J15 A/B Investigational Device Exemption *Request Form*

Instructions for Completing the CGS IDE Form

(incorrect information will result in a delay of your approval)

1. **Point of Contact:** All contact regarding submission will be directed to this person
2. **E-mail Address:** Approval letters/communication will go to this email address
3. **Address:** Point of contact physical address including City/State/Zip
4. **NCT Registry Number:**
   - **a.** **REQUIRED,** submissions will be returned if this is missing/inaccurate
   - **b.** **NOT applicable for HUD studies**
5. **IDE/HUD Number:** **REQUIRED**, submissions will be returned if this is missing/inaccurate
6. **Study Name/Short Version:** Do not include the name of the protocol, this should be the abbreviated name
7. **Type of Request:**
   - **a.** Initial Request
     - **i.** **Prior to 01/01/2015** CGS will approve the study include the following supporting documents
       1. IRB Approval of the Study
       2. FDA Approval of the Study (send the initial and any subsequent approvals)
       3. Protocol
       4. CGS Submission Form (page 2 does not have to be completed on initial)
     - **ii.** **After 01/01/2015**
       1. Completed CGS Submission Form
       2. IRB Approval
       3. CMS Approval Letter (your sponsor will have this)

     NOTE: For CMS approved studies your study must be "REGISTERED" with CGS in order to update all Medicare Payment systems, to do this you MUST include the above documents.
   - **b.** Roster Change
     - **i.** Submit CGS Form
       1. Complete the top section with study/contact information
       2. Completed participating facility
       3. Include practitioners, designation (MD/DO), NPI (include change next to name (i.e. ADD or DELETE))
       4. IRB approval/notification of change
   - **c.** Extension
     - **i.** Submit completed CGS form, including completed page 2
     - **ii.** IRB Approval
     - **iii.** Summary of any protocol changes that are of a clinical nature
     - **iv.** Summary of any Adverse Events
   - **d.** Adverse Event
     - **i.** Submit CGS Form, complete the top section with study/contact information
     - **ii.** Summary of Adverse Events

e. Protocol Changes
   i. CGS Submission Form, complete top section
   ii. Protocol Summary (administrative changes only need not be reported BUT include copy of most recent protocol with next submission)
   iii. IRB Approval

8. Participating Facility
   a. Facility Name
   b. Facility Physical Address
   c. **REQUIRED Facilities Billing PTAN/Medicare Number**
      i. Submissions will be returned if this is missing/inaccurate
      ii. **NPI numbers are NO LONGER ACCEPTABLE**

      NOTE: Instruction for reporting additional facilities below:

      - **On the last line (#3) type in ADDTL FACILITIES Attached**
      - **On a separate paper list the same information as above and title the document Addtl Facilities**

9. Participating Practitioners
   a. Practitioner Name
   b. Designation (MD/DO)
   c. NPI Number

   NOTE: Instruction for reporting additional facilities below:

   - **On the last line type in ADDTL Practitioners Attached**
   - **On a separate paper list the same information as above and title the document Addtl Practitioners**

PAGE 2: DO NOT COMPLETE FOR INITIAL STUDY REQUESTS

1. IDE Number (be sure to complete this line with the same IDE number listed on page 3)
2. Paragraph 1: Adverse Events
   a. Type Print Principal Investigator's name
   b. Check appropriate box
      i. No Adverse events, drop down to PI signature and Date
      ii. REPORTABLE Events (attach a SUMMARY of all events, PI must sign/date)
3. Paragraph 2: Protocol Changes
   a. Type Print Principal Investigator's name
   b. Check appropriate box
      i. No Protocol Changes, drop down to PI signature and Date
      ii. REPORTABLE Protocol Changes (attach a SUMMARY of all clinical changes, PI must sign/date)

Questions/Concerns can be emailed to J15IDE@cgsadmin.com.

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The following form must be included when submitting ALL IDE/HUD Request, please follow instruction on preceding pages. Requests can be submitted via email to J15IDE@cgsadmin.com or faxed to 1.615.664.5961

1. Point of Contact:
2. E-mail Address (approval letters will be emailed to this address):
3. Address (approval letters will be sent to this address when an email address is not available):
4. NCT Registry Number:
5. IDE/HUD:
6. Study Name:

Type of Request (check all that apply):

- ☐ CED Approval
- ☐ Initial Request/Registration Only (CMS approval must be attached)
- ☐ FDA Approval (initial and most recent)
- ☐ Extension
- ☐ Roster Change (include IRB notification/approval)
- ☐ Adverse Event (include a one list/summary of events)
- ☐ Protocol Change (include versions)

Participating Facility			
	Name	Address	OSCAR/PTAN
1			
2			
3			

Participating Practitioner(s)			
	Name	MD/DO	NPI
PI			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			
Sub			

Number of Enrollees Anticipated at the Facility:

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COMPLETE ONLY FOR EXTENSIONS, PROTOCOL CHANGES, AND ADVERSE EVENTS

IDE/HUD #:

The Principal Investigator must respond to both the Adverse Event and Protocol attestations below (when the request is for a new study this page does not need to be completed).

J15 A/B Investigational Device ADVERSE EVENT Attestation:

I _____ hereby attest that in the above named study there have been
PI Printed/Typed Name

- ☐ NO Adverse Events
- ☐ REPORTABLE Events (attach event summary with submission)

since our last submission. I do hereby attest that this information is true, accurate, and complete to the best of my knowledge.

PI Signature:

Date:

J15 A/B Investigational Device PROTOCOL Attestation:

I _____ hereby attest that in the above named study there have been
PI Printed/Typed Name

- ☐ NO Protocol Changes
- ☐ Protocol Changes (attach summary of changes with submission)

since our last submission. I do hereby attest that this information is true, accurate, and complete to the best of my knowledge.

PI Signature:

Date: