Mapping of the MCW Basic Study Binder Footprint

The Footprint was developed with guidance & input of the MCW Super Admin Team.
Requests for modification can be submitted to Florence@mcw.edu but impact to all enterprise researchers will be weighed. Any change to template will require a configuration change to the MCW Florence Production platform.

1.0 Study Subject Information		**Comments in red are informational**
1.1 Individual Subject Folders		Add template for individual participant folders
1.2 Logs		All sponsor logs can be edited to be an e-signable document
	1. Study Visit Log	
	2. Enrollment Log	
	3. Screening Log	
	4. Subject ID Code List	
	5. Master Subject Log	
1.3 Equipment Assigned to Subject		
1.4 Decoding Procedures		
1.5 Example Blank Source Worksheets		
2.0 IRB and Safety Committee Reviews		
2.1 Initial IRB Protocol		
	*1. IRB Approval	Final IRB Approval Letter
	2. IRB Modification Requests	
	*3. Final Smartform	Final IRB Approved Smartform
	4. Informed Consent or Assent	
		1. Final Consent Version
		2. Drafts or Working Versions for Submission
	*5. ICH E6 Worksheet	
		That correspondence which was done outside of eBridge, i.e. emails or phone conversations
	6. IRB Correspondence	
	7. IRB Roster at date of Initial and Final Review	Can be copy of document or short-cut
	8. Notification of Approval	
		*1. OCRICC
		2. Other Affiliate

		3. Sponsor
	9. Affiliate Correspondence	Affiliate would be OCRICC, IDS, WDL, etc.
	10. Sponsor Correspondence	Regarding this submission
2.2 Protocol Amendments		Add template for each amendment
2.3 Continuing Progress Reports		Add template for each CPR
2.4 Reportable Events		Add template for each RE
2.5 MCW QA-QI Reviews and Audits		
	1. Notice of Review or Audit	Email received indicating review would be conducted
	2. Summary of Findings	Email received indicating review findings
	3. Corrective Action Plan	
	4. Correspondence	
2.6 Safety Committee Submissions		Copies of application packet documents for any of the subcommittee's
2.7 Study Closure Notifications		
	1. IRB	
	2. Safety Committee's	
3.0 External Monitoring and Auditing		
3.1 Site Initiation Visit		
	1. SIV Confirmation Letter	
	2. SIV Follow-up Report	
	3. SIV Correspondence	
3.2 Interim Monitoring Visits		
	1. IMV Confirmation Letter	
	2. IMV Follow-up Report	
	3. IMV Correspondence	
3.3 Closeout		
	1. Confirmation Letter	
	2. Follow-up Report	
	3. Correspondence	
3.4 Monitor Visit Log		MCW Template document forthcoming, may upload sponsor document as editable PDF and e-sign
3.5 Sponsor Auditor Visits		
	1. Compliance Notification Letter	
	2. Follow-up Report	
	3. Correspondence	

		The following are all required components of documentation of a regulatory audit
3.6 Regulatory Auditor Visits		
	1. Regulatory Audits Notice of Inspection	
	2. Copy of All Documentation Provided to Auditor	
	3. Inspection Report	
	4. Site Response to Inspection Report	
	5. Correspondence	
4.0 Sponsor Documents		
4.1 Protocols		
	1. Sponsor Protocol	
	2. Redline Version	
	3. Signature Page	
4.2 Investigator Brochure		
	1. Investigator Brochure	
	2. Acknowledgement Receipt	
	3. Redline Version	
4.3 Informed Consent or Assent		
	1. IRB Approved Consent(s) or Assent(s)	
	2. Consent Translations with Translation Certificate	
		Participants will not be provided access to complete questionnaires in Florence eBinders
4.4 Subject Facing Materials		
	1. Questionnaires	
		Copyright Certificates
	2. Instructional Materials	
	3. Diaries	
	4. Advertisements	
4.5 Safety Reports		
	1. Data Safety Monitor Board Charter	
	2. DSMB Reports	
	3. External Safety Reports	Cover Letter template found in MCW Template Binder
		1. Safety Report Log

