

**DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION**

CLINICAL TRIAL CHECKLIST**For all Studies, the following documents:**

	Yes	No
1. The completed application form and this checklist	<input type="checkbox"/>	<input type="checkbox"/>
2. A copy of the proposed protocol	<input type="checkbox"/>	<input type="checkbox"/>
3. Information on the new drug (e.g. the investigator's brochure)	<input type="checkbox"/>	<input type="checkbox"/>
4. The pre-clinical data of the new drug	<input type="checkbox"/>	<input type="checkbox"/>
5. A sample of the trial medication	<input type="checkbox"/>	<input type="checkbox"/>
6. The letter from the principal investigator confirming his involvement in the trial	<input type="checkbox"/>	<input type="checkbox"/>
7. The Curriculum Vitae of the principal investigator	<input type="checkbox"/>	<input type="checkbox"/>
8. Letter of approval by the Ethics Committee of the institution in which the trial is to be conducted (may be submitted when available at a later date)	<input type="checkbox"/>	<input type="checkbox"/>
9. The proposed patient consent form in both English and Chinese, or in Chinese only	<input type="checkbox"/>	<input type="checkbox"/>
10. Evidence that the trial medication is manufactured in accordance with Good Manufacturing Practices (GMP) (e.g. a copy of the GMP Certificate of the manufacturer)	<input type="checkbox"/>	<input type="checkbox"/>
11. A sample certificate of analysis of the drug	<input type="checkbox"/>	<input type="checkbox"/>

For studies for which a clinical trial certificate was issued previously but has expired/will soon expire, the following additional documents:

12. A copy of the previous clinical trial certificate	<input type="checkbox"/>	<input type="checkbox"/>
13. Progress report(s) of the study (if not available, please provide justification. If the trial has not been started, please provide justification also)	<input type="checkbox"/>	<input type="checkbox"/>

For studies which are also the subject of an application for approval by the State Food and Drug Administration (SFDA), the following additional documents:

14. A copy of the drug clinical trial approval document (藥物臨床研究批件) issued by SFDA (may be submitted when available at a later date);	<input type="checkbox"/>	<input type="checkbox"/>
15. A copy of the protocol submitted to SFDA.	<input type="checkbox"/>	<input type="checkbox"/>