Expedited IND Pilot Program

Qualified Research Institution

Application for Pilot Participation

HHS Operation TrialBlazer

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Part 1 of 2 — Qualified Research Institution (QRI) Information

Section 1 QRI Identification

QRI Legal Name:

Principal Business Address:

City, State, ZIP:

Primary Contact Name & Title:

Primary Contact Email:

Primary Contact Phone:

Q1. QRI Institution Type *(select one)*

- ○ Academic Medical Center (AMC)
- ○ Health Network (HN)
- ○ Contract Research Organization (CRO)
- ○ Non-profit research institute
- ○ Other (please specify):

Section 2 QRI Prioritization Characteristics

QRIs should check all boxes that apply under this pilot program application. Failure to confirm any item may result in exclusion from consideration in the pilot program.

☐ The QRI is a legal entity organized or incorporated in the United States, with a principal place of business in the United States. The QRI's core program management, regulatory affairs, and scientific leadership functions are U.S.-based.

☐ The QRI commits to providing integrated development support across nonclinical, CMC, and clinical disciplines for the IND program identified in this application. This includes vetting and guiding the sponsor's nonclinical program, providing CMC regulatory oversight or direct manufacturing support as applicable, and supporting Phase 1 FIH clinical trial execution in the United States through owned infrastructure or formally executed and documented partnership arrangements.

☐ The QRI affirms compliance with all applicable FDA statutes and applicable law.

☐ The QRI commits to documenting conflict-of-interest procedures during the duration of the pilot program, as outlined on the pilot program website.

☐ The QRI commits to participating in the rolling IND submission model as defined by the Expedited IND Pilot Program.

☐ The QRI commits to participating in post-pilot evaluation activities, including debriefs, surveys, and any structured data collection requested by FDA to assess pilot outcomes.

Section 3 QRI Qualifications

Complete all subsections. Attach supporting documentation and note attachment titles in relevant narrative fields.

3A — Nonclinical Leadership & Personnel

Q2. Nonclinical Leadership Credentials *(select all that apply)*

- ☐ Diplomate of the American Board of Toxicology (DABT)
- ☐ Ph.D. in pharmacology, toxicology, or a related discipline, or the equivalent demonstrated expertise through regulatory toxicology practice
- ☐ Prior pharmacology/toxicology experience as an FDA reviewer or in industry
- ☐ ICH working group participant (e.g., S7A, S7B, M3, S9)
- ☐ Published expertise in FIH dose selection methodology
- ☐ Other (please specify):

Q3. Number of FIH INDs Previously Supported as sponsor or consultant *(select one)*

- ○ None-1
- ○ 2–5
- ○ 6–15
- ○ More than 15

Q4. Nonclinical Personnel Narrative *Required. Describe key nonclinical personnel, FIH IND experience, starting dose calculation expertise, and fit-for-purpose study design approach. CVs for all key personnel described in the narrative are required and must be attached.*

3B — CMC Leadership & Personnel

Q5. CMC Leadership Credentials *(select all that apply)*

- ☐ Ph.D. in biological or pharmaceutical sciences, analytical chemistry, or related discipline
- ☐ Prior industry CMC experience (pharmaceutical or biotech)
- ☐ Prior FDA CMC review and/or inspection experience
- ☐ CMC regulatory submission experience (IND CMC section authoring)
- ☐ Technology transfer and manufacturing scale-up expertise
- ☐ Process development and validation experience
- ☐ Other (please specify):

Q6. Number of INDs Previously Supported in a CMC Role *(select one)*

- ○ None-1
- ○ 2-5
- ○ 6-15
- ○ More than 15

Q7. CMC Personnel Narrative *Required. Describe key CMC personnel, regulatory submission experience, inspection history, and phase-appropriate GMP compliance expertise. CVs for all key personnel described in the narrative are required and must be attached.*

3C — Clinical Leadership & Personnel

Q8. Clinical Leadership Credentials *(select all that apply)*

- ☐ Board-certified physician with subspecialty expertise in the relevant therapeutic area
- ☐ Extensive Phase 1 protocol design experience (dose escalation, safety monitoring)
- ☐ QTc / cardiac safety assessment expertise (ICH E14)
- ☐ Drug-drug interaction (DDI) study design experience
- ☐ Experience with adaptive trial designs (BOIN, mTPI, CRM)
- ☐ Active participation in relevant clinical research consortia or networks
- ☐ Prior FDA reviewer or contractor experience
- ☐ Other (please specify):

