Clinical Trial Lifecycle

(Phases I – IV)

UCR Identified as a potential clinical trial site

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PI identifies the research location
(i.e., hospital or other facility)

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SPA negotiates and executes a Confidential Disclosure Agreement
(if required) prior to release of the Protocol by Sponsor/CRO

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PI and Subcontractor (Hospital/Facility) conduct a
Feasibility Assessment

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PI should start columns A and B concurrently

A	B
PI contacts Office of Research Compliance (ORC for IRB review	PI and Subcontractor negotiate study budgets with Sponsor
↓	↓
ORC reviews project for compliance	PI submits proposal and supporting documents via Kuali Research to SPA
↓	↓
WIRB reviews & approves protocol	SPA negotiates Clinical Trial Agreement (CTA)
↓	↓
IRB provides SPA with copy of IRB approval	SPA negotiates a Subcontract with facility

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SPA signs CTA and Subcontract after
all regulatory approvals are in place

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SPA processes Notice of Award

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PI conducts the clinical trial