

E-SUBMISSION GUIDE FOR SUBSEQUENT NOTIFICATION OF DEVICE STUDY

NO	SUBSEQUENT OPTIONS	REQUIREMENTS	SECTION OPEN					
			A	B	C	D	E	F
DEVICE STUDY NOTIFICATION TYPE								
1.	Add Device Quantity	Sec C : Update Date of Device Importation Sec D : Investigational Device Table - Add Quantity Sec E : Update Entry Point Sec F : Attestation & Declaration	X	X	√	√	√	√
2.	Add Study Site and Device	Sec C : Update <ul style="list-style-type: none"> - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - Date of Device Importation - CI/Study site Table Sec E : Update Entry Point Sec F : Attestation & Declaration	X	X	√	√	√	√
3.	Additional Investigator	Sec C : Update <ul style="list-style-type: none"> - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - CI/Study site Table – Coordinating Investigator & EC/IRB Sec F : Attestation & Declaration	X	X	√	√	X	√
4.	Extension of Study Duration	Sec C : Update <ul style="list-style-type: none"> - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - Estimated duration of Clinical Investigation / Study, - Proposed date of Completion of CI / Study - CI/Study site Table Sec F : Attestation & Declaration	X	X	√	√	X	√

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5.	Change Study Site	Sec C : Update - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - CI/Study site Table – Site, Coordinating Investigator & EC/IRB Sec F : Attestation & Declaration	X	X	√	√	X	√
6.	Change EC/IRB	Sec C : Update - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - CI/Study site Table – Coordinating Investigator & EC/IRB Sec F : Attestation & Declaration	X	X	√	√	X	√
7.	Change/ Remove Principal / Co-Investigator	Sec C : Update - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - CI/Study site Table – Coordinating Investigator & EC/IRB Sec F : Attestation & Declaration	X	X	√	√	X	√
8.	Changes on CIP / IB	Sec C : Update - Clinical Investigational Plan (CIP) Documents - Changes Summary in CIP Documents - CI/Study site Table – Coordinating Investigator & EC/IRB Sec D : Update - Investigator's Brochure (IB) - Changes Summary in IB Sec F : Attestation & Declaration	X	X	√	√	X	√
9.	Submission of Progress Report	Sec C : Update Progress Report Sec F : Attestation & Declaration	X	X	√	X	X	√

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			A	B	C	D	E	F
10.	Completion / Termination of Study	Sec C : Update Progress Report Sec F : Attestation & Declaration	X	X	√	X	X	√