Q9. Number of FIH Trials as Principal Investigator or Clinical Lead *(select one)*

- ○ None-1
- ○ 2–5
- ○ 6–15
- ○ More than 15

Q10. Clinical Personnel Narrative *Required. Describe key clinical personnel, FIH experience, therapeutic area expertise, and clinical leadership qualifications. CVs for all key personnel described in the narrative are required and must be attached.*

3D — Clinical Partnerships & Capabilities

Q11. Phase 1 Clinical Infrastructure *(select all that apply)*

- ☐ Active P1 CRU within parent organization
- ☐ Access to, or owned Phase 1 Clinical Research Unit (CRU) — inpatient beds
- ☐ Access to, or owned Phase 1 outpatient / ambulatory research clinic
- ☐ Phase 1 capability via documented site partnership
- ☐ Institutional IRB (owned)
- ☐ Reliance on external / central IRB
- ☐ Master Clinical Trial Agreement (MCTA) templates in place
- ☐ AI-enabled patient matching or EMR-to-EDC integration tools
- ☐ Other (please specify):

Q12. Number of Phase 1 Trials Conducted or supported *(select one)*

- ○ None-1
- ○ 2–5
- ○ 6–20
- ○ More than 20

Q13. IRB First-Review Average Timeline: *As applicable, since not all QRIs may have access to IRBs or run sites. e.g., 30 days from submission*

Q14. Average Time-to-Contract (term sheet to executed agreement): *As applicable, since not all QRIs may have access to IRBs or run sites. e.g., 45 days*

Q15. Clinical Capabilities Narrative *Required. Describe Phase 1 CRU infrastructure, IRB capability, contracting mechanisms, or relevant clinical trial portfolio. Note any attached Phase 1 CRU description.*

3E — Nonclinical and CMC Capabilities & Infrastructure

Q16. Nonclinical and CMC Capabilities Narrative *Required. Describe the depth and breadth of nonclinical infrastructure, cGMP manufacturing infrastructure, analytical capability, QA/QC systems, and any partnership arrangements that the QRI plans to utilize on behalf of the sponsor's IND submission, if any. Note any attached CMC facility description or inspection records.*

3F — Cross-Cutting Track Record & Integration

Q17. Modalities for Which the QRI Has Relevant IND or Phase 1 Experience *Required. List the modalities for which the QRI has relevant experience supporting IND-enabling development, IND submissions, or phase 1 clinical trials. Experience may include work performed for sponsors or through the QRI's own research or development programs. Examples include small molecules, Antibody-drug conjugate (ADC), Peptide therapeutic (non-antibody), Oligonucleotide (e.g. ASO, siRNA, mRNA), gene therapies – viral vectors, gene therapies – non-viral, vaccines, etc.*

Q18. Total IND Submissions Supported Across All Modalities *(select one)*

- ○ None-1
- ○ 2–5
- ○ 6–15
- ○ 16–30
- ○ More than 30

Q19. Additional Sponsor Support Capabilities *Optional but encouraged. Describe any capabilities the QRI offers in support of sponsor IND development that are not captured in the sections above. This may include, but is not limited to, regulatory affairs expertise, biostatistics and clinical pharmacology support, patient advocacy engagement, health economics and outcomes research (HEOR), translational science, or any other service the QRI considers a meaningful differentiator in supporting FIH IND programs.*

If regulatory affairs expertise is described here, specify whether this capability is provided by dedicated in-house personnel, through a documented external partnership, or both.

Q20. Track Record & Integration Narrative *Required. Describe experience integrating nonclinical, clinical, and CMC development planning to support IND submissions. Highlight successful IND submissions and examples of incorporating FDA feedback. Do not include sponsor-identifying or other confidential information.*

Part 2 of 2 — Authorized Signatures & CV Attachments

By signing below, the authorized representatives of the Qualified Research Institution certify that: (1) all information contained in this application is accurate and complete to the best of their knowledge; and (2) the QRI agrees to the terms of participation described in the Expedited IND Pilot Program webpage.

Qualified Research Institution (QRI) Name: _____

Authorized Representative Name: _____

Title: _____

Signature: _____

Date: _____

Required. List the file name of each CV attached to this application and the corresponding individual's name.

#	Key Personnel Name	Area of Expertise	File Name