Community Healthcare System

Central Institutional Review Board
901 MacArthur Blvd., Munster, IN 46321
Phone: 219-836-6862

CHS CIRB Institutional Authorization Agreement

Name of Institution or Organization Designated to Provide IRB Review (Institution A)

Name:
Federal Wide Assurance Number: FWA#
Institution Organization Number: IORG#

Name of the Institution Relying on the Designated IRB (**Institution B)**

Name:
Federal Wide Assurance Number: FWA#
Institution Organization Number: IORG#

The Officials signing agree that _____ may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects' research covered by Institution B's FWA.

(___) This agreement is limited to the following specific protocol(s):

Name of Research Project:
Name of Principal Investigator:
Sponsor or Funding Agency:

(___) Other
(*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

1) RIGHTS, DUTIES, AND RESPONSIBILITIES OF INSTITUTION A:

a) Institution A will perform all of the functions required under 45 CFR Part 46, 21 CFR Parts 50, 56, and 312 and 812 (where applicable), 45 CFR Parts 46.160 & 164 HIPAA Privacy Rule (where applicable), and the human subjects protection requirements of

Institution B's OHRP-approved FWA for the review and continuing oversight of human subjects research conducted under the auspices of the research outlined in Section 2.

b) Institution A will have the authority to suspend the research for failure to comply with conditions of approval or regulatory requirements.
c) Institution A will notify Institution B of any unanticipated problems, termination or suspension of research.
d) Institution A, or its authorized representatives, including the FDA and HHS to the extent permitted by law, will be permitted to conduct the following:
    i. Examine and inspect the local Institution's facilities used for the performance of the studies, including storage and use of any investigational products.
    ii. Observe the conduct of the studies.
    iii. Inspect and copy all documents relating to the studies, including research records, patient medical records, informed consent documents, Investigational Product logs, and other study specific data.
e) Interview, as necessary, all necessary personnel involved in patient care for the studies.
f) Institution A shall maintain all documents reviewed in connection with Institution B's research, including any relevant communication with investigators. Institution A will make its records for studies approved under this agreement available upon written request to appropriate officials at Institution B.
g) Institution A will cooperate fully with Institution B and make appropriate records available to regulatory and accrediting entities at such time as the HRPP of Institution B is under review to include making appropriate records available to the reviewers.

2) RIGHTS, DUTIES, AND RESPONSIBILITIES OF INSTITUTION B

a) Institution B is ultimately responsible and bears full responsibility for all research covered under its Federalwide Assurance.
b) Institution B assures and warrants that all investigators participating in research specified in this agreement are and will remain members of the Institution's staff in good standing and are credentialed and privileged to perform the procedures outlined in the studies.
c) Institution B shall remain responsible, in connection with the clinical research study specified in this agreement, for its own compliance and in assuring compliance by its investigators and research staff with:
    i. The determinations, policies and procedures of the Institution A IRB
    ii. The terms of Institution B's FWA
    iii. 21 CFR Parts 50, 54, 56, 312, and 812 and 45 CFR Part 46, HIPAA, and all other applicable requirements
    iv. The Belmont Report
d) Institution B is responsible for educating and training its investigators and research staff to perform human subject research and for maintained documentation of that training
e) Institution B will notify, within three business days, Institution A of the termination, suspension, or modification of any clinical privileges of members of its Staff who are participating in the study covered by this agreement.
f) Institution B will notify, within three business days, Institution A of any: 1) unanticipated problems involving risks to subjects or others; or 2) any serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s).
g) Institution B will inform the Institution A of any contact by the FDA, HHS, or any other persons or entities regarding any of the research covered in this agreement within three

business days of contact. Institution B will also notify Institution A within three business days, in the event that the FDA or other governmental agency issues the institution any "Notice of Inspectional Observations", "Warning Letters", or other communications citing improper or inadequate research practices with respect to the research specified in this agreement.

h) Institution B will maintain this Agreement as part of the institution's HRPP records.
i) Institution B is responsible for ensuring compliance with the terms of its OHRP approved Federalwide Assurance.
j) Institution B investigators will comply with the education requirement and other human research related policies.
k) Following the Institution A approval, Institution B may require additional review as determined by the Institution B Institutional Official and may be subject to additional administrative requirements as determined by Institution B policy.

2) REPORTING

a) Institution A will report to the Institution B's IRB Office the following that is relative to research covered under this agreement:
   i. Reports of serious or continuing non-compliance
   ii. Reports of unanticipated problems involving risks to subjects or others
   iii. Suspension of IRB approval
   iv. Terminations of IRB approval
   v. Allegations of scientific misconduct
   vi. Oversight agency or other organization initiates any action (including audits, compliance monitoring, and reporting)
   vii. Any modification to the Federalwide Assurance or changes to the status of the Assurance documents

b) Institution B will promptly report to Institution A the following that is relative to research covered under this agreement:
   i. Reports of serious or continuing non-compliance
   ii. Reports of unanticipated problems involving risks to subjects or others
   iii. Suspension of Institution B IO approval
   iv. Terminations of Institution B IO approval
   v. Allegations of scientific misconduct
   vi. Oversight agency or other organization initiates any action (including audits, compliance monitoring, and reporting)
   vii. Any modification to the Federalwide Assurance or changes to the status of the Assurance documents
   viii. Changes in the IRB Point of Contact information

c) Institution A will work collaboratively with Institution B to promptly report (i) unanticipated problems involving risks to subjects or others, (ii) serious or continuing noncompliance, and (iii) suspensions or terminations of previously approved research related to the Institution B Federalwide Assurance to OHRP and FDA as appropriate.

_____	_____
Signature Institutional Official, Institution A	Print Name
_____	_____
Title	Date
_____	_____
Signature Institutional Official, Institution B	Print Name
_____	_____
Title	Date

Form date: 7/2017