OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

POST-IRB APPROVAL
FDA DEVICE (IDE) SPONSOR AND INVESTIGATOR RESPONSIBILITY (21 CFR 812)

Purpose: Investigators who initiate and submit an IDE application to the FDA assume the responsibilities of both the investigator and the sponsor. Under FDA regulations, an academic sponsor or sponsor-investigator has the same obligations as a multi-national device manufacturer that sponsors or holds an IDE.

This form is for Sponsor-Investigators to conduct a self-assessment of their IRB approved studies to ensure that they are meeting their institutional and regulatory requirements. Onsite documents (listed in the right column) correspond to the regulations written in 21 CFR 812 (investigational devices) and the institutional policy and can provide evidence that the Sponsor-Investigator has fulfilled his/her responsibilities. Depending on the specific study, additional documents may be needed. All investigational devices at the University of Michigan must be inspected for safety. For further information contact the IRB staff owner for the study.

The Office of Research Compliance Review (ORCR) recommends using this checklist during study initiation and as an ongoing internal review tool. For more information or questions, please contact: orcr-deptemail@umich.edu.

Additional information on sponsor-investigator responsibilities can be found on the following websites: OM Part 8: Studies Regulated by FDA & Use of Investigational Articles; MIAP IND/IDE Consultation & Development; MICHR Study Monitoring; IRBMED Guidance on Federal Regulations

STUDY INFORMATION	
HUM #	
Study Title	
PI Name	
Date Self-Assessment Completed	
Person Completing Self-Assessment	

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SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
TRAINING Completed the U-M required educational session for Sponsor-Investigators	MIAP training sign-in sheet completed	Yes ◯ Date:	No ◯
CLINICALTRIALS.GOV Completed registration of the protocol on ClinicalTrials.gov		Yes ◯	No ◯
Registration date within 21 days of the first subject being enrolled.		Yes ◯	No ◯
The consent form contains the mandatory language.	IRB approved consent form	Yes ◯	No ◯
MAINTAIN AN EFFECTIVE IDE (consult with MICHR/MIAP and consider using their services for document preparation assistance, application review, and maintenance of an active IDE)	Original IDE application	Yes ◯	No ◯
Protocol supplements are required for (21 CFR 812.35): New protocol Changes to existing protocol (amendments) New investigator New study site Changes to investigational device	FDA letter of approval	Yes ◯	No ◯
	IDE supplements	Yes ◯	No ◯
	Investigator agreements	Yes ◯	No ◯
	Other correspondence with FDA (e.g. response to a clinical hold, general correspondence)	Yes ◯	No ◯

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SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
IDE safety reports (21 CFR 812.46(b)), 812.50(b)) Serious, related, unexpected or significant preclinical findings (written reports, e.g. MedWatch 3500A to FDA, and all participating investigators if applicable within 10 calendar days) Follow-up information to a safety report (submitted as soon as available)	IDE safety reports Evidence of correspondence to other investigators	Yes ◯ Yes ◯	No ◯ No ◯
Annual reports (21 CFR 812.150(b)) Before or on the anniversary date that the IDE went into effect	Annual report	Yes ◯	No ◯
Current investigator list Provide FDA, at 6-month intervals, a current list of names and addresses of all investigators participating in the study (21 CFR 812.150(b)(4))	Investigator list (every 6 months)	Yes ◯	No ◯
INFORMING INVESTIGATORS (21 CFR 812.45) Provide all clinical investigators with instructions for use or clinician's manual. Inform investigators of new observations discovered by or reported to the sponsor on the investigational product.	Instructions for use or clinician's manual *For multi-site studies:* Documentation that all sites have received the instructions or clinician's manual Documentation of communication with investigators regarding new observations and adverse events	Yes ◯ Yes ◯ Yes ◯	No ◯ No ◯ No ◯

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SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
SELECT QUALIFIED INVESTIGATORS AND MONITORS (21 CFR 812.43; 812.140(b)(3)) Select PIs qualified by training and experience	Signed Investigator Agreement	Yes ◯	No ◯
	Current Investigator CV and license	Yes ◯	No ◯
	IRB approval	Yes ◯	No ◯
Ship investigational product only to those investigators participating in the trial	*For Multi-site studies (applies to training and shipping investigational product):* Investigator information is required for **each** site	Yes ◯	No ◯
Keep accurate records of financial disclosure according to 21 CFR 54	PI CV is provided to FDA	Yes ◯	No ◯
	Financial disclosure from such as FDA form 3455 for PI and Co-Investigators listed on 1572/Investigator Agreement	Yes ◯	No ◯
Select monitors qualified by training and experience	*For Monitoring of Study* MICHR Monitoring Services	Yes ◯	No ◯
	Other (specify):		
	CV and training experience of monitor	Yes ◯	No ◯
	Ensure monitor is trained on protocol	Yes ◯	No ◯

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Regulations	**Corresponding Onsite Documents**	**Response**	
ENSURE ONGOING MONITORING (21 CFR 812.46) Ensure proper monitoring Ensure PI compliance or discontinue shipments of investigational device Review and evaluate device safety and effectiveness Discontinue investigation within 5 working days when unreasonable and significant risks to subject are identified.	Documentation of safety monitoring plan	Yes ◯	No ◯
	Who will be reviewing safety data: Sponsor (or Sponsor-Investigator)	Yes ◯	No ◯
	DSMB	Yes ◯	No ◯
	Medical monitor	Yes ◯	No ◯
	Other (specify):		
	Reports/meeting minutes from DSMB and/or medical monitor	Yes ◯	No ◯
	Documentation of data monitoring plan	Yes ◯	No ◯
	Research team has been trained on data collection sheets and/or CRFs	Yes ◯	No ◯
	Correspondence with monitor	Yes ◯	No ◯
	Documentation of monitoring	Yes ◯	No ◯
	Timely notifications to all investigators, IRB and FDA if investigation discontinued.	Yes ◯	No ◯

