



Transfer of IND Ownership Overview

At the time of transfer the new and former owners are required to submit information to the FDA as follows:

1. A **letter from the former owner** stating that all rights to the application have been transferred to the new owner (include effective date, IND #, new owner's name, address and contact numbers) and that the new owner will receive or has received the complete IND record.
2. A **letter from the new owner** containing the following:
 - a. The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application;
 - b. The date that the change in ownership is effective;
 - c. A statement that the new owner has a complete copy of the approved IND application. If necessary, the FDA will provide a copy of the application to the new owner under the fee schedule in § 20.45 of FDA's public information regulations.
 - d. A statement that the new owner agrees
 - i. to the promises and conditions made by the former owner, as well as to those agreements, promises and conditions contained in the IND application
 - ii. maintain a complete copy of the approved application, including supplements and records that are required to be kept under 21 CFR 314.81
 - iii. to amend the IND within 60 days to cover any and all changes in the IND that result from the change in ownership
 - iv. to provide subsequent changes by amendments in accordance with the IND regulations

The submission to the FDA should include the above letters in triplicate along with the following supporting documents (in triplicate):

- FDA Form 1571
- Updated FDA Form 1572
- CVs for the new investigators
- Letter of support from the study drug manufacturer
- IRB approval letter and approved ICF
- Updated protocol with references to previous owner deleted and replaced with new owner.