I. **POLICY**

The Food and Drug Administration (FDA) has authority to inspect any entity involved in the conduct or oversight of FDA regulated research. Children’s National entities with facilities and records subject to FDA inspection include:

- Research team
- Human Research Protections Program (HRPP)/Institutional Review Board (IRB)
- Investigational Drug Service (IDS)
- Ancillary facilities doing protocol prescribed activities (e.g. laboratories, radiology)
- Investigational product manufacturing site(s) (if applicable)

Children’s National employees, including investigators and research staff, are expected to cooperate with the FDA in its inspection.

Upon notification of FDA inspection, the notified parties will:

1) Inform the appropriate Children’s National entities and stakeholders as listed in Procedure CNMC:A:52 - FDA INSPECTION, PREPARATION AND STUDY TEAM ACTIVITIES

2) Follow all requirements within HRPP Procedure CNMC:A:52 - FDA INSPECTION, PREPARATION AND STUDY TEAM ACTIVITIES.

II. **ACCOUNTABLE EXECUTIVE(S) AND REVIEWER(S)**

A. Accountable Executive: Chief Academic Officer, Institutional Official for the Federalwide Assurance (FWA)

B. Department Responsible for Review: Clinical Research Institute

C. Committee Responsible for Review: Research Policy/Procedure Working Group
III. **APPROVAL**
Approved by:

Clinical Research Institute 05/09/17
Date

Research Policy/Procedure Working Group 05/09/17
Date

(Signature on File) 05/09/17
Date

Chief Academic Officer

IV. **APPLICABILITY**

Areas where the policy and procedure applies: Children's National Medical System departments and employees involved with FDA regulated research.

V. **REVIEW OR REVISION DATE**

Original: 06/21/17

VI. **REFERENCES**

Children’s National Food and Drug Administration Inspection Preparation Guide and Checklist

CNMC:A:52P - FDA Inspection, Preparation and Study Team Activities