newly arising issues, or categories designated by rule or guidance.

(4) A sponsor feasibility response or engagement determination within ten business days after receipt of the materials identified by the department for feasibility review in the standardized checklist, applicable guidance, and any applicable institution-specific addendum permitted by this Chapter, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(5) Concurrent review, to the maximum extent permitted by applicable law and by previously adopted written institutional requirements specifically identified in the participation agreement, not based solely on institutional preference, generalized practice, or staffing limitations, and that cannot reasonably be performed

concurrently, of contracts, budgets, coverage analysis, ancillary reviews, pharmacy review, operational readiness, and other nonduplicative startup functions that need not await completion of another function.

(6) An initial contract response within ten business days after receipt of a sponsor draft or applicable model agreement, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(7) An initial budget response within ten business days after receipt of the sponsor budget or budget template, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(8) Escalation to designated research-entity and department personnel upon failure to meet a benchmark, which may include executive-level review and may be carried out in accordance with any applicable participation agreement. Escalation may be initiated by the department or its designee, the sponsor, or the contract research organization.

B.(1) For a covered clinical project for which reliance on an external institutional review board is permitted by applicable federal law, a research entity shall rely on an external institutional review board unless the research entity documents in writing one of the following:

(a) A specific federal or state legal requirement requires local review.

(b) A project-specific participant safety consideration requires nonreliance.

(2) Nonreliance shall not be based solely on institutional policy, preference, or generalized practice.

C. Any written determination of nonreliance pursuant to Subsection B of this Section shall be issued within ten business days after receipt of a complete submission, shall state with reasonable specificity the federal or state legal requirement or project-specific participant safety consideration supporting the determination, and shall be provided to the sponsor and the department or its designee.

D. Nothing in this Chapter shall be construed to eliminate lawful local review relating to investigator qualifications, conflict of interest, privacy, HIPAA, billing compliance, site feasibility, ancillary safety committees, credentialing, or other site-specific institutional responsibilities expressly required by law or by previously adopted written institutional policy directly related to local operational readiness or participant safety and not based solely on institutional preference, generalized practice, or duplication of ethical review of the protocol.

E. Nothing in this Chapter shall be construed to require a research entity to waive or disregard legal requirements, safety obligations, or documented institutional responsibilities in order to satisfy a benchmark established in accordance with this Chapter.

F. Nothing in this Chapter shall be construed to require a research entity to accept or activate a covered clinical project for which the research entity reasonably determines that sufficient patient population, relevant clinical expertise, or operational capability is lacking. This Subsection shall not be construed to excuse compliance with the timelines and process standards applicable to making such determination.

§3307. Performance benchmarks and reporting

A. The framework outlined in this Chapter shall include benchmark categories related to clinical trial startup and execution for covered clinical projects.

B. Participation agreements shall incorporate expectations aligned with benchmark categories and may provide for pilot implementation by benchmark category.

C. Benchmark categories may include but are not limited to the following:

(1) Acknowledgment of feasibility inquiry.

(2) Time to completeness confirmation.

(3) Time to sponsor feasibility response.

(4) Time to external institutional review board reliance determination.

(5) Contract and budget execution timelines.

(6) Time to site activation.

(7) Time to first patient enrollment.

D. Research entities shall provide information reasonably necessary to support evaluation of performance pursuant to this Chapter.

E. The department or its designee shall compile aggregated, non-identifiable information regarding performance benchmark categories and shall publish such aggregated information in the annual report required by Subsection H of this Section.

F. Reporting shall be implemented in a manner that avoids unnecessary duplication and utilizes existing data sources to the extent practicable. The department or its designee shall seek, where reasonably available, to distinguish institution-controlled time, sponsor-controlled time, and total elapsed time in aggregated reporting.

G. Public reporting shall not include patient-identifying information or sponsor proprietary commercial terms and shall be designed to minimize disclosure of sensitive nonpublic business information.

