August 24, 2026

Kyle A. Diamantas, J.D.
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Expedited Investigational New Drug Pilot Program; Request for Information; Correction (07/06/2026) [Docket No. FDA-2026-N-4699]

Dear Acting Commissioner Diamantas:

The Association for the Accreditation of Human Research Protection Programs (AAHRPP), National Advisory Committee on Human Research Protections (NACHRP), and Public Responsibility in Medicine and Research (PRIM&R) respectfully submit this joint comment on the request for information (RFI), **Expedited Investigational New Drug Pilot Program; Request for Information**. We represent Human Research Protection Programs (HRPPs), professionals dedicated to protecting participants in research, and Institutional Review Boards (IRBs).

We support collaboration between the Federal government and the research institutions across the United States to accelerate improvements in the health of all Americans. The Expedited Investigational New Drug Pilot Program represents a meaningful opportunity to gather data that could inform improvements to core regulatory review requirements and processes, provided it is implemented rigorously and objectively evaluated.

As requested, we are responding to the RFI question most relevant to our organizations' expertise.

II. Considerations for Pilot Development
A. Pilot Program Design and Implementation
1. QRI Qualification and Capabilities

i. What specific changes, if any, would you recommend regarding FDA's thinking on the capabilities, infrastructure, and/or leadership expertise research institutions must demonstrate to qualify for the pilot program?

The FDA should consider requiring Qualified Research Institutions (QRIs) to demonstrate robust human research protections through accreditation or certification from a recognized body or through documented institutional safeguards meeting equivalent standards. Examples include accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), certification through comparable external review processes, or internal assessment mechanisms that systematically evaluate and document the institution's research protection infrastructure. Through

such mechanisms, an organization can demonstrate its commitment to protecting research participants by implementing comprehensive policies, maintaining effective communication and integration across organizational units, allocating adequate resources, and pursuing ongoing quality improvement.

We urge the FDA to require that QRIs implement and follow written policies and procedures for identifying, managing, minimizing, or eliminating financial conflicts of interest, including those involving the organization, its employees, students, and agents, that could influence the development, management, review, or conduct of research. Such a requirement would strengthen participant protection and is consistent with standards expected of accredited organizations or those with robust governance frameworks.

v. To ensure faster FIH initiation, should QRIs be required to have a self-owned and operated IRB and/or clinical trial site? If not, would a partnership with an IRB and/or trial site network be sufficient?

The ability of a QRI to effectively communicate with the IRB responsible for reviewing the clinical trial is more important than whether the IRB is internal to the QRI. The QRI model will work best with institutions who have a collaborative approach to regulatory support, IRB review, and continued oversight and monitoring.

While target dates for review completion could be proposed, there should not be rigid deadlines or quotas placed on the associated IRBs. Further, IRBs must be allowed to ask regulatory and ethical questions of sponsors, QRIs, and others and have them answered satisfactorily.

QRIs should have regulatory staffing with the requisite expertise, knowledge, and skills to ensure a complete, thorough submission to the reviewing IRB, which enhances review timing and reduces the time burden associated with the process. FDA might consider requiring QRIs to meet a minimum standard for overall protocol-development-to-study-activation timeframes, reflecting the combined background, expertise, and knowledge of both regulatory and IRB staff. A QRI meeting this standard would demonstrate either a track record of improving development-to-activation timeframes or an active pilot process working toward that goal, and this standard could be met with a local (in-house), commercial, or network IRB. Requiring QRIs to provide high-quality regulatory support to research teams for IRB review process navigation would significantly enhance application quality and timeliness leading to reduced IRB review times.

vi. If the QRI serves in a dual capacity as both an IRB and regulatory advisor, are there additional considerations or reporting that would be helpful to prevent potential conflicts of interest and ensure QRIs are objective and reliable?

QRIs need not be required to have a self-owned and operated IRB and/or clinical trial site. If a QRI has an internal IRB, it should have and follow written policies and procedures to:

- Allow the IRB to function independently of other organizational entities in protecting research participants and have robust mechanisms to respond to attempts to influence the independence of the IRB or others responsible for the oversight of research.
- Separate competing business interests from ethics review functions. Competing business interests can influence the review process when individuals responsible for business

development serve on the IRB or are involved in the day-to-day operations of the IRB. The IRB review process should be free of conflict of interest so that the IRB member's obligation to protect participants and to ensure the integrity of the review process is not compromised by competing business interests.

2. Pre-IND and IND Review Process
iii. How can the pilot ensure QRIs provide independent, objective review while partnering with sponsors?

Payments to QRIs should never be conditioned on the outcome of the IND review process. Further, QRIs should have robust conflict of interest policies in place to prevent business interests from influencing scientific, clinical, operational and regulatory assessments. Finally, QRIs should document the rationale for their assessments and recommendations and share them with the FDA and IRB(s) reviewing the research.

5. Implementation and Feasibility
ii. Are there existing models, research networks, pilot programs, or international examples that could inform implementation? Please describe relevant examples and lessons learned.

