Allina Health

System-wide Policy:

Registration of Clinical Trials on clinicaltrials.gov

Reference #: SYS-ADMIN-RA-007

Origination Date: February 2017
Next Review Date: February 2020
Effective Date: February 2017

Approval Date: February 2017
Approved By: Research Oversight Committee

System-wide Policy Ownership Group: Research Administration
System Policy Information Resource: Director, Research Compliance

Stakeholder Groups
Research Compliance
Research Directors
Human Research Protection Program

SCOPE:

Sites, Facilities, Business Units	Departments, Divisions, Operational Areas	People applicable to:
Abbott Northwestern Hospital, Buffalo Hospital, Cambridge Medical Center, District One Hospital, Mercy Hospital, New Ulm Medical Center, Owatonna Hospital, Phillips Eye Institute, River Falls Area Hospital, Regina Hospital, St. Francis Regional Medical Center, United Hospital; West Health; Orthopedic Institute Surgery Center at COC; Allina Health Group; Allina Health Home Care Services; All other business units	Research Administration	Any person or entity performing research at Allina Health.

POLICY STATEMENT:

When Allina Health is the Responsible Party, as defined in FDAAA 801, Allina Health will comply with all requirements of a Responsible Party, including registering applicable clinical trials and submitting required result information on clinicaltrials.gov (See procedure).

Allina Health is also committed to registering and submitting required result information for applicable clinical trials consistent with requirements imposed by funding sources (e.g., National Institutes of Health) and/or publications(e.g., ICMJE).

PROCEDURES:

Clinicaltrials.gov Registration and Submission for trials with Allina Health as the Responsible Party

1. Using the Applicable Clinical Trial (ACT) decision tree below, the record owner should identify if the study is an "applicable clinical trial" under the FDAAA 801 definition.
2. If the study meets the definition of applicable clinical trial, identify who the Responsible Party (Sponsor) is.
3. If Allina Health is the Responsible Party (Sponsor), the record owner (the designated PI) should login to clinicaltrials.gov and create a new submission. If the record owner does not have an account, please complete the PRS Administrator Contact Request Form (Organization=AllinaHS) or email osp@allina.com.
4. Once the submission is complete, the record owner should review it for errors and click "Entry Complete". The Allina Health Clinicaltrials.gov Administrator will then review and approve.
5. Once the submission is approved by the Allina Health Clinicaltrials.gov Administrator, it will go into a review queue for the clinicaltrials.gov reviewer (PRS Reviewer) to review before it is released on the public webpage. If there are any comments or errors from the PRS Reviewer, those will need to be addressed and resubmitted for approval to the Allina Health Clinicaltrials.gov Administrator.
6. The submission must be updated every 6-12 months or as needed by the record owner.
7. Follow the FDAAA 801 and the Final Rule for all other requirements and information.

FORMS:

PRS Administrator Contact Request Form

ALGORITHM:

Applicable Clinical Trial (ACT) decision tree

ADDENDUM:

Clinicaltrials.gov Resource Document

DEFINITIONS:

Applicable Clinical Trial: The final rule considers all interventional clinical trials with one or more arms and with one or more pre-specified outcome measures to be controlled clinical trials. The final rule does not consider any expanded access use (*e.g.,* access under treatment INDs or treatment protocols, which provide widespread access, access for intermediate-sized patient populations, or access for individual patients) to be an applicable clinical trial. The final rule also describes an approach for evaluating, prior to registration, whether a particular clinical trial or study is an applicable clinical trial (see Section IV.A.5 and Section IV.B.2). (See clinicaltrials.gov for more information)

PROTOCOL: Not applicable.

FAQs: Not applicable.

REFERENCES:

Links: clinicaltrials.gov ; NIH Policy; ICMJE

Related Regulation and Laws: FDAAA 801; Final Rule (42 CFR Part 11)

RELATED POLICIES/DOCUMENTS:

Name of Policy	Content ID	Business Unit where Originated
N/A		

POLICIES/DOCUMENTS REPLACING:

Name of Policy	Content ID	Business Unit where Originated
N/A		