Froedtert ThedaCare

Office of Clinical Research & Innovative Care Compliance (OCRICC)
Checklist for Investigational Device Ordering and Billing Considerations

- **The purpose of this checklist is to ensure all necessary steps for compliant billing and ordering of an investigational device have been considered and agreed upon prior to final FT OCRICC Administrative Approval Letter being sent.**
- **It is to be used to facilitate collaboration between MCW (Research Team, Grants & Contracts and FT (Department-specific Inventory Specialists/Implant Coordinators/Billing Specialists/Managers/Supervisors/Service Line Coordinators/Medical Assistants, Supply Chain Contracting and OCRICC Nurse Consultants and Billing Specialists).**

PRIOR TO OCRICC ADMINISTRATIVE APPROVAL		
Investigational Device Type and Provisioning		
Responsible Party	**Task**	**Key Detail**
MCW Research Team + Sponsor	Determine IDE Type and Provisioning	☐ IDE Category A - Must be provided for free by Sponsor ☐ IDE Category B o Provided for free by Sponsor o Provided by Sponsor with intent to have FH bill patient/insurance
Purchase / Supplier Agreement		
Responsible Party	**Task**	**Key Detail**
MCW Research Team + Sponsor + MCW Grants and Contracts + FT OCRICC	Initiate CTA	☐ MCW Research Team works with Sponsor, MCW Grants and Contracts (G&C) and IRB to create/submit. o Submit Draft CTA via Funding Proposal (FP) in eBridge. ☐ Send Draft CTA to FT OCRICC.
FT OCRICC + FT Supply Chain Contracting	Initiate Review of CTA (ONLY if billing a Category B IDE)	☐ Send CTA to FT Supply Chain Contracting.
FT Supply Chain Contracting + FT Office of General Counsel	Review and Align Contract Terms and Initiate Purchase/Supplier Agreement (ONLY if billing a Category B IDE)	☐ Review CTA for alignment with FT Standard Terms and Conditions (STCs) and other requirements for FT purchase orders. o For a **commercially** available device being studied as an IDE, there won't be a separate Purchase/Supplier Agreement, FT will follow the Terms we have already established with the vendor. o For a **non-commercially** available IDE, F&MCW preference is to have the Purchase/Supplier Agreement be a separate document from the main CTA. If Sponsor presses, F&MCW can accept a Purchasing Addendum to the CTA. ☐ Send Purchase/Supplier Agreement to FT Office of General Counsel o Push through normal process, flagged as a research IDE agreement within tool o Email MCW Grants and Contracts alerting them of a submission of a research IDE agreement that needs to be expedited.
FT Office of General Counsel + MCW Grants and Contracts + FT Supply Chain Contracting	Resolve Non-Standard Terms (ONLY if billing a Category B IDE)	☐ Works with FT Supply Chain Contracting and MCW Grants and Contracts to resolve terms not aligned with FT STCs and other requirements for FT purchase orders.

Office of Clinical Research & Innovative Care Compliance (OCRICC)
Checklist for Investigational Device Ordering and Billing Considerations

FT Office of General Counsel	Approves Purchase/Supplier Agreement Language (ONLY if billing a Category B IDE)	☐ Notifies FT Supply Chain Contracting of approval.
FT Supply Chain Contracting + MCW Grants and Contracts	Submits Purchase/Supplier Agreement to MCW Grants and Contracts	☐ Sends Purchase/Supplier Agreement to MCW Grants and Contracts.
MCW Grants and Contracts + MCW Research Team + Sponsor	Finalizes Purchase/Supplier Agreement as a separate document or with a Purchasing Addendum to the CTA (ONLY if billing a Category B IDE)	☐ Works with MCW Research Team and Sponsor to finalize CTA.
MCW Research Team	Complete CTA	☐ Submits Final CTA that includes device Purchase/Supplier Agreement or Purchasing Addendum to the CTA via Funding Proposal (FP) in eBridge.
Steps Needed to Support Billing		
Responsible Party	**Task**	**Key Detail**
FT OCRICC	Initiate Device Charge Request	☐ Sends Research-Only ADR Request Email to FT Department Leaders where the device will be utilized: o FT Implant Coordinator (for OR/MPA/Hybrid) o FT Billing Specialist (for Cath Lab and IR) o FT Manager, FT Supervisor, FT Service Line Coordinator, and FT Medical Assistant (for GI Advanced Procedures and URO/CYSTO Procedures)
FT Department Leader	Create Device Charge	☐ Sends device charge request to ADR Submission shared box and sends to FT OCRICC when final
FT OCRICC	Initiate Infor Number Request (ONLY if billing a Category B IDE)	☐ Sends Research-Only PO Email to FT Supply Chain/Purchasing and FT Department Leaders: o FT Inventory Specialists (for OR/MPA/Hybrid and Cath Lab) o FT Billing Specialist and FT IR Supervisor (for IR) o FT Manager, FT Supervisor, FT Service Line Coordinator, and FT Medical Assistant (for GI Advanced Procedures and URO Procedures/CYSTO)
FT Supply Chain Contracting	Create Infor Numbers (ONLY if billing a Category B IDE)	☐ Based on MCW Purchase Agreement/ Supplier Agreement pricing
FT OCRICC + FT EPIC Orders	Create Procedure Charge (if needed)	☐ Only if device procedure is not like anything we do clinically today. OCRICC works with appropriate FT EPIC Orders team based on procedure location

