「受美國 FDA 管轄案件確認事項」表

<<美國 FDA 管轄案件申請台大醫院研究倫理委員會審查時須提供之額外資訊>>

請勾選符合者：

☐When research involves the use of a drug other than a marketed drug in the course of medical practice, the drug has an IND or the research meets one of the FDA exemptions from the requirement to have an IND.
研究中使用全球未上市藥品，該試驗用藥須取得 FDA 核發之 IND 證明文件，或者是符合免申請 IND No.
(請回答問題 A)

☐When research is conducted to determine the safety or effectiveness of a device, the device has an IDE issued by the FDA, the device fulfills the requirements for an abbreviated IDE, or the research meets one of the FDA exemptions from the requirement to have an IDE.
當研究目的是為了確認新醫材的安全性或效能，必須有美國 FDA 核發之 IDE 證明文件，或者是符合免申請 IDE.
(請回答問題 B)

問題 A:

When research involves the use of a drug other than the use of a marketed drug in the course of medical practice, please confirm that:

☐**The drug has an IND; please provide the IND No._____**

若勾選此項，請續填並提供所勾選之證明文件：

☐The number is imprinted on the sponsor's protocol.

☐The number is noted in written correspondence from the sponsor.

☐The number is noted in written correspondence from the FDA (*required if the Investigator holds the IND*)

or

☐**The protocol meets one of the FDA exemptions from the**

☐**Exemption 1**

- The drug product is lawfully marketed in the United States.
- The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- If the drug that is undergoing investigation is lawfully marketed as a

prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.

- The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- The investigation is conducted in compliance with 21 CFR 50 and 56.
- The investigation is conducted in compliance with the requirements of 21 CFR 312.7.

☐**Exemption 2**

- A clinical investigation is for an in vitro diagnostic biological product that involves one or more of the following:
  -Blood grouping serum.
  -Reagent red blood cells.
  -Anti-human globulin.
- The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- The diagnostic test is shipped in compliance with 21 CFR 312.160.

☐**Exemption 4**

- A clinical investigation involving use of a placebo if the investigation does not otherwise require submission of an IND.

問題 B:

When research is conducted to determine the safety or effectiveness of a device, please confirms that:

☐**The device has an IDE issued by the FDA; please provide the IDE No._____**

若勾選此項，請續填並提供所勾選之證明文件：

☐The number is imprinted on the sponsor's protocol.

☐The number is noted in written correspondence from the sponsor.

☐The number is noted in written correspondence from the FDA (*required if the Investigator holds the IDE*)

☐**The device fulfills the requirements for an abbreviated IDE.**

- ■ The device is not a banned device.
- ■ The sponsor labels the device in accordance with 21 CFR 812.5.
- ■ The sponsor obtains REC approval of the investigation after presenting the

reviewing REC with a brief explanation of why the device is not a significant risk device, and maintains such approval.

- ■ The sponsor complies with the requirements of 21 CFR 812.46 with respect to monitoring investigations;
- ■ The sponsor maintains the records required under 21 CFR 812.140(b) (4) and (5) and makes the reports required under 21 CFR 812.150(b) (1) through (3) and (5) through (10);
- ■ The sponsor ensures that participating investigators maintain the records required by 21 CFR 812.140(a)(3)(i) and make the reports required under 812.150(a) (1), (2), (5), and (7); and
- ■ The sponsor complies with the prohibitions in 21 CFR 812.7 against promotion and other practices.

□**The device fulfills one of the IDE exemption categories:**

- ■ A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
- ■ A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

□**A diagnostic device, if the sponsor complies with applicable requirements in 21 CFR 809.10(c) and if the testing:**

- ■ Is noninvasive.
- ■ Does not require an invasive sampling procedure that presents significant risk.
- ■ Does not by design or intention introduce energy into a participant.
- ■ Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- ■ A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put participants at risk.
- ■ A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.
- ■ The REC makes a determination whether or not the device is a significant risk device.

請注意：

Prior to conducting a human trial involving drugs, devices including in vitro diagnostic devices, or biological specimens, an application must be submitted for review of the proposed clinical trial by the Department of Health Executive Yuan, Taiwan Food and Drug Administration (TFDA), and once approved, clinical trial reports must be submitted as specified by the TFDA.

所有受到美國 FDA 管轄案件在執行前皆須獲得衛生福利部 TFDA 之核准，且依 TFDA 之規定繳交進度報告。

Above is confirmed by _____(by title of position)

Signature:_____Date_____(DD/MMM/YYYY)