Box 1-4 should be identical to boxes 1-4 from FDA-1571

Box 5 should be the same as the list in box 5 FDA-1571

Box 7 is the IND number (if you have one). Box 8 is the same as Box 10 of FDA-1571

Check Date!
A. This submission does not reference a clinical study.

B. My study is required to be posted but I have not listed yet. I will list it in the future at the appropriate time.

OR

B. My study is exempt from registration requirements.

C. My study is posted.

List the assigned NCT number(s) if you check Box C.

<table>
<thead>
<tr>
<th>CERTIFICATION STATEMENT / INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)</td>
</tr>
<tr>
<td>□ A. I certify that the requirements of 42 U.S.C. § 282(a), Section 402(g) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.</td>
</tr>
<tr>
<td>□ B. I certify that the requirements of 42 U.S.C. § 282(a), Section 402(g) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.</td>
</tr>
<tr>
<td>□ C. I certify that the requirements of 42 U.S.C. § 282(a), Section 402(g) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.</td>
</tr>
</tbody>
</table>

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(a)(1)(A)(ii), SECTION 402(g)(1)(A)(ii) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

   NCT Number(s): ____________________________ ____________________________ ____________________________

   The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(a)(3)(B), section 402(g)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

   Warning: A willfully and knowingly false statement is a criminal offense. U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

   (Name) ____________________________________________

   (Title) ____________________________________________

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11

13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)

14. TELEPHONE AND FAX NUMBER (Include Area Code)

   (Tel) ____________________________________________

   (Fax) ____________________________________________

15. DATE OF CERTIFICATION

FDA-3674 (1/08) (FRONT)

- Signed and dated by the Sponsor. Date in box 15 is the day the sponsor signs the form! Does not have to match the submission date listed in Box 2.
- Original goes to FDA but make a good copy for yourself!
### Which Trials Must be Registered?

The trials that must be registered are called “applicable clinical trials.” Under the statute, these trials generally include:

1. **Trials of Drugs and Biologics:** Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation

   *Note: ICMJE requires registration of Phase I trials with efficacy endpoints. Therefore, the phase I exemption probably does not apply to your trial.*

2. **Trials of Devices:** Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

### When is the Deadline for Registration?

- In order to publish in ICJME journals, you must register prior to enrollment of the first subject.
- In order to comply with 42 USC § 282(j), you must register no later than 21 days after enrollment of the first subject.

### How do I Register my Study?

Duke Clinical Trials must be registered through the Office of Research Support (Wesley G. Byerly, PharmD, Associate Dean).

Please contact them by sending an email to: rebeka.branagan@duke.edu. From there, you will get your username and password.