# IIT Grant Request Form

In order for KCI to process your Investigator Initiated Trial (IIT) Grant Request, we kindly ask you to complete this form. Please note that this is not a mere protocol and that it should contain only key information on various aspects of the research project. Please submit completed information to Professional Affairs at professional.affairs@kci1.com .

## General Information

### Primary Institution

**Name:**

Address:

City, State or Country:

Website:

### Other Institutions – *add more lines if needed*:

**Name:**

Address:

City, State or Country:

Website:

### Principal Investigator (applicant)*

***Please attach current CV (required) with submission of grant request. The contact information below will be used to communicate the final decision from KCI on the grant request.**

**Name and Title:**

Position:

National Provider Identifier Number (NPI#):

Address:

City, State or Country:

Phone: E-Mail:

### Co-Investigator (s)*: *add more lines if needed*:

***Please attach current CV (required) with submission of grant request.**

**Name and Title:**

Position:

National Provider Identifier Number (NPI#):

Address:

City, State or Country:

Phone: E-Mail:

## Contact person for safety event handling and reporting:

**Name and Title:**

Position:

Address:

City, State or Country:

Phone: E-Mail:

## Type of IIT Grant Requested:

☐ Basic Science (Bench or Laboratory) ☐ Pre-Clinical (Animal) ☐Clinical (Human)

## Experience in Area of:

A. Number of Investigations or Studies you have conducted in the requested area of research as Principal Investigator in the past five years? _____Academic _____ Investigator Sponsored _____ Industry Sponsored _____ NIH _____ Other-(please specify in area below) **Total** _____
Other:

B. How many Investigations/Studies have you been involved in total in the requested area? _____ Academic _____Investigator Sponsored _____Industry Sponsored _____NIH _____ Other-(please specify in area below) _____ Total
Other:

C. Other relevant research experience:

D. As the sponsor of the study, do you have dedicated staff to assist with the maintenance of study, related documentation, reporting or regulatory issues? ☐ Yes or ☐ No

E. As the sponsor of the study, do you have dedicated staff to with experience in handling and regulatory reporting of safety events? ☐ Yes or ☐ No

F. As the sponsor of the study, do you have experience with IRB submission, and obtaining IRB approval? ☐ Yes or ☐ No and/or
IACUC approval process ☐ Yes or ☐ No?

G. Does your facility or institution have an IRB or the IACUC ☐ Yes or ☐ No? If no, do you use an external IRB ☐ Yes or ☐ No or the IACUC ☐ Yes or ☐ No?

# STUDY SYNOPSIS

## I. Study Title*:

*** Please include study subject type (eg. Human population, animal model, etc.) and unmet clinical/scientific need this study intends to address.**

## II. Introduction:

## III. Hypothesis and Rationale:

## IV. Objectives:

A. Primary Efficacy Endpoint:
B. Secondary Efficacy Endpoint(s):
C. Safety Endpoint(s):

## V. Design:

A. ☐ Basic Science (Bench or Laboratory) ☐Pre-Clinical (Animal) ☐ Clinical (Human)
B. ☐ Care Report ☐ Registry ☐ Study (Trial)
C. ☐ Retrospective ☐ Prospective
D. ☐ Non-randomized ☐ Randomized
E. ☐ No Control or Sham ☐ Sham-controlled ☐ Reference-controlled
F. ☐ Single-arm ☐ Multiple-arms - Specify (#): ____
G. ☐ Single-center ☐ Multiple-centers - Specify (#): ____

## VI. Duration:

A. Retrospective Study: Start Date _____ End Date_____
B. Date First Patient (FPI) or Subject (FSI) In:
C. Date Last Patient (LPO) or Subject (LSO) Out:
D. Total Duration:

## VII. Population:

A. Study Population – Brief Description:
B. Inclusion criteria (if appropriate):
C. Exclusion criteria (if appropriate):
D. Informed Consent Requirements (if appropriate):

## VIII. Sample Size Calculation:

A. Event Rate Assumption(s):
B. Study Group (%):

C. ☐ Comparator or ☐ Sham Group (%):
D. Power Estimation: ☐ 95% ☐ 90% 85% ☐ 80% or Other – Specify: ___%
E. Evaluable Rate Consideration: Specify: ___%
F. Sample Size Calculation: ____ Total Number of Subjects. When population is not divided evenly, please specify how it will be divided and rationale for doing so:

G. Interim Analysis - Sample Size Re-calculation: ☐ Yes ☐ No Specify rationale:

H. Number of Centers Projected: ____

## IX. Specific Study and/or Reference Product(s) Treatment Protocol(s):

A. KCI Study Product(s):
B. Reference Product:

## X. Data Collection & Methods:

A. Primary Efficacy Endpoint:
B. Secondary Efficacy Endpoint(s):
C. Safety Endpoint(s):

## XI. Health Economics (if appropriate):

A. Are there plans to conduct Health economics assessment with this study? ☐ Yes or ☐ No
If yes, please attach a summary of the Health economics Analysis Plan.
B. Will it require additional resource data collection? ☐ Yes or ☐ No If yes, please specify:

## XII. Budget Summary: (Please attach detailed budget)

**A.** Currency: ☐ US Dollars ☐ EMEA Euros Other –Specify: _____

**B.** Product(s) Requested - Estimated Costs: ……..... _____

**C.** Supplies Requested - Estimated Costs: ……..... _____

**D.** Patient or Subject Fees - Amount Requested: ……..... _____

**E.** Laboratory Fees - Amount Requested: ……..... _____

**F.** Other Fees - Amount Requested – Specify type of fee:
1. _____ : ……..... _____
2. _____ : ……..... _____
3. _____ : ……..... _____
4. _____ : ……..... _____
5. _____ : ……..... _____
Sub-total (F): ..... _____

**G. Institutional Overhead (__%) : ……..._____**
**H. KCI IIT Grant – Total Amount Requested (B+C+D+E+F+G): _____**
**I. NON-KCI IIT Grant(s) (additional funding requested from other sources) – Total Amount Requested***:* _____

**J. Total Cost of IIT Grant Proposal– Projected Amount (I+J): _____**

**Signature of Requestor: _____ Date: / /**