



Investigator Initiated Study: IIS PROPOSAL SYNOPSIS FORM

All fields are required. If a field is not applicable, please fill in N/A with noted reason.

Date:

Principal Investigator and Contact Information

Primary Investigator (PI):

PI Address:

PI Phone Number:

PI Affiliation:

Institution Phone Number:

(Hospital, University, Dialysis Provider, etc.)

Institution Address:

Study Information

Title of Proposed Investigation:

Investigational Drug:

Number of Subjects:

Dose and Regimen:

Number of Planned Sites (Identify if US or ex-US):



Investigator Initiated Study: IIS PROPOSAL SYNOPSIS FORM (continued)

All fields are required. If a field is not applicable, please fill in N/A with noted reason.

Type of Support Requested (check one):

Drug Financial Drug and Financial

Non-American Regent Drugs (if applicable):

Total Budget Requested (detailed below):

\$

Study Start Date:

Study Type: (observational, prospective etc.)

Study End Date:

Background and Study Rationale

Please discuss how this study will address evidence gaps and answers questions that are not known or published to support the scientific question



Investigator Initiated Study: IIS PROPOSAL SYNOPSIS FORM (continued)

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Study Objectives

Please list primary and secondary objectives

Primary Endpoint

Please list the primary endpoint this study plans to achieve



Investigator Initiated Study: IIS PROPOSAL SYNOPSIS FORM (continued)

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Study Design

Please provide a detailed and high-level overview of study design, including but not limited to, control and experimental group, number of treatment arms, inclusion/exclusion criteria, treatment duration, relevant endpoints, patient population)



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Study Design (continued)

Please provide a detailed and high-level overview of study design, including but not limited to, control and experimental group, number of treatment arms, inclusion/exclusion criteria, treatment duration, relevant endpoints, patient population)



Investigator Initiated Study: IIS PROPOSAL SYNOPSIS FORM (continued)

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Statistical Methods

Please provide planned sample size and statistical powering justification

Detailed Proposed Budget

Please provide specific itemized budget amounts

Direct Costs (i.e. subject-related, personnel, diagnostic, data management):

Indirect Costs (i.e. publication, IRB review fees, supplies):

Other Costs:

Total Budget Cost:

Additional Funding? Please describe below:



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Study Drug

If required, please list drug name and number of vials:

Publication Planning

Please detail plans to present at conferences and/or manuscript submission.

Please list details of target journals and meetings for submission

Please ensure the following documentation has been submitted through the portal in order to ensure a full evaluation of the IIS proposal:

Investigator CV (signed and dated)

Itemized budget detailed in proposal form

Relevant supplemental literature