ZOGENIX	FORM NO: ZMA-IIS-CRS-001	EFFECTIVE DATE: 5/1/2015
ISSUED BY: **Medical Affairs Department**	PAGE: 1	
SUBJECT: **Investigator Initiated & Collaborative Research Study Proposal Submission Form**		

Instructions:
This form should be used to provide the committee with a summary of the proposed study for review and comment prior to submitting a formal protocol. Please fill out completely and submit via email along with a copy of your CV to Zogenix **Medical Affairs**:

Zogenix, Inc.
E-mail: IIS@Zogenix.com

Institution/Organization Information:

Princip Investigator: _____

Tax ID: _____

Co-Investigator(s) *(if applicable):* _____

Phone: _____

Institution or Practice Name:_____

Address:

_____

E-mail:

_____

Study Information:

STUDY DRUG: *(check the appropriate response)*	☐ ZX008 (fenfluramine) ☐ Non-drug study (i.e. observational study, retrospective database study)
STUDY TITLE:	
STUDY OVERVIEW: (please include description of the study concept and key objective(s), of the trial.	

STUDY SUBJECTS: (*i.e. sex, age group, diagnosis, etc.)*	
DESIGN: (*check all that apply*)	☐ Single-dose ☐ Multiple-dose ☐ Randomized ☐ Non-randomized ☐ Blinded: ☐ single-blind *or* ☐ double blind ☐ Parallel ☐ Cross-over ☐ Single-site ☐ Multiple-site _____ _____ _____ (*if none of the above apply to your study, please briefly describe the design in the space below):*
DURATION OF STUDY (i.e. how long will patients be treated or what period of time will be covered in a retrospective or observational study)	_____ Weeks _____ Months

TREATMENT PERIOD: *(Briefly describe how patients will be handled during the treatment period.)* Include: 1. Inclusion/exclusion criteria 2. # of visits, 3. Outcome assessment tools (pain measures, QOL measures, etc.), 4. Dose titration (if applicable), 5. Adverse event monitoring ATTACH EXTRA SHEET IF NEEDED. **NOTE: If there is no Treatment being tested as in the case of an observational study or restrospective database study, etc., please use this space to describe your methodology.**	
LOCATION: (*i.e. name of clinic/office, address, phone, fax, etc.)*	
NO. OF SUBJECTS: *(Number of subjects you think will meet inclusion criteria within the allowed enrollment period or number of subjects that will be included in your observational study, retrospective study, etc.)*	
EFFICACY: *(Primary and/or secondary efficacy outcomes.(i.e. reduction in seizure frequency, sleep quality, behavioral outcomes, quality of life, etc.)* ATTACH EXTRA SHEET IF NEEDED.	

SAFETY: *(How and when will safety be assessed or adverse events be monitored)*	
ESTIMATED BUDGET: (*Provide a rough estimate as we understand that the final budget cannot be determined until a full protocol is developed)*	

Contact Information & Signature of Individual Submitting Study Proposal:

Name: _____

Email: _____

Title: _____

Phone: _____

Study Submission Date: _____

Signature of Individual Submitting Study Proposal:

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