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 Investigational Device Exemption (IDE) application to the Federal Drug Administration (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 middle 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 their responsibilities. Depending on the specific study, additional documents may be needed. Investigational devices at the University of Michigan may need to 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: Operations Manuel Part 8: Studies Regulated by FDA & Use of Investigational Articles; MIAP IND/IDE Consultation & Development; MICHR Study Monitoring

Note: Any U-M employee serving or seeking to serve as the sponsor or sponsor-investigator of an IND or IDE in conjunction with his or her University appointment must utilize MICHR MIAP services for document preparation assistance, application review, and maintenance of an active IND or IDE. In addition, 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 (UMMS-RegAffairs@med.umich.edu) and IRB of Record.

STUDY INFORMATION	
HUM #	Click or tap here to enter text.
Study Title	Click or tap here to enter text.
PI Name	Click or tap here to enter text.
Date Self-Assessment Completed	Click or tap here to enter text.
Person Completing Self-Assessment	Click or tap here to enter text.

SPONSOR RESPONSIBILITIES				
Requirement	**Corresponding Documents**	**Response**		
TRAINING • Principal Investigator completed the required MIAP IND/IDE Sponsor-Investigator Training	• Documentation of completed MIAP training	☐ Yes Date: Click or tap to enter a date.	☐ No	☐ N/A
CLINICALTRIALS.GOV • Completed registration of the protocol on Clinicaltrials.gov. • Registration date within 21 days of the first subject being enrolled. • The consent form contains the mandatory language regarding registration and results reporting on ClinicalTrials.gov. See IRBMED Standard Informed Consent Template	• Form 3674 (Certificate of Compliance) submitted to FDA • Registration within 21 days of first subject enrollment and assigned NCT # • IRB approved consent form	☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A

SPONSOR RESPONSIBILITIES				
Requirement	**Corresponding Onsite Documents**	**Response**		
MAINTAIN AN EFFECTIVE IDE (consult with MICHR/MIAP for document preparation assistance, application review, and maintenance of an active IDE) 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	Original IDE application FDA letter of approval IDE supplements Investigator agreements Other correspondence with FDA (e.g. response to a clinical hold, general correspondence)	☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A
IDE SAFETY REPORTS (21 CFR 812.46(b)), 812.150(b)) Adverse device effects (written reports, e.g. MedWatch 3500A to FDA, and all participating investigators if applicable within 10 working days) Follow-up information to a safety report (submitted as soon as available)	IDE safety reports Evidence of correspondence to other investigators, if applicable	☐ Yes ☐ Yes	☐ No ☐ No	☐ N/A ☐ N/A
ANNUAL REPORTS (21 CFR 812.150(b)) Before or on the anniversary date that the IDE went into effect	Annual report	☐ Yes	☐ No	☐ N/A

SPONSOR RESPONSIBILITIES				
Requirement	**Corresponding Onsite Documents**	**Response**		
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	☐ N/A
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 (AEs)	☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A

SPONSOR RESPONSIBILITIES				
Requirement	**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	☐ N/A
	Current Investigator CV and license	☐ Yes	☐ No	☐ N/A
	IRB approval letter	☐ Yes	☐ No	☐ N/A
Ship investigational product only to those investigators participating in the trial.	*Multi-site studies (applies to training and shipping investigational product):*			
	Investigator information is required for each site.	☐ Yes	☐ No	☐ N/A
	PI CV is provided to FDA.	☐ Yes	☐ No	☐ N/A
Keep accurate records of financial disclosure according to 21 CFR 54.	Financial disclosure form, such as FDA form 3455 for PI and all Co-Investigators	☐ Yes	☐ No	☐ N/A
Select monitors qualified by training and experience.	*For Monitoring of Study:*			
	MICHR Monitoring Services Other (specify): Click or tap here to enter text.	☐ Yes	☐ No	☐ N/A
	CV and training experience of monitor	☐ Yes	☐ No	☐ N/A
	Ensure monitor is trained on protocol	☐ Yes	☐ No	☐ N/A

