CLINICAL**DEVICE**GROUP

Request for Proposal & Confidential Disclosure Agreement

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Instructions

Clinical Device Group needs certain information from you in order to prepare a proposal for services. This form is meant to help you focus your thinking and identify your needs. Please indicate which services you want and provide additional information as you think necessary. We will prepare an estimate of actual and pass-through costs; but due to the dynamic nature of clinical research projects, actual billings will be based on fee-for-service. Do to today's competitive marketplace; a mutual confidentiality agreement is incorporated into this request. Please telephone or email if you have any questions.

—NJ Stark, President

Office Use Only

Project Number:	Date of Receipt:

Requester Information

Your name:	Title or Department:
Company name:	Phone (land line)
Address1:	Fax
Address2:	Email
City, State, Country, Zip	Web address
How long in business?	EIN (Tax ID Number) or Dun & Bradstreet Number

Project Information

Project name:

Product name and brief description:

Service requests

Which of the following services do you want included in the proposal?

1. Biological Safety

Prepare a safety testing strategy..... ☐ Prepare a risk assessment..... ☐
Review existing safety data..... ☐ Coordinate testing with test house ..... ☐
Write a safety protocol. ..... ☐
Other. _____ ☐

2. Market Analysis

Identify competitors and products..... ☐ Identify competitor's investigators..... ☐
Other. _____ ☐

3. Regulatory Affairs

Coordinate IDE application* ..... ☐ Coordinate PMA application*..... ☐
Coordinate 510(k) application* ..... ☐ Serve as your US agent/sponsor ..... ☐

**What do you want us to do?* *(Required field—we cannot provide an estimate without specifications.)*

1. Write the application de novo ..... ☐
2. Assemble existing information ..... ☐
3. Review an existing application ..... ☐

4. Clinical Research

A. Prestudy Tasks

Prepare or revise a protocol..... ☐ Prepare a Report of Prior Investigations. .. ☐
Calculate sample sizes..... ☐ Conduct prestudy visits to qualify sites..... ☐
Prepare the statistical analysis plan. ..... ☐ Prepare Investigator Agreements. ..... ☐
Do content & layout for case report forms. . ☐ Propose investigative site budgets. ..... ☐
Draft an informed consent form. ..... ☐ Coordinate IRB or EC submissions. ..... ☐
Prepare an Investigator's Brochure..... ☐ Conduct study initiation visits. ..... ☐
Other. _____ ☐

B. Study Tasks

Monitor investigative sites..... ☐ Monitor core laboratories..... ☐
Monitor clinical laboratories. . ..... ☐ Process and track investigator invoices..... ☐
Other. _____ ☐

C. Data Tasks

Design database to receive data. ..... ☐ Enter data in database. ..... ☐
I prefer Excel ..... ☐ Part 11 compliance required ..... ☐
I prefer Access ..... ☐ Statistically analyze data..... ☐
Other. _____ ☐

D. Post-Study Tasks

Close out study. ..... ☐ Prepare sponsor's final report. ..... ☐
Other. _____ ☐

How big is your study going to be? *(Required fields—we cannot provide an estimate without specifications.)*

1. Total number of test and control subjects:..... ☐
2. Number of case report form pages per subject:..... ☐
3. Number of US investigative sites:..... ☐
4. Number of investigative sites outside the US: ..... ☐

5. Estimated enrollment period (in months) .....
6. Estimated treatment or intervention period per subject (in months) .....
7. Additional follow-up period after treatment or intervention (in months).....
8. Number of core laboratories: .....
9. Number of laboratories at each site: .....

Why are you conducting a clinical study?

Pilot, feasibility, proof of concept..... ☐ Post-market surveillance ..... ☐
510(k) or PMA approval ..... ☐ Marketing support, publication ..... ☐
Other_____ ☐

5. Other Activities

Network Staff training. ..... ☒ Coordinate an FDA meeting. ..... ☐
Plan an investigator's meeting. ..... ☐ Audit investigative sites. ..... ☐
Other. _____ ☐

Regulatory status of your device, in the US:

Class I ..... ☐ Significant risk ..... ☐ Device is investigational ..... ☐
Class II ..... ☐ Non-significant risk .... ☐ Device has approved 510(k) .... ☐
Class III ..... ☐ Device has approved PMA..... ☐

Regulatory status of your device, in Europe:

Class I ..... ☐ Device is investigational..... ☐
Class IIa..... ☐ Device has approved CE Mark ..... ☐
Class IIb..... ☐
Class III ..... ☐
Active implantable ..... ☐

Is there any other information CDG needs?

Mutual Confidential Disclosure Agreement

The above-named Requester and Clinical Device Group Inc (CDG) (the "Parties") intend to discuss potential business arrangements between each other in which CDG may provide consulting and/or contract research organization services to Client ("Services"). In exchange for the mutual disclosure of confidential and proprietary information by both Parties, Requester and CDG agree that the following Confidential Disclosure Agreement ("CDA") shall govern the conditions of disclosure of any and all technical data, including documents, materials, reports, instructions, inventions, software, and data ("Information") disclosed by one party to the other during this period of proposal and negotiation.

1. Requester and CDG agree to retain in confidence all Information disclosed to it by or on behalf of the other Party and that they will not, without the prior written consent of the other Party, use the Information supplied under this CDA for any purpose other than execution of the Request for Proposal and performance of any resulting contracted Services.
2. Requester and CDG shall use the same standard of care to protect the confidentiality of Information provided to them by the other Party as they use to protect their own confidential information, and shall limit disclosure of the Information to those of their personnel and consultants who have an actual need to know and have a written obligation to protect the confidentiality of the Information.

3. Notwithstanding the preceding provisions, the obligations of Requester and CDG regarding confidentiality of the Information disclosed hereunder shall not include Information: a) which, at the time of disclosure, was published, known publicly, or otherwise in the public domain; b) which, after disclosure, is published, becomes known publicly, or otherwise becomes part of the public domain through no fault of the other party; c) which, prior to the time of disclosure, is known to the other party as evidenced by its written records; d) which, after disclosure, is made available to the other party in good faith by a third party under no obligation of confidentiality; and e) which is required by applicable law or regulation to be disclosed.
4. Any amendments or modifications to this Agreement must be in writing and signed by the parties.
5. Neither this Agreement nor any disclosure hereunder shall be deemed, by implication or otherwise, to vest in Recipient any license or other ownership rights to or under any patents, know how, or trade secrets.
6. This Agreement shall be governed by the laws of the Illinois without regard to the conflict of laws, rules or principles thereof.
7. The obligations of confidentiality and nonuse set forth herein shall remain in effect for a period of ten (10) years after the effective date of this Agreement.
8. Requester and CDG agree to promptly return all Information supplied to it by the other party upon request.

The effective date of this Agreement shall be the latest date of signature as set forth below.

Client	**Clinical Device Group, Inc.**
By:_____ *Signature*	By:_____ *Dr. Nancy J Stark, President*
Date:_____	Date:_____