H. The department or its designee shall submit an annual report to the House Committees on Appropriations and Commerce and the Senate Committees on Finance and Commerce, Consumer Protection and International Affairs by January first of each year summarizing research entities, active benchmark categories, number of covered clinical projects, median timelines by benchmark category to the extent practicable, aggregate counts of external institutional review board reliance and nonreliance determinations, including to the extent practicable such counts by benchmark category, barriers encountered in implementation, including to the extent identified by research entities patient-population limitations, subspecialty workforce gaps, referral-network limitations, infrastructure gaps, and category-specific operational issues, department or designee implementation capacity constraints and resource needs for effective administration of this Chapter, and recommendations for statutory, administrative, or budgetary changes.

I. A research entity that demonstrates repeated failure to meet applicable benchmark expectations may have its inclusion in department-coordinated feasibility responses, site-identification efforts, sponsor-facing coordination, or presentation of verified capabilities modified, limited, or conditioned in accordance with rule or guidance and any applicable participation agreement.

J. For benchmark categories designated by rule or guidance as bone marrow transplant, cellular therapy, cell-therapy, gene-therapy, or other highly specialized modalities, the department shall establish specialized process standards, in consultation with research entities conducting such trials, that account for the clinical urgency, specialized infrastructure, relevant subspecialty expertise, and operational requirements of such categories.

§3308. Confidentiality and legal effect

A. The department or its designee may collect only such information as is reasonably necessary to administer this Chapter and may enter into confidentiality agreements or rely upon confidentiality provisions in participation agreements to protect nonpublic business information and other information protected by law.

B. Nothing in this Chapter shall be construed to do any of the following:

(1) Create a state warranty of site performance, patient outcome, sponsor selection, enrollment success, or commercial success.

(2) Create a private cause of action based solely on benchmark expectations, participation decisions, referrals, feasibility coordination, or public reporting in accordance with this Chapter.

(3) Require a research entity to disclose information prohibited from disclosure by federal or state law or by enforceable contractual obligation.

(4) Require the department or its designee to collect or maintain identifiable patient information except as otherwise expressly authorized by federal and state law and by patient consent.

§3309. Rulemaking and implementation

A. The department may adopt rules in accordance with the Administrative Procedure Act as necessary to implement this Chapter.

B. Implementation may also occur through participation agreements, guidance, templates, benchmark-category publications, and other nonregulatory mechanisms consistent with applicable law.

C. The department may phase implementation by benchmark category, project type, institution type, therapeutic area, or pilot cohort in order to promote operational reliability and early-phase clinical trial readiness within existing resources.

§3310. Funding

Nothing in this Chapter shall be construed to require a specific appropriation of funds or the creation of new positions. This Chapter shall be implemented within existing resources unless otherwise provided by law.

Section 2. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 1223 Engrossed 2026 Regular Session McFarland

Abstract: Provides relative to the La. Early-Phase Clinical Trial Acceleration Framework.

Proposed law provides for legislative findings and purpose.

Proposed law defines "benchmark category", "complete submission", "contract research organization", "covered clinical project", "department", "external institutional review board", "receipt", "repeated failure", "research entity", "participation agreement", "patient-access support", and "sponsor".

Proposed law requires La. Economic Development (department) to administer a clinical trial acceleration coordination function within existing resources.

Proposed law provides for how the department may implement provisions of proposed law.

Proposed law provides that nothing in proposed law shall be construed to require department approval of a protocol, contract, local operational determination, or site activation decision, or to transfer clinical decision-making authority from a research entity to the department or its designee.

Proposed law provides that participation in the framework established by proposed law is mandatory for any research entity with respect to any covered clinical project conducted at a site located in this state.

Proposed law requires a research entity to enter into a participation agreement with the department or its designee.

Proposed law requires a participation agreement to establish expectations for all of the following:

(1) Benchmark categories or project types for research entities.