		2. Safety Reports
	4. Notification to Investigators of Safety Information	These are not External Safety Reports
4.6 Sample Case Report Forms		
4.7 Operations Manuals		
	1. Interactive Response Technology (IVRS, IWRS)	
	2. Data Management Systems	
	3. Central Laboratory Documents	
	4. Core Lab Documents	
	5. Study Shipping and Supply Accountability	
4.8 MCW Equipment Maintenance Records		
	1. Biomedical Evaluation of Sponsor Provided Equipment	
	2. Calibration Records	
	3. Temperature Log Maintenance	
4.9 Local Laboratory Documents		
	1. Lab Manual	
	2. Lab Normal Reference	
	3. Lab Sample Storage Condition Log	
	4. Retained Samples Log	
	5. Lab Shipment Records	
	6. CLIA	See Central Resources Binder
	7. CAP	See Central Resources Binder
4.10 Pharmacy		
	1. Pharmacy Manual	Provide access to IDS so they have access to this & other study materials
	2. Closeout Documents	
5.0 Communications		
5.1 Site Generated		
	Team Correspondence	
5.2 Sponsor Generated		
	1. Investigator or Study Newsletters	
	2. Clinical Study Report	

- 6.0 General Regulatory and Personnel Management
  - 6.1 Contacts
    - 1. Site Contact Details
    - 2. Sponsor Contact Details
  - 6.2 Regulatory Documents
    - 1. Delegation of Authority Log
    - 2. Site Signature Log — This only includes signatures, not roles.
    - 3. FDA 1572
    - 4. Fully Executed Investigator Agreement — This is not Confidentiality Agreements (7.1.2 for CDA's)
    - 5. Fully Executed Sub-Investigator Agreements
    - 6. Investigator Regulatory Agreement
    - 7. Financial Disclosure Forms
  - 6.3 Notes to File
    - 1. Sponsor Memos to File
    - 2. Site Notes to File
  - 6.4 Staff Qualifications & Training — Create Folder for each team member
    - 1. Study Related Training
    - 2. Affiliate Staff Training
    - 3. PI Credentialing
    - 4. Sub-Investigator Credentialing
    - 5. Study Staff Credentialing
- 7.0 Feasibility and Qualification
  - 7.1 Interest and Feasibility
    - 1. Site Interest Notification
    - 2. Disclosure Agreements
      - 1. Fully Executed Confidentiality or Non-Disclosure Agreement
      - 2. Draft(s) Confidentiality or Non-Disclosure Agreement(s)
    - 3. Feasibility Questionnaire and Supportive Documents
    - 4. MCW Research Standard Operation Procedures and Processes
    - 5. Facility Standards (EPIC, Part 11 Compliance, etc.)
  - 7.2 Qualification Notification

7.3 Initiation Planning for Project		
8.0 Contracts and Financials		Financials folder access only granted to Investigator & Coordinator roles.
8.1 Investigator Agreements		
	1. Clinical Trial Agreements	
		1. Fully Executed Clinical Trial Agreement(s) 2. Draft(s) Clinical Trial Agreement(s)
	2. Insurance Documentation	
	3. Data Privacy Use Agreement	
	4. Vendor & Site Communications	
8.2 Third Party Contracts (External)		
	1. Vendor Contracts	
	2. Communications	
8.3 Pricing - Budgeting Components (Internal)		
	1. OCRICC	
	2. MCW CPS	
	3. Radiology	
	4. Wisconsin Diagnostic Laboratories	
	5. Opthalmology	
	6. CTSI	
	7. MCW ATRU	
	8. MCW External Departments	
	9. Investigational Drug Service	
	10. Cell Therapy Lab	
8.4 Coverage Analysis		
	1. OCRICC	
	2. Guidestar	
	3. MCW CPS	
8.5 Medicare Submission		
8.6 Financial Documentation		
	1. Clinical Trial Budget or Grant	
		1. Final Budget or Grant
		2. Drafts Budget(s) or Grant(s)
	2. Justifications used for Budget Negotiation	
	3. Subject Reimbursement Tracking	

	4. Sponsored Programs Notification of Account Activation 5. Billing (Invoices) 6. Credits (Checks)
8.7 Internal Closeout Procedures	
	1. Internal and Affiliate Partner Notifications 2. Account Reconciliation and Closure 3. GCO Closure Notification