# A Study to Investigate Safety and Pharmacokinetics of Intravenous Cefiderocol/Xeruborbactam in Participants With Renal Impairment

NCT07104162

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| **Status** | RECRUITING |
| **Phase** | Phase 1 |
| **Sponsor** | Qpex Biopharma, Inc. |
| **Enrollment** | 40 participants |

## Key Eligibility Criteria

### Inclusion (19)

- An individual will be eligible to be included in the study only if all of the following criteria apply:
- All participants
- Able to understand the study conduct and tasks required of the participants, sign the informed consent form and willing to cooperate with all tests and examinations required by the protocol.
- Aged 18 to 80 years, inclusive, at the time of consent.
- If male, agrees to be sexually abstinent or agrees to use 2 approved methods of contraception (refer to Inclusion Criterion 4) when engaging in heterosexual activity from Day -1 through 90 days following the last administration of the study intervention, and to not donate sperm during this same period of time. If the sexual partner is surgically sterile, contraception is not necessary.

... and 14 more (see full listing online)

### Exclusion (24)

- Has unstable or new medical condition(s)
- Has had surgery under general anesthesia within the past 3 months prior to Day -1, determined by the investigator to be clinically relevant.
- Documented hypersensitivity reaction or anaphylaxis to any medication.
- History of seizures, convulsions
- Current evidence or history of malignancy

... and 19 more (see full listing online)

## Locations (2 total)

University of Miami Clinical Pharmacology, Miami, Florida, United States
Orlando Clinical Research Center, Orlando, Florida, United States