International jurisdictions have adopted varying early-phase clinical trial pathways that differ from the U.S. sequential IND review model. Some propose these models as potential ways to accelerate Phase 1 timelines in the United States. However, claims about safety, efficiency, and equity outcomes should be grounded in evidence, not timelines alone. Before FDA considers adopting any international model's structural elements, a rigorous comparative evaluation framework is necessary to examine documented outcomes, limitations, and applicability to the U.S. regulatory, statutory, and liability context.

We recommend that FDA establish a structured evaluation framework for assessing any international early-phase clinical trial model before proposing permanent regulatory changes. Stakeholders proposing international models should provide evidence addressing the following questions:

1. What does the existing comparative literature document regarding the outcomes of proposed international models (including Phase 1 serious adverse event rates, safety signal detection, protocol amendment frequency, timeline acceleration, and participant safety) versus the current U.S. IND pathway, and what critical evidence gaps remain unaddressed in the published data?

2. What is the documented evidence that specific operational or structural elements accelerate time-to-first-dose without increasing safety risks, compromising regulatory oversight, or creating inequitable access? What evidence distinguishes operational acceleration from regulatory mechanism changes?

3. What statutory, liability, and infrastructure requirements would be necessary to implement any international model's elements in the U.S. context, and which elements are transferable without Congressional action?

4. If the U.S. adopts or adapts elements of any international model (whether delegating authority to institutional committees, running reviews in parallel, using rolling submissions, or other mechanisms), what federal safeguards, liability protections, and uniformity mechanisms would be necessary to address: (a) variation in institutional expertise and capacity across IRBs; (b) state-level tort law exposure; and (c) maintenance of standardized FDA scientific gatekeeping?

5. What prospective empirical methodology and validation thresholds should FDA require within a pilot program to conclusively demonstrate safety equivalence and participant protection prior to proposing permanent statutory changes?

B. Risks, Oversight, and Evaluation

1. Risks and Safeguards

ii. Could the pilot inadvertently compromise clinical trial participants' safety, scientific rigor, or ethical standards, and if so, what suggestions does the commenter have for mitigating such an outcome?

A primary risk to manage is ensuring that this pilot program or other FDA initiatives to accelerate drug or device development do not compromise scientific integrity or compromise the rights and welfare of research participants. The FDA should consider requiring sponsors to provide a rationale for not adopting QRI recommendations to both the reviewing IRB and the FDA.

Relatedly, many IRBs rely on the FDA IND review process to help ensure scientific value, validity, and integrity. The QRI model may help fill that gap if the QRI can provide sufficient background information in the protocol to allow the IRB to determine whether risks to participants are: 1) minimized by using procedures consistent with sound research design and that do not unnecessarily expose participants to risk; and 2) reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. QRIs should ensure that any scientific review of the research that occurs independently of the IRB is shared with the IRB.

3. Success Metrics and Evaluation

i. What data should be collected throughout the pilot to enable evaluation? Who should collect this data (FDA, QRIs, sponsors, third party evaluators)?

Any expedited-pathway pilot should be designed as a formal demonstration project with explicit data-collection objectives. The pilot should measure: (a) review timeline components and clarification cycle frequency; (b) Phase 1 safety outcomes (SAE/SUSAR rates, unexpected safety signals, early terminations); (c) institutional burden and resource utilization; (d) participant recruitment, equity, and informed consent quality; (e) comparative safety data with trials conducted under alternative review pathways where available; these data should inform any subsequent decision to propose permanent structural changes to the IND review process; and (f) feedback from all relevant stakeholders, including any known complaints or participant concerns. We also strongly recommend that the FDA publish the aggregated, de-identified findings of these evaluations at the pilot's conclusion to enable independent review by institutional stakeholders.

IRBs currently rely on the FDA sign off on the IND for scientific review. Without FDA weighing in on an IND before IRB review, we recommend collecting data on whether IRBs are bringing in more outside experts, more scientific reviewers, or doing anything different to fill the gap left by not having

an FDA assessment prior to its review. Additionally, we urge the FDA to collect data on ethical and regulatory issues that IRBs are identifying in these proposals; this would provide a meaningful sense of their extent and frequency and provide context to IRB review turnaround times.

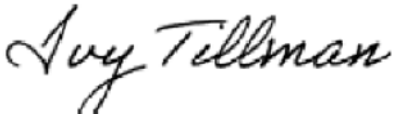
C. Additional Considerations

4. Are there important considerations or concerns not addressed in the questions above?

We urge the FDA to ensure that sponsors and QRIs provide safe, confidential, and reliable channels for current, prospective, or past research participants (or their designated representatives) to discuss problems, concerns, and questions related to the research and ensure this information is documented and taken into account when evaluating the pilot.

We appreciate the opportunity to comment and welcome the chance to provide additional information to assist on this matter.

Elyse I. Summers, JD
President and CEO
AAHRPP



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