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SPONSOR RESPONSIBILITIES
COMMENTS ON SPONSOR RESPONSIBILITIES:

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INVESTIGATOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
Assure IRB review and approval and prompt reporting according to IRB guidelines (21 CFR 812.110, 812.150(a))	Initial IRB approval	Yes ◯	No ◯
	Scheduled continuing review (SCR)	Yes ◯	No ◯
	Amendments describing any study changes	Yes ◯	No ◯
	Adverse event reports according to IRBMED guidance or study specific plan	Yes ◯	No ◯
	Unanticipated problems (UaPs)	Yes ◯	No ◯
	Protocol deviations reported to the IRB (ORIOs)	Yes ◯	No ◯
	Instructions for use or clinician's manual	Yes ◯	No ◯
	Other IRB correspondence	Yes ◯	No ◯
Maintain adequate and accurate case histories on each subject's participation in the trial (21 CFR 812.140(a)(3))	Signed and dated consent forms for all subjects	Yes ◯	No ◯
	Supporting data (source documents)	Yes ◯	No ◯
	Case report forms (CRFs)	Yes ◯	No ◯
	Subject eligibility documentation	Yes ◯	No ◯
	Progress notes	Yes ◯	No ◯
	Concomitant medications recorded	Yes ◯	No ◯
Obtain informed consent in accordance with provisions in 21 CFR50	Approved consent form document that includes all required elements	Yes ◯	No ◯

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INVESTIGATOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
Supervise the conduct of the clinical investigation (21 CFR 812.100) ensuring: Appropriate delegation of tasks Adequate training to protocol Adequate supervision	Delegation log	Yes ◯	No ◯
	Staff training log	Yes ◯	No ◯
	Minutes from research team meetings to review trial progress, AEs, protocol changes	Yes ◯	No ◯
	Notes from meetings with study monitor	Yes ◯	No ◯
	Written procedures for internal review of data	Yes ◯	No ◯
Protect the rights, safety and welfare of study subjects (21 CFR 812.100)	Adhere to protocol	Yes ◯	No ◯
	Provide reasonable medical care for AEs	Yes ◯	No ◯
	Inform subject when medical care is needed for conditions unrelated to research	Yes ◯	No ◯
	Investigator is available to subjects during conduct of study	Yes ◯	No ◯
	Appropriate delegation to co-investigators if PI is not available	Yes ◯	No ◯
Investigator is responsible for providing sponsor with reports (21 CFR 812.150(a)) Progress reports Safety reports Deviations from investigational plan Final reports Financial disclosure reports	Investigator has provided sponsor with pertinent correspondence (enrollment numbers, adverse events, financial information, and any changes in financial information).	Yes ◯	No ◯
	N/A, Single center study	Yes ◯	No ◯

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INVESTIGATOR RESPONSIBILITIES
COMMENTS ON INVESTIGATOR RESPONSIBILITIES:

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DEVICE ACCOUNTABILITY			
Regulations	**Corresponding Onsite Documents**	**Response**	
Sponsor is responsible for record of device disposition (21 CFR 812.43(b), 812.140(b)(2)) Maintain adequate record of receipt and shipment of investigational device Assure return of all unused investigational devices from individual investigators participating in the trial or authorize alternative disposition of unused product. Maintain written records of any disposition of devices.	*Receipt:* Device received from industry. Device accountability log includes: Receipt date Quantity Lot # Return/disposition Method of disposal *Device manufactured on-site* *Shipment:* Single center study – no device shipment Device shipped to multiple sites. Device accountability log includes: Date Destination Who shipped Quantity Lot # Return/disposition Method of disposal	Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯	No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯

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DEVICE ACCOUNTABILITY			
Regulations	**Corresponding Onsite Documents**	**Response**	
Investigator is required to maintain adequate records of the disposition of the device (21 CFR 812.140(a)(2))	Device dispensing record includes: Date Lot # Quantity ID of subject administered Disposition/record of return ID of person dispensing Return of device: Count Reason	 Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯	 No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯
Investigator is responsible to ensure control of investigational device (21 CFR 812.110(c)) Device will be administered only to those subjects enrolled in the clinical study and under investigator or designee's supervision.	Enrollment / randomization log Delegation of responsibility log	Yes ◯ Yes ◯	No ◯ No ◯

DEVICE ACCOUNTABILITY
COMMENTS ON DEVICE ACCOUNTABILITY:

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RECORD RETENTION			
Regulations	**Corresponding Onsite Documents**	**Response**	
Sponsor and Investigator requirement for inspection of investigator's records and reports: Upon request, permit University, FDA officer and/or other governmental officials to access copy and verify any records or reports made by the investigator to ensure that the study is conducted in a safe and proper manner. When contacted by the FDA to schedule an inspection (or the FDA has arrived without advance notice), the PI or a member of the research team is expected to immediately contact the following offices: Office of Regulatory Affairs and IRB of Record. The following offices may also need to be notified at the earliest opportunity: Office of the General Counsel U-M Office of Research MIAP Sponsor (if other than Principal Investigator)	Records on file	Yes ◯	No ◯

RECORD RETENTION
COMMENTS ON RECORD RETENTION: