OFFICE OF
RESEARCH PROTECTIONS

Clinical Trails Registration and Results Reporting Guidelines

(v.1.17.19)

I. PURPOSE

These Guidelines are intended to describe the structure and support provided by the Office of Research Protections to University researchers responsible for complying with regulation, grantor requirements and/or publication standards for registration and reporting of clinical trial data via ClinicalTrials.gov (or any successor or replacement portal or publicly-accessible registry). To comply with the National Institutes of Health (NIH) and the Center for Medicare and Medicaid Services (CMS), Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA), requires grantees conducting clinical trials to register and report results information to ClinicalTrials.gov. Further, the International Committee of Medical Journal Editors (ICMJE) established similar standards investigators must follow if they wish to publish in participating journals. These Guidelines describe the responsibilities, requirements and support for compliance with the NIH, CMS, ICMJE and other similar or related requirements.

II. DEFINITIONS

Clinical Trial:

Clinical Trial (NIH): A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. NIH requires registration and results reporting for all NIH-supported clinical trials, regardless of study phase, type of intervention, or whether or not they are subject to FDAAA.

Clinical Trial (ICMJE): A clinical trial is a research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes—includes drugs, biologics, devices, surgical procedures, and behavioral treatments (see The Uniform Requirements for Manuscripts Submitted to Biomedical Journals). This definition includes Phase I studies.

CMS: The Center for Medicare and Medicaid Services

FDAAA: Title VIII of the Food and Drug Administration Amendment Act of 2007

ICMJE: The International Committee of Medical Journal Editors

IRB: Villanova University's Institutional Review Board

NIH: The National Institutes of Health

ORP: Villanova University's Office of Research Protections

Principal Investigator (PI): The individual who is responsible and accountable for conducting the clinical trial. FDAAA defines the responsible party as the person who is responsible for conducting a clinical trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial and must meet all of the requirements under this regulation. The University deems the terms Principal Investigator and Responsible Party to be synonymous for purposes of this Guidelines.

Protocol Registration System (PRS): The PRS is a web-based data entry system used by ClinicalTrials.gov for investigators to register a clinical study or submit results information for a registered study. Investigators must have a PRS account to register study information on ClinicalTrials.gov. ClinicalTrials.gov establishes one PRS account for an organization (such as a company, university, or medical center). All investigators from that organization who are conducting studies are typically designated as users of this single PRS account.

III. GUIDELINES STATEMENT

A. General Guidelines

The University supports and facilitates the registration and results reporting requirements at ClinicalTrials.gov (or any successor or replacement portal or publicly-accessible registry) to promote responsible dissemination of information about clinical trials to the public, ensure compliance with pertinent Federal and State law and funding agency requirements, and to meet professional publication standards.

The ORP does not have the technical and scientific expertise to register applicable studies on behalf of the PI, but can facilitate and oversee the process to assure that requirements are met. It is the responsibility of the Principal Investigator to work with the University via the Office of Research Protections to ensure registration and results reporting are completed and updated within the timeframes required by FDAAA, NIH, CMS and/or ICMJE.

B. Clinical Trials Requiring Registration

The following new or ongoing clinical trials are required to be registered at http://www.clinicaltrials.gov (or any successor or replacement portal or publicly-accessible registry):

(1) Applicable clinical trials defined by the FDAAA;

(2) Clinical trials funded, either in whole or in part, by NIH;

(3) Qualifying clinical trials which will render claims for items and services to CMS;

(4) Any other research protocols for which registration and reporting is required by applicable laws, regulations or sponsor or grantor policies or procedures;

(5) Clinical trials that meet the clinical trial definition of the ICMJE and, the results of which, the investigator plans to publish in a member journal.

C. Registration

Principal Investigators are responsible for registering research classified as a clinical trial at http://www.clinicaltrials.gov (or any successor or replacement portal or publicly-accessible registry), review the content of the information uploaded to the registry to verify completeness and accuracy, and ensure all data-entry activities occur within applicable required time frames. The Villanova ORP facilitates registration in order to assure that regulatory requirements are met, and results can be published.

Studies registered on ClinicalTrials.gov should be registered through the Villanova University's organization account at the http://www.clinicaltrials.gov (or any successor or replacement portal or publicly-accessible registry) website.

The University will assign an IRB Protocol Number at the time the IRB application is created in the CAYUSE system. The Principal Investigator should initiate study registration after the IRB Protocol Number is assigned.

D. Updating Records

Principal Investigators are responsible for assuring the record for accuracy, updating the research protocol when changes occur, and entering summary results within the applicable required time frames.

For studies registered in ClinicalTrials.gov, the National Clinical Trial Number (NCT#) assigned by ClinicalTrials.gov must appear on all Continuing Reviews and Study Closure Reports submitted to the University's IRB. Failure to provide the

applicable registration number will cause delays in the IRB review and approval process.

E. Results Reporting

Principal investigators are responsible for reporting results of clinical trials as required by the registry.

F. Other Clinicaltrials.Gov Site Responsibilities

The Principal Investigator is responsible to respond to registry reviewer requests for information or changes, as applicable, in a timely fashion.

G. Transfer of Principal Investigator (PI) Responsibilities

During the course of a clinical trial, the PI may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PI. Before leaving the University, the PI must work with the Department Chair, the Dean, ORP and the Office of Grants and Contracts to ensure an orderly transition of his/her responsibilities to the new PI at the University or to initiate transfer of the registry account/record(s) and PI responsibilities to the new institution.

If a clinical trial remains at the University and there are continuing registry reporting obligations without a named PI, the Department or Division Chair will designate a PI to serve and assume any remaining reporting obligations.

IV. PROCEDURE (if applicable)

Investigator guidance on how to register a clinical trial in the ClinicalTrials.gov Protocol Registration System is found at: https://clinicaltrials.gov/.

Detailed instructions for submission of study results are found on the ClinicalTrials.gov website at https://clinicaltrials.gov/ct2/manage-recs/how-report.

V. RELATED INFORMATION/FORMS

REFERENCES

- FDAAA 801: https://clinicaltrials.gov/ct2/manage-recs/FDAAA
- Clinical Trials Registration and Results Information Submission (Final Rule): https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

- NIH Elaboration Document of Responsible and Applicable Clinical Trial: https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf
- NIH Guidelines & Compliance ClinicalTrials.gov and FDAAA: FAQs https://grants.nih.gov/ClinicalTrials_fdaaa/faq.htm
- ClinicalTrials.gov website: www.clinicaltrials.gov
- ICMJE FAQ: http://icmje.org/about-icmje/faqs/

VI. HISTORY

Effective January 2, 2020

VII. QUESTIONS/ SUPPORT

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To join Clinical Trials support group email one of us.

VIII. RESPONSIBLE UNIVERSITY DIVISION/ DEPARTMENT/

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IX. RESPONSIBLE ADMINISTRATIVE OVERSIGHT

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