



Orange County Government

Orange County
Administration Center
201 S Rosalind Ave.
Orlando, FL 32801-1393

Legislation Text

File #: 26-0103, **Version:** 1

Interoffice Memorandum

DATE: December 22, 2025

TO: Mayor Jerry L. Demings and County Commissioners

THROUGH: Raul Pino, MD, MPH, Department Director

FROM: Christian Zuver, MD, Medical Director

CONTACT: Sandra D. Roe

PHONE: 407-836-7611

DIVISION: EMS, Office of the Medical Director

ACTION REQUESTED:

Approval and execution of Individual Investigator Agreement by and between Orlando Health Inc. and Orange County, Florida for EMS research to improve patient outcomes. The term of this agreement shall be from the effective date of the last signature added and shall continue until completion of research and satisfaction of the Investigator's responsibilities, unless terminated earlier (in accordance with the terms outlined in the agreement). (EMS, Office of the Medical Director)

PROJECT: N/A

PURPOSE: The Office of the Medical Director participates in EMS research to improve the quality and standard of care for patients in Orange County. Federal regulations require an Institutional Review Board (IRB) to participate in such research. The IRB serves to ensure ethics and safety in research. Orange County and Orlando Health are both interested in working together as Research Parties. Orange County desires to use Orlando Health's IRB as the IRB of record for certain studies. The EMS Office of the Medical Director is requesting approval for an individual investigator agreement to facilitate clinical research activities that may contain both retrospective and prospective data collection efforts. This agreement will continue a longstanding relationship between the county and Orlando Health that supports the highest standard of care to individuals in the Orange County EMS System.

BUDGET: N/A

INDIVIDUAL INVESTIGATOR AGREEMENT

This Individual Investigator Agreement (IIA), made effective as of the date of the last signature below ("Effective Date"), is by and between Orlando Health Inc. (Institution), with an address of 1414 Kuhl Avenue, Orlando, FL 32806 and Orange County, Florida with an address of 201 South Rosalind Avenue, Orlando, Florida 32802 (County), on behalf of the County's Office of the Medical Director/EMS Division located at 4654 35th Street, Orlando Florida, 32811 (Site). The Institution and County are referred together herein as "Research Parties".

Recitals:

- A. The County conducts Emergency Medical Services research activities and desires to use Orlando Health IRB as the IRB of record for certain studies.
- B. The Site is at any time under the direction of a Medical Director and Assistant Medical Directors with a focus on Emergency Medical Services.
- C. Clinical research at Site is under the sole direction of the current Medical Director. Site shall have full autonomy with respect to choice and performance of studies.
- D. The County represents that projects submitted by its Investigator (as identified below) have received internal approvals prior to IRB review.
- E. The research governed by this IIA may contain both retrospective and prospective data collection efforts. Data will be obtained from the medical records obtained during the usual business activities of the Site, who have the right and authority to conduct research activies on such data.
- F. Research activities incorporating patients or facilities of Orlando Health or other entities outside of the Site will be subject to further review by Orlando Health's Corporate Research Operations.
- G. Sponsored research activities will be subject to the prevailing Orlando Health IRB fee schedule, as applicable. Unfunded investigator-initiated activities undertaken in concert with Orlando Health will be reviewed without generating IRB fees.
- H. The Orange County Medical Director may designate a Principal Investigator for individual projects but remains responsible for the research activities of all investigators and other personnel engaged in research activities at Site and mandates their adherence to the terms contained herein, including, but not limited to, regulations regarding the conduct of research.
- I. The County agrees to adhere to the obligations detailed below.

IIA:

Name of Institution with the Federalwide Assurance (FWA): Orlando Health, Inc.

Applicable FWA #: FWA00000384

Responsible Investigator's Name: Dr. Christian C. Zuver, Orange County Medical Director

Institutional Review Board (IRB): Orlando Health IRB

Individual Investigator Obligations:

- (1) The above-named Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.)

Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

- (2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
- (3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this Agreement.
- (4) The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
- (5) The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
- (6) The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
- (7) The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
- (8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.
- (9) The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.
- (10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the IRB.
- (11) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable federal regulations and state law.
- (12) This IIA only applies to research reviewed by Orlando Health IRB. This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement. The Investigator is under no obligation to use Orlando Health IRB as the IRB of record; however, Investigator acknowledges that any research activity involving Orlando Health patients, facilities, or medical records **MUST** be reviewed by Orlando Health IRB.
- (13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Term and Termination:

- A. This IIA shall commence as of the Effective Date and shall continue until completion of research and satisfaction of Investigator's responsibilities, unless it is terminated earlier in accordance with this section.
- B. Institution may terminate this IIA, with or without cause, prior to the conclusion of the trial at any time by

giving 60 days prior written notice of termination to Investigator.

C. The IRB may immediately terminate any approved studies under this agreement for reasons of subject safety or investigator non-compliance with federal or local regulations.

No Partnership or Joint Venture:

A. Nothing in this IIA is intended or shall be deemed to constitute a partnership or joint venture between Institution and County or Investigator.

B. In relation to Institution, Investigator is a non-employed physician and will not be remunerated in any form by the Institution for research activities unless agreed to by both parties in separate agreement.

Signatories:

A. Each signatory for the Research Parties below represents and warrants that they have full power and are duly authorized by their respective party to enter into and perform under this IIA.

B. The Research Parties acknowledge and agree that the Investigator's execution of this IIA is solely intended to individually attest to those certain requirements specific to the Investigator in the "**Individual Investigator Obligations**" section of this IIA on the Investigator's own behalf. The Investigator is not authorized, nor does the Investigator purport, to bind the County to this IIA.

IN WITNESS WHEREOF, Institution and County have caused this IIA to be executed as of the date set forth below.

County:



ORANGE COUNTY, FLORIDA

By: The Board of County Commissioners

By:

Brynni Burks
Jerry L. Demings, Orange County Mayor

Date:

13 January 2026

for
ATTEST: Phil Diamond, CPA, County Comptroller
As Clerk of the Board of the County Commissioners

By: *Philip Giordano*
Date: *JAN 13 2026*

Institution:

Signature: *Philip M* Date: *10/27/2025*
Name: Philip Giordano, MD Title: Institutional Official
Address: 1414 Kuhl Avenue, MP 131 Orlando FL, 32806

Investigator:

Signature: *Christian C. Zuver* Date: *10/31/2025*
Name: Christian C. Zuver, MD Title: Orange County Medical Director
Address: 4654 35th Street, Orlando, Florida 32811