(2) Primary contacts and internal routing procedures for intake, contracts, budgets, institutional review board reliance, ancillary reviews, and escalation.

(3) Institution-specific addenda, if any, that supplement the standardized checklist.

(4) Local review categories that remain applicable when an external institutional review board is used.

(5) Provision of information reasonably necessary to support performance evaluation and fair distinction between institution-controlled time and sponsor-controlled time.

(6) Escalation contacts and internal accountability procedures applicable when a covered clinical project becomes stalled or repeatedly misses benchmark expectations.

(7) Any category-specific limitations, capacity constraints, or participation conditions the research entity elects to disclose.

Proposed law prohibits a participation agreement from waiving or reducing any duty imposed by proposed law except in certain circumstances.

Proposed law requires the department or its designee to publish standardized completeness checklists and intake procedures for covered clinical projects within benchmark categories.

Proposed law provides for coordination between the department and other entities to implement the provisions of proposed law.

Proposed law allows the department or its designee to maintain, subject to applicable confidentiality protections and participation agreements, a registry of research investigators, sites, benchmark categories, and verified operational capabilities for use in sponsor, contract research organization, and site-selection coordination. Proposed law further provides what may be included in the registry.

Proposed law allows the department or its designee to facilitate lawful referral, navigation, and patient-access support activities in coordination with research entities and community providers.

Proposed law requires compliance with proposed law to be a condition for inclusion in any department-coordinated feasibility response, site-identification effort, sponsor-facing coordination, or presentation of verified capabilities conducted by the department or its designee.

Proposed law requires that certain benchmark categories designated by rule or guidance to cooperate in department-coordinated feasibility review, de-identified prescreening, referral pathways, and specialist-access planning, subject to applicable privacy law, patient consent requirements, institutional credentialing requirements, and clinical appropriateness.

Proposed law requires that for each covered clinical project, a research entity will do all of the following, unless modified by rule or guidance for a specified benchmark category:

(1) Acknowledge receipt by the designated intake contact or its designee of a sponsor, contract research organization or site-selection feasibility inquiry within two business days, provided that acknowledgment of receipt shall not constitute acceptance of feasibility or commitment to participate in the study.

(2) Complete confirmation or a single consolidated deficiency notice not later than five business days after receipt of a submission. A submission shall be deemed complete on the sixth business day if no such notice is issued.

(3) Provide no serial deficiency notices for items that were reasonably available to be identified in the initial completeness review, except for sponsor-requested changes, newly arising issues, or categories designated by rule or guidance.

(4) Provide a sponsor feasibility response or engagement determination within 10 business days after receipt of the materials identified by the department for feasibility review in the standardized checklist, applicable guidance, and any applicable institution-specific addendum permitted by proposed law, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(5) Provide for concurrent review not based solely on institutional preference, generalized practice, or staffing limitations, and that cannot reasonably be performed concurrently, of contracts, budgets, coverage analysis, ancillary reviews, pharmacy review, operational readiness, and other nonduplicative startup functions that need not await completion of another function.

(6) Provide an initial contract response within 10 business days after receipt of a sponsor draft or applicable model agreement, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(7) Provide an initial budget response within 10 business days after receipt of the sponsor budget or budget template, unless a different benchmark is designated by rule or guidance for a specified benchmark category.

(8) Upon failure to meet a benchmark, escalation to designated research-entity and department personnel which may include executive-level review and may be carried out in accordance with any applicable participation agreement.

Proposed law requires that for certain covered clinical projects, a research entity will rely on an external institutional review board except for circumstances provided for in proposed law.

Proposed law provides relative to any written determination of nonreliance outlined in proposed law.

Proposed law provides that nothing in proposed law shall be construed to eliminate lawful local review relating to certain responsibilities expressly required by law or by previously adopted written institutional policy directly related to local operational readiness or participant safety and not based solely on institutional preference, generalized practice, or duplication of ethical review of the protocol.

