Single Patient IND (sIND) Checklist

Documents Required for the FDA submission	
1. Cover Letter	☐ Complete
2. FDA Form 3926	☐ Complete
3. Treatment Plan	☐ Complete
4. Letter of Authorization	☐ Complete
5. Informed Consent Form[1]	☐ Complete ☐ N/A
6. Investigator's Brochure / Package Insert	☐ Complete
7. Sponsor's CV or Biosketch	☐ Complete
8. 2-3 Key Publications[2]	☐ Complete

1. Usually not required but may be requested by FDA reviewer
2. Please include, especially for novel treatments

Contact Information IND/IDE Support Office (for help with IND filings):

- Office Mailbox at INDIDE@chop.edu
- Mark Wentworth at wentworthm@chop.edu
- Greg Podsakoff at podsakoff@chop.edu

Documents Required for the eIRB submission	
1. FDA Form 3926	☐ Complete
2. Treatment Plan / Protocol	☐ Complete
3. Letter of Authorization from Manufacturer[3]	☐ Complete
4. Informed Consent Form	☐ Complete
5. Investigator's Brochure (if available)	☐ Complete
6. FDA Acknowledgement or Authorization Letter[4]	☐ Complete

3. Email authorization from the drug manufacturer is generally acceptable
4. May be provided to IRB in subsequent submission once FDA letter is received.