Is an Investigational New Drug (IND) Application Needed?
Bioavailability or Bioequivalence Studies

Does the drug:
- contain a “new chemical entity” or
- does the study involve a radioactively labeled drug product or
- Does the study involve a cytotoxic drug product?

Yes → An IND is required.
No → Is the study:

- A single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the approved labeling; or
- A multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the approved labeling; or
- A multiple-dose study on an extended release product on which no single-dose study has been completed

Yes → An IND is required.
No → Will the person conducting the study retain reserve samples of any test article and reference standard used in the study and release the reserve samples to FDA upon request and consistent with other FDA requirements described below?

Yes → An IND is required.
No → If the formulation of the test article is the same as the formulation(s) used in the clinical studies demonstrating substantial evidence of safety and effectiveness for the test article’s claimed indications, a reserve sample of the test article used to conduct an in vivo bioavailability study comparing the test article to a reference oral solution, suspension, or injection.

Yes → Will the study be conducted consistent with the requirements of 21 C.F.R. part 50 (human subjects protections) and part 56 (IRB requirements)?

Yes → No IND is required.
No → An IND is required.

Note: additional exceptions exist for research on radiopharmaceuticals in some instances. See 21 C.F.R. § 361.1. Contact MICHRA or the Health System Legal Office for assistance.