SPONSOR RESPONSIBILITIES				
Requirement	**Corresponding Onsite Documents**	**Response**		
ENSURE ONGOING MONITORING (21 CFR 812.46) Monitor the progress of the clinical investigation. Ensure PI compliance or discontinue shipments of investigational device and end the PI's participation in the investigation. Review and evaluate device safety and effectiveness. Discontinue investigation within 5 working days when unreasonable and significant risks to subject are identified.	• *Documentation of data and safety monitoring plan* • *Reports/meeting minutes from DSMB and/or medical monitor* • *Documentation of data monitoring* • *Research team has been trained on data collection sheets and/or case report forms (CRFs)* • *Correspondence with monitor* • *Documentation of monitoring* • *Timely notifications to all investigators, IRB and FDA if investigation discontinued.*	☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A

SPONSOR RESPONSIBILITIES

COMMENTS ON SPONSOR RESPONSIBILITIES:

INVESTIGATOR RESPONSIBILITIES				
Requirement	**Corresponding Onsite Documents**	**Response**		
IRB APPROVAL Ensure IRB review and approval and prompt reporting according to IRB guidelines (21 CFR 812.110, 812.150(a))	• Initial IRB approval	☐ Yes	☐ No	☐ N/A
	• Scheduled continuing review (SCR)	☐ Yes	☐ No	☐ N/A
	• Amendments describing any study changes	☐ Yes	☐ No	☐ N/A
	• Adverse event reports according to IRBMED guidance or study specific plan	☐ Yes	☐ No	☐ N/A
	• Unanticipated problems (UaPs)	☐ Yes	☐ No	☐ N/A
	• Protocol deviations reported to the IRB (ORIOs)	☐ Yes	☐ No	☐ N/A
	• Instructions for use or clinician's manual	☐ Yes	☐ No	☐ N/A
	• Other IRB correspondence	☐ Yes	☐ No	☐ N/A
CASE HISTORIES 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	☐ N/A
	• Supporting data (source documents)	☐ Yes	☐ No	☐ N/A
	• Case report forms (CRFs)	☐ Yes	☐ No	☐ N/A
	• Subject eligibility documentation	☐ Yes	☐ No	☐ N/A
	• Progress notes	☐ Yes	☐ No	☐ N/A
	• Concomitant medications recorded	☐ Yes	☐ No	☐ N/A

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

INVESTIGATOR RESPONSIBILITIES				
Requirement	**Corresponding Onsite Documents**	**Response**		
INFORMED CONSENT • Obtain informed consent in accordance with provisions in 21 CFR 50 • Electronic signatures should be 21 CFR Part 11 compliant	• Approved consent form document that includes all required elements • Documentation of 21 CFR Part 11 compliant option for electronic consent	☐ Yes ☐ Yes	☐ No ☐ No	☐ N/A ☐ N/A
SUPERVISION Supervise the conduct of the clinical investigation (21 CFR 812.100) ensuring: Appropriate delegation of tasks Adequate training to protocol Adequate supervision	• Delegation log • Staff training log • Minutes from research team meetings to review trial progress, AEs, protocol changes • Notes from meetings with study monitor • Written procedures for internal review of data	☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☒ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A
SUBJECT OVERSIGHT Protect the rights, safety and welfare of study subjects (21 CFR 812.100)	• Documentation of adherence to protocol • Documentation of reasonable medical care for AEs • Inform subject when medical care is needed for conditions unrelated to research • Investigator is available to subjects during conduct of study • Appropriate delegation to co-investigators if PI is not available	☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Yes	☐ No ☐ No ☐ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A

INVESTIGATOR RESPONSIBILITIES				
Requirement	**Corresponding Onsite Documents**	**Response**		
REPORTING 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

INVESTIGATOR RESPONSIBILITIES
COMMENTS ON INVESTIGATOR RESPONSIBILITIES:

DEVICE ACCOUNTABILITY				
Requirement	**Corresponding Onsite Documents**	**Response**		
OVERSIGHT 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	☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A

DEVICE ACCOUNTABILITY				
Requirement	**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 ☐ Yes	☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No ☐ No	☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A ☐ N/A
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	☐ N/A ☐ N/A

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

DEVICE ACCOUNTABILITY

COMMENTS ON DEVICE ACCOUNTABILITY: