IND Application — Printable Checklist

• Administrative Information

- Cover Letter
- Form FDA 1571
- Form FDA 1572
- Form FDA 3674
- Financial Disclosure (FDA 3454/3455)
- Table of Contents
- Introductory Statement & General Investigational Plan
- IRB Information
- Meeting Information (if applicable)

• Investigator’s Brochure (IB)

- Summary of nonclinical, clinical, product information
- Potential risks, adverse effects
- Monitoring recommendations

• Clinical Protocol(s)

- Study objectives & design
- Eligibility criteria
- Treatment plan & dosing
- Safety monitoring plan
- Statistical considerations
- Data handling

• CMC (Chemistry, Manufacturing, Controls)

- Drug Substance: manufacturer, structure, process, specs, stability
- Drug Product: formulation, process, specs, stability, labeling
- Placebo description (if applicable)
- Environmental Assessment / exemption

• Nonclinical Information

- Pharmacology studies
- Safety pharmacology
- Toxicology studies
- Genotoxicity / carcinogenicity (if applicable)
- Reproductive toxicity (if applicable)
- ADME data
- Justification of starting dose

• Previous Human Experience

- Prior clinical study data
- Foreign trial data
- Relevant literature

• Additional Information

- Abuse potential assessment
- Pediatric study plan
- Special population considerations
- Immunogenicity evaluation (biologics)