Date & Time of Submission: _____

Clinical Trial Participation Attestation Form

For submission to a group health plan or health insurance issuer

This form encompasses information to attest that a clinical trial meets the criteria of an "approved clinical trial" and that a patient is a "qualified individual."[1] used under Section 2709 of the Public Health Service Act as established by the Affordable Care Act. Group health plans or health insurance issuers should not require additional information beyond what is included on this form.

Patient Name _____ Patient DOB _____

Diagnosis _____ Diagnosis Code _____

Insurance Name and Policy Number_____

Provider Name _____ Provider's Tax ID# _____

Office Contact, Phone, and Fax _____

ClinicalTrials.gov Identifier _____

(The identifier is typically 11 characters in length and begins with "NCT")

Questions 1 through 4 to be completed by a physician participating in the clinical trial described above. Please answer "yes" or "no" to each of the following questions.			
1.	Is the trial "a phase I, phase II, phase III or phase IV clinical trial"?	Yes ☐	No ☐
2.	Is the trial "conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition,"[2] including trials of supportive care?	Yes ☐	No ☐
3.	Does the clinical trial satisfy at least **one** of the following: • (A) federally "approved or funded",[3] • (B) is either: 1. "Conducted under an investigational new drug application reviewed by the Food and Drug Administration," 2. "A drug trial that is exempt from having such an investigational new drug application"[4]	Yes ☐	No ☐
4.	Is the individual's participation in the clinical trial "appropriate" (i.e. the patient satisfies all trial eligibility criteria, subject to any additional testing that may be required by the protocol)?	Yes ☐	No ☐

Confirmation requested from the insurer

The group health plan or health insurance issuer concurs that clinical trials participation for this patient meets the requirements of Section 2709 of the Public Health Service Act.

◯ Yes

◯ No

Rationale must be provided if no: _____

Contact Person for Health Plan or Insurance Issuer:

Name: _____ Title: _____

Phone: _____ Email: _____

Footnotes-

[1]42 USCS 300gg-8 (2012): Coverage for individuals participating in approved clinical trials.

[2]The term **"life-threatening condition"** means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

[3]**''Federally funded trials"-**The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(i) The National Institutes of Health.
(ii) The Centers for Disease Control and Prevention.
(iii) The Agency for Health Care Research and Quality.
(iv) The Centers for Medicare & Medicaid Services.
(v) A cooperative group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.
(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
(vii) Any of the following if the conditions described in paragraph (2) are met:
(I) The Department of Veterans Affairs.
(II) The Department of Defense.
(III) The Department of Energy.

[4]Definition of **"exemptions"** according to the Code of Federal Regulations (21 CFR§ 312.2(b)):

"(b)Exemptions. (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply:
(i) 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;
(ii) 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;
(iii) 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;
(iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
(v) The investigation is conducted in compliance with the requirements of 312.7."