Investigational device exemption (IDE) approval requirements (For IDEs that have an approved FDA letter prior to January 1, 2015)

Initial submission request

Please submit the following required documentation to First Coast Service Options Inc., via email, to clinicaltrials@fcso.com for review. **Incomplete requests are not acceptable and will not be reviewed.**

Please include a cover letter to include the following information:

- ☐ Identification of the sponsor of the clinical trial and of the funding agency and/or organization if different from the sponsor.
- ☐ Identification of the principle investigator (PI) and sub-investigators of the clinical trial. Please include a list of all other contact persons (anyone we are allowed to exchange information with regarding the clinical trial and phone numbers or email addresses).
- ☐ Identification of the facility (place of service of the clinical trial) including the provider number(s) and the address of the facility/ hospital/institution.

Submit the following items for review:

- ☐ A copy of the complete FDA approval letter(s) provided to the PI and/or the sponsor or manufacturer of the device. Redacted letters and/or letters with blacked-out areas are not acceptable. Conditional letters are accepted if all patient safety issues have been addressed. Sending only page one of the FDA letter is not acceptable. Each site requesting an IDE approval letter must provide the entire FDA letter.
- ☐ A copy of the approval letter from the Institutional Review Board (IRB) with the meeting date and the expiration date and the identifiers of the PI and sponsor listed.
- ☐ A copy of the complete study protocol, including patient inclusion criteria. Abbreviations or summaries of the protocol are not acceptable.
- ☐ A copy of the IRB-approved informed patient consent form with PI and sponsor identifiers listed.
- ☐ A copy of the protocol for obtaining informed patient consent.
- ☐ Copies of all agreements between the sponsor and the PI, including but not limited to, complete financial agreements, any and all payments for each aspect of the study with PI and sponsor identifiers listed.

Consideration for approval of the clinical trial will occur within 45 days of receipt of all of the required documentation.

Please submit this document with all of the above required items via email to clinicaltrials@fcso.com. Incomplete requests are not acceptable and will not be reviewed.

I certify the above is accurate and complete and understand that it is my responsibility to ensure that claims are submitted in compliance with Medicare guidelines.

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Signature of principle investigator (PI) or proxy

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