Proposed law further provides that nothing in proposed law shall be construed to require a research entity to waive or disregard legal requirements, safety obligations, or documented institutional responsibilities in order to satisfy a benchmark established in proposed law.

Proposed law provides that nothing in proposed law shall be construed to require a research entity to accept or activate a covered clinical project for which the research entity reasonably determines that sufficient patient population, relevant clinical expertise, or operational capability is lacking.

Proposed law requires that the framework outlined in proposed law includes benchmark categories related to clinical trial startup and execution for covered clinical projects.

Proposed law requires participation agreements to incorporate expectations aligned with benchmark categories and may provide for pilot implementation by benchmark category.

Proposed law provides for what the benchmark categories may include.

Proposed law provides relative to information from a research entity for the department to compile and publish.

Proposed law prohibits certain information in public reporting.

Proposed law outlines what the department shall report to the legislature.

Proposed law provides for what may happen to a research entity that demonstrates repeated failure to meet applicable benchmark expectations.

Proposed law requires that for certain benchmark categories designated by rule or guidance, the department will establish specialized process standards.

Proposed law provides relative to confidentiality requirements.

Proposed law provides proposed law shall not be construed to do any of the following:

(1) Create a state warranty of site performance, patient outcome, sponsor selection, enrollment success, or commercial success.

(2) Create a private cause of action based solely on benchmark expectations, participation decisions, referrals, feasibility coordination, or public reporting in accordance with proposed law.

(3) Require a research entity to disclose information prohibited from disclosure by federal or state law or by enforceable contractual obligation.

(4) Require the department or its designee to collect or maintain identifiable patient information except as otherwise expressly authorized by federal and state law and by patient consent.

Proposed law designates the authority for rulemaking and implementation to the department for proposed law.

Proposed law provides that nothing in proposed law shall be construed to require a specific appropriation of funds or the creation of new positions. Proposed law shall be implemented within existing resources unless otherwise provided by law.

Effective upon signature of governor or lapse of time for gubernatorial action.

(Adds R.S. 51:3301-3310)

Summary of Amendments Adopted by House

The Committee Amendments Proposed by House Committee on Commerce to the original bill:

1. Make technical changes.

2. Add language relative to legislative findings and purpose.

3. Amend the definitions of "benchmark category" and "research entity".

4. Add the definitions of "receipt" and "repeated failure".

5. Add that nothing in proposed law shall be construed to require department approval for certain actions or to transfer clinical decision-making authority from a research entity to the department.

6. Amend proposed law relative to participation in the framework and relative to entering into a participation agreement.

7. Amend proposed law relative to what shall be established in a participation agreement.

8. Provide that a participation agreement shall not waive or reduce any duty imposed by proposed law except as expressly authorized.

9. Add what may be included in the registry that may be maintained by the department or their designee.

10. Provide that compliance with proposed law shall be a condition for inclusion in certain actions by the department. Further provide relative to cooperation with certain department actions for certain benchmark categories.

11. Amend what a research entity shall do relative to acknowledgment of receipt, a sponsor feasibility response or engagement determination, concurrent review, and escalation to designated research-entity and department personnel.

12. Amend proposed law relative to the issuance of any written determination of nonreliance.

13. Add relative to lawful local review that proposed law shall not be construed to eliminate.

14. Provide that nothing in proposed law shall be construed to require a research entity to accept or activate a covered clinical project in certain circumstances.

15. Remove "admitted" from admitted covered clinical projects.

16. Amend relative to the compiled information in the annual report.

17. Amend the annual report requirements.

18. Amend relative to what may happen when a research entity demonstrates repeated failure to meet applicable benchmark expectations.

19. Add proposed law regarding benchmark categories for certain circumstances.

20. Provide that nothing in proposed law shall be construed to require the department or its designee to collect or maintain identifiable patient information except in certain circumstances.