Froedtert ThedaCare

Office of Clinical Research & Innovative Care Compliance (OCRICC)
Checklist for Investigational Device Ordering and Billing Considerations

AFTER OCRICC ADMINISTRATIVE APPROVAL IS GIVEN TO RESEARCH TEAM		
Device Chain of Custody (when not billing patient/insurance for a negotiated cost, i.e. provided free by Sponsor)		
Responsible Party	**Task**	**Key Detail**
MCW Research Team + Sponsor	Order, Receive, Store and Return of Device	☐ Responsibility remains with MCW Research Team o Ordering: Devices are to be ordered as outline in the study protocol (I.E. automatically shipped by Study Sponsor, via EDC data entry, etc.) o Receiving: Devices will be delivered to designated MCW Research Staff desk location. o Storing: Devices will be stored at MCW in the locked research closet. o Returning: Devices will be returned as outlined in the study protocol by MCW Research Staff
MCW Research Team	Deliver Device to Location of Use	☐ MCW Research Team coordinates with FT Department Leaders: o FT Inventory Specialists (for OR/MPA/Hybrid and Cath Lab) o FT Billing Specialist and FT IR Supervisor (for IR) o FT Manager, FT Supervisor, FT Service Line Coordinator, and FT Medical Assistant (for GI Advanced Procedures and URO Procedures/CYSTO)
Device Chain of Custody (when billing a Category B IDE patient/insurance)		
Responsible Party	**Task**	**Key Detail**
MCW Research Team	Order - Initiate Device Order Request	☐ Follow FT Standard Terms and Conditions (STCs) required for FT purchase orders as outline in fully executed CTA, Purchase/Supplier Agreement and/or Addendum to the CTA. ☐ Communicate details (quantity, sizes, timing, etc.) of devices to be ordered by FT Department Leaders: o FT Inventory Specialist (for OR/MPA/Hybrid, Cath Lab) o FT Billing Specialist and FT IR Supervisor (for IR) o FT Manager, FT Supervisor, FT Service Line Coordinator, and FT Medical Assistant (for GI Advanced Procedures and URO Procedures/CYSTO)
FT Department Leader	Order - Initiate PO Process	☐ Enter a PO/No Charge PO Requisition for FT Supply Chain Purchasing including ship to address: *Froedtert Memorial Lutheran Hospital, Dock A,* *9200 West Wisconsin Avenue* *Milwaukee, WI 53226* ☐ Enter Sponsor Rep into Trackcore (only for OR)
FT Supply Chain Purchasing	Order - Create and Send PO to Sponsor	☐ Includes address where to ship devices (same as listed in above section) with FT Standard Terms and Conditions
FT Receiving	Receive - Receive and Deliver to FT Department Leader who Placed Order	☐ Receives items into system ☐ Delivers to the appropriate FT Department location: o IPP Breakdown Room (for OR/MPA/Hybrid, Cath Lab, and IR) o Lower Level of Specialty Clinics – GI/Uro Procedure Platform (for GI Advanced Procedures and URO/CYSTO Procedures)

Office of Clinical Research & Innovative Care Compliance (OCRICC)
Checklist for Investigational Device Ordering and Billing Considerations

FT Department Leader	Storage - Transfer Custody to MCW	☐ Engages MCW Research Team to review what was received ☐ Transfers custody to the MCW Research Team for storage (ONLY exceptions to this are for early morning cases or in urgent situations where device may require being on hand more than 24 hours prior to a case- this exception will be discussed at the Operational Planning meeting)
MCW Research Team + Sponsor	Payment (when initially brought in via No Charge PO)	☐ After the case, the Sponsor rep will process their request for a Bill Only PO through the Supplier or through the Trackcore automated system (only for OR)
MCW Research Team + Sponsor	Replenish Stock	☐ Engages FT department leader to replenishment items in the same way they were originally purchased
FT Department Leader	Return – Unused Device	☐ All devices ordered by a specific FT Department will be returned to that department by the MCW Research Team for return