

IND ANNUAL REPORT CHECKLIST

Required with 60 days of the anniversary date of IND

Information on Individual Studies – A brief summary of the status of each study in progress and each study completed during the previous year. The individual study information should include the following:

ELEMENT	INCLUDED
Title of the study (with protocol number)	
Purpose of the study	
Patient population	
Study Status (ongoing or completed)	
Total enrollment goal	
Number enrolled to date: tabulated by age, gender, race	
Number who completed the study	
Number who dropped out of the study and reasons why	
Brief description of any available study results	

Summary Information – This section should include all additional product-related information collected during the previous year. The summary information should include the following:

ELEMENT	INCLUDED
A narrative or tabular summary showing most frequent and SAEs by body system	
Summary of all IND Safety Reports submitted during the past year	
List of subjects who died during participation and reasons for deaths	
List of subjects dropped during the study due to AE whether drug related or not	
Brief description of information that was learned regarding the drugs actions (e.g., dose response, bioavailability).	
List of preclinical studies (including animal studies) completed or in progress and summary of major preclinical findings (If applicable)	
Summary of any significant manufacturing or microbiological changes made during the past year (If applicable)	

General Investigational Plan – A brief description of the general investigational plan for the coming year. It should include: rationale; indications; general approach in evaluating the drug; clinical trials to be conducted; estimated number of patients; and risks. If the plans are not yet formulated, the sponsor must indicate this fact in the report.

ELEMENT	INCLUDED
Description of general investigational plan for the coming	
When the investigator's brochure has been revised, the sponsor must include a description of the revision and a copy of the new brochure	
A description of any significant protocol modifications made during the previous year and not previously reported to the IND in a protocol amendment	
If desired by the Sponsor, a log of any outstanding business with respect to the IND for which the sponsor requests or expects a reply, comment or meeting	

Completed by: _____ Date: _____