UC Irvine
School of Medicine

Research Participant Transportation Policy

I. PURPOSE

To establish a uniform and consistent framework for providing transportation services to clinical research participants at UCI Health. Transportation services under this policy are solely to reduce transportation barriers for protocol-required research participation. These services are not intended to induce clinical research enrollment, reward participation, influence continued participation, or encourage utilization of UCI Health services beyond the scope of the clinical research study.

II. SCOPE

This policy applies to all faculty, employees, contractors, consultants, students, and volunteers engaged in the conduct of clinical research within UCI Health and the School of Medicine that may provide transportation services to clinical research participants, unless otherwise prohibited by the study sponsor, funding agency, or applicable law.

This policy operates in parallel with the UCI Health Bus and Onward Transportation policy, which governs transportation for clinical (i.e., non-research) care and does not supersede or replace it.

III. DEFINITIONS

A. **Protocol-required visit** refers to an in-person research appointment mandated by an IRB-approved protocol, conducted for research-related activities.
B. **Rural area** refers to a geographic area that falls outside of the U.S. Census Bureau's classification of Urbanized Areas (densely settled areas with a population of 50,000 or more) and Urban Clusters (areas with a population between 2,500 and 50,000). For purposes of this policy, a participant's residence is considered rural if it meets this federal standard, and the extended one-way transportation distance limit of 75 miles applies only to participants whose residence qualifies as rural under this definition.
C. **Per-beneficiary compensation** refers to a payment structure in which a transportation vendor or driver receives a fixed fee or rate based solely on the number of beneficiaries or participants transported, regardless of trip distance, duration, or other service factors. The model is prohibited under this policy because it may create a financial incentive tie directly to the volume of federal health program beneficiaries served, potentially violating the Anti-Kickback Statute and related regulations. Transportation vendors

operating under dynamic pricing models—in which fares are calculated based on distance, time, and demand rather than the number of beneficiaries served—are not considered to be compensating drivers on a per-beneficiary basis and are therefore consistent with this policy.

IV. POLICY

UCI clinical research programs may provide transportation services to clinical research participants when the transportation is necessary to support participation in an IRB-approved research study and is provided in accordance with this policy.

Transportation must be arranged through a UCI-designated transportation vendor, Onward, or another transportation provider approved by UCI. Transportation may be provided at no cost or at a reduced cost to the research participant.

Transportation provided under this policy must be limited to research-related purposes and must comply with the eligibility and other restrictions described below. This policy does not authorize emergency medical transportation.

Medical Center counsel, compliance, and/or risk offices should be involved in the consideration of proposed arrangements for cases outside of this policy.

V. GUIDELINES

UCI clinical research programs must maintain standard operating procedures for oversight and management of transportation services that are consistent with this policy.

A. Eligibility Requirements for Transportation Services

Clinical research participants requesting transportation services must meet all the following criteria:

1. Be consented and actively enrolled in an IRB-approved clinical research study conducted at UCI, or have a documented prior relationship with UCI research staff (e.g., documented pre-screening or pre-eligibility review indicating interest to participate, even if informed consent has not yet been obtained); and
2. Be attending a protocol-required, in-person research visit; and
3. The visit must be for research-related activities and must not be solely for routine clinical care services.

B. Eligible Transportation Vendors

1. Onward: UCI's designated transportation vendor may provide standard ridesharing, non-luxury, and companion-assisted transportation services for clinical research participants.
2. Study sponsor-designated vendors: Where a study sponsor has contracted with a specific transportation vendor as part of the Clinical Trial Agreement (CTA), the sponsor-designated transportation vendor may provide transportation services to clinical research participants, subject to the terms of the applicable research agreement and the applicable requirements of this policy.

C. Restrictions

The following policy restrictions apply to transportation services provided to clinical research participants:

1. **Distance:** Transportation is limited to a one-way distance of 25 miles from the UCI Health research site.
2. **No advertisement or solicitation:** Transportation availability must not be advertised, marketed, or communicated to prospective participants as a benefit of enrollment.
3. **No marketing during transport:** No marketing of UCI Health care services or any other health care items or services may occur during transportation or by drivers at any time.
4. **No tie to federal health program business:** Transportation must not be offered, structured, or conditioned in any way tied to past or anticipated federal health program (Medicare or Medicaid) business volume at UCI.
5. **Service Level Limitations:** Transportation is limited to standard ride-share, taxi, wheelchair-accessible transportation, and non-emergency medical transportation. Air, luxury and emergency ambulance transportation is not permitted. Clinical research participants who are experiencing an emergency should be directed to contact 9-1-1.
6. **Research visits only:** Transportation is limited to protocol-required research study visits. Transportation may not be provided solely for routine clinical care that is unrelated to the research study.
7. **Driver compensation:** Transportation vendors used under this policy must not compensate drivers on a per-beneficiary-transported basis. Vendors must certify compliance with applicable UCI Health requirements, including restrictions on per-beneficiary compensation where applicable.

D. Funding Requirements

UCI clinical research teams must identify and document the funding source, cost allocation, and applicable UCI research account for transportation services for each study before offering

transportation services to any clinical research participant. UCI clinical research teams must maintain standard operating procedures for this documentation process.

Transportation costs for research services must not be billed to Medicare, Medicaid, or any other federal health program or commercial insurer.

1. **Sponsor-Funded Studies:** UCI Health research programs are responsible for routing transportation costs to the appropriate UCI research account in accordance with the applicable research agreement (e.g. clinical trial agreement). UCI Health research programs may incur the initial transportation costs and seek reimbursement from the study sponsor, when applicable and consistent with the terms of the research agreement.
2. **Institution-Supported or Investigator-Initiated Studies:** If no funding source is available, transportation services may not be provided under this policy. Nothing in this policy creates an entitlement to transportation services or obligates UCI Health to fund transportation for a clinical research study.
3. **Federally Funded Studies (E.g., NIH, NCI, etc.):** UCI research programs are responsible for ensuring that transportation services are allowable under the terms of the applicable funding award and that any required approvals from the funding agency are obtained prior to providing transportation services.

No transportation can be arranged by clinical research staff unless it meets the requirements of this policy.

VI. QUESTIONS

Questions about transportation needs for clinical research that do not meet the requirements of this policy should be directed towards the UCI Health Compliance and Privacy Office. All other questions regarding this policy can be directed to Eric Vilain, Vice Dean for Clinical Research (evilain@hs.uci.edu), Carey Berkowick, Director of Research Operations (cberkow1@hs.uci.edu) or Shauna Stark, Assistant Dean of Research Operations (starks@hs.uci.edu).

VII. REFERENCES

Anti-Kickback Statute 42 USC Section 1320a-7b(b)

Anti-Kickback Statute Safe Harbor Regulations 42 CFR Section 1001.952

Civil Monetary Penalties 42 USC Section 1320a-7a

VIII. RELATED POLICIES

Policy Stat, UCI Health Bus and Onward Transportation policy.