**Investigational Drug: Patient ID:
Physician: Sponsor of Original IND:**

# FDA website: [Requirements for Expanded Access to Use Investigational Drugs for Treatment Use](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.9)

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| **Task- Submission of application for an Individual Patient Expanded Access IND-non-Emergency***This checklist provides a list of items needed for an Individual Patient Expanded Access non-Emergency IND submission. The checklist includes links to various optional document templates and form links for your use in preparing an Expanded Access IND submission. The checklist is* ***not*** *part of the IND application submission to FDA.***Note: The submission and its mailing cover must be plainly marked:** “EXPANDED ACCESS SUBMISSION.” | **Date completed and initials** | **Comments**  |
| [ ] Cover letter with contact information (see [template](http://ora.emory.edu/research-compliance/oric/documents1/EA_Cover_letter.docx)) |  |  |
| [ ]  Form 3926Click on link to obtain FDA [Form 3926](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM504572.pdf)Click on link to obtain [instructions for FDA Form 3926](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM504574.pdf) |  |  |
| [ ]  Attachment Field 6 – Letter of Authorization from Sponsor of original IND |  |  |
| [ ]  Attachment Field 7 – Physician’s Qualification StatementMay attach relevant portion of Curriculum Vitae, usually first few pages. |  |  |
| [ ]  Forms submitted to FDA**For a Drug**:Food and Drug AdministrationCenter for Drug Evaluation and ResearchCentral Document Room5901-B Ammendale Rd.Beltsville, Md. 20705-1266**For a Therapeutic Biological Product:**Food and Drug AdministrationCenter for Biologics Evaluation and Research Document Control Center10903 New Hampshire AvenueWO71, G112Silver Spring, MD 20993-0002 |  | Date of submission**\_\_\_\_\_\_** |
| [ ]  Permanent file started for IND submission materials and all related FDA correspondence  |  | File location (electronic &/or paper) |
| [ ]  Create and submit as a new study in eIRB The Emory IRB must approve in advance any non-emergency Expanded Access use. **Refer to** [**IRB P & P 70 Investigational New Drugs -Expanded Access**](http://www.irb.emory.edu/documents/PoliciesAndProcedures.pdf) **for IRB submission procedures** |  | eIRB #\_\_\_\_\_\_\_\_\_\_ |
| **[ ]  Checklist for IND Application Submission Completed**Retain checklist for your records; this is not part of submission to FDA. |  | **Print name** |

Expanded Access IND non-Emergency Checklist

Version 8/30/21

Form produced by Office of Research Integrity and Compliance