Investigational Device Exemption (IDE)

JH & JL

SUBMISSION CHECKLIST

Please type or print legibly the information below, print the form, and include it in your submission packet.

☐ **JH Region** (AR, CO, LA, MS, NM, OK, TX, & Indian Health Services & 04911)			☐ **JL Region** (DC, DE, MD, NJ, PA, & 12901)		
6-Digit IDE Study Number:	G	P	501(k)	I	Q
Requesting Approval for:	☐ A ☐ B ☐ A & B		**Clinical Trial 8-Digit Registration Number (NCT)**		
Study Name:					

Participating Provider Facility/Hospital Name(s) & 6-Digit Provider Transaction Access Number (PTAN)
(where procedure is to be performed)

Hospital/Facility Name	PTAN	Hospital/Facility Name	PTAN

Participating Physician(s) and Sub-Physician(s) Name(s) and/or Group Name & 10-Digit National Provider Identifier (NPI)
(For additional physicians please attach names on a separate sheet.)

Physician Name(s)	NPI	Physician Name(s)	NPI

Contact Information
List name of person submitting documents. Approval letter will be sent to contact below unless indicated elsewhere in documents.

Title (Ms., Mr., etc.)		**First and Last Name:**			
Job Title:		**Post-nominal initials** Ex: RN			
Company Name:					
Department Name:					
Street:					
City:		**State:**		**Zip:**	
Phone:		**Extension:**		**Fax:**	
Email:					

Signature of Principal Investigator (PI):	**"Signed on behalf of" the Principle Investigator:**

★ Documents to Include in Submission Package ★

- ☐ Completed Submission Checklist Form with either the **Signature** of the **Primary Investigator** or "Signed on behalf of" the Primary Investigator.
- ☐ FDA Un-redacted/Unconditional Letter for IDE studies approved by FDA before 1/1/2015
  - Cannot have any **blackouts**, **whiteouts**, or missing text.
  - Must have a signature page.
  - All FDA letters must be submitted by the Institution or person requesting approval, not a 3rd party representative, such as sponsor
- ☐ IRB Approval letter must show the Expiration Date
- ☐ Informed Patient Consent which includes the Patient Signature page
- ☐ Study Protocol or Summary which includes "Therapeutic Intent"

Fax to

410-891-5231

Attn: JH IDE Applications
or
Attn: JL IDE Applications

★ If providing additional information, then please attach a cover page explaining the extra documents.

For a complete list of submission documents please visit our website at:
http://www.novitas-solutions.com