Guidance Tool
Preparing for Research at Children's Wisconsin
Pre-Submission Checklist

PURPOSE	
This is a tool for investigators that includes considerations and steps to take when assessing feasibility prior to submitting the proposed research. Use of this tool will help to ensure an efficient and timely Local Context and IRB review process. This tool should not be included with the submission for IRB approval. Contact the CW HRPP at any time with questions: cwhrpp@childrenswi.org.	
☐	Determine the project type (this impacts the review process and submission requirements) ➢ Is the project human subjects research? If yes, continue with this checklist. o Projects that are not research or human subjects research do not require a submission IRB oversight. o If you are unsure whether your project is human subjects research, or whether it is something else such as a case/study case/report, or a quality improvement activity, please review this guidance. If you need a formal, written determination the guidance has a link to the request form.
Some access mechanisms involving FDA regulated products are not research but do require IRB oversight (these are special categories of treatment use) ➢ Treatment use of an investigational agent (drug, biologic or medical device) ➢ Humanitarian Use Devices	
☐	If the project is human subjects research, determine whether Children's Wisconsin is engaged in the research.
☐	If Children's Wisconsin is considered engaged in the research, review the following materials to determine if applicable to the project. ➢ Multi-site research o This guidance contains important information, considerations, and submission instructions when the research will be conducted at more than one site. o NOTE: Children's is a separate location (institution) from Froedtert Hospital/Versiti/ MCW. ➢ FDA regulated research (CW HRPP SOP Manual Section 16)
☐	If this project is a clinical trial, particularly one that is investigator initiated, a feasibility assessment is **critical** and should be done early. We have resources to help with feasibility. Feasibility can be assessed by using one of these tools: ➢ Clinical Trial Feasibility Checklist ➢ Protocol Feasibility Checklist Contact the CW HRRP and we can provide guidance and engage other appropriate resources such as the Clinical Trials Operations Director (Theresa Kump) and CW Corporate Compliance (Maria Vallejo).

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☐	➢ Determine whether the Principal Investigator meets CW qualifications to be the PI; review PI responsibilities (CW HRPP SOP Manual Section 23) and FDA Investigator Responsibilities. For investigators who are not CW providers, review multi-site research for additional considerations.
ADDRESS CONSIDERATIONS FOR SPONSORED RESEARCH	
☐	If required, ensure study team is knowledgeable and has a plan to maintain compliance with ICH GCP E6(R3). To determine if required: • Review sponsor contract and protocol • Consult with CW HRPP
☐	Determine who will serve as IRB of record • If CW designated MCW pediatric IRBs, no reliance request is needed • If an external IRB is being requested or is required, a reliance agreement/deferral needed
☐	Determine whether all proposed study team members have current required training in place
☐	Assess any conflicts of interest of the PI and all study team members, disclose as needed • CW COI Supplemental Disclosure
Assess whether any CW departments, clinics, or hospital space will be needed to conduct the research and obtain appropriate departmental sign offs. ***This sign off process should be completed, and all approvals obtained prior to submitting the project in eBridge. A copy of required approvals should be included with the submission in section 52. Failure to do so will cause delays in the review process.*** Link to the CW Research Resources Request REDCap Form	
☐	The following departments utilize the online REDCap CW Research Resources Request Form (link above). The request only needs to be filled out once even if services of more than one department are needed. The form will be auto routed to the appropriate areas for review and approval. • **Cardiology/HHI** • **Imaging** • **Neurology/Neuropsych** • **NICU** • **pTRU** • **PICU** • **PT/OT** • **Primary Care** • **Pulmonary Function Laboratory**

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	For questions about the CW Research Resources Request REDCap form or process, contact Theresa Kump at TKump@childrenswi.org. If services from any other CW department not listed above are needed, submit the form included in the CW HRPP guidance Departmental Sign-Off for Research. Essential contacts for CW departments is available here. This document is on the Children's Connect intranet. If you have trouble accessing the listing, please contact the CW HRPP office.
☐	Address funding requirements A Billing Plan should be completed and submitted to CW Research Compliance well prior to IRB submission. Contact Maria Vallejo, Research Compliance Program Manager, CW Corporate Compliance and Theresa Kump, Clinical Research Operations Director, Research Administration, for assistance preparing a billing plan.
☐	Obtain required sign off and approvals if imaging with radiation is part of the study procedures • Radiation and Imaging in Research at CW Flowchart • Complete the resource request linked previously above • It is very important to determine early what imaging is considered standard of care versus research only. Any imaging done solely for research purposes or additional images for research purposes requires CW Radiation Safety Research Subcommittee review and sign off. Theresa Kump, Clinical Research Operations Director, can assist with this. • Submit Appendix M variance to the state if needed (submit the study once this approval is in hand and can be included with the submission)
☐	Create plans for obtaining assent/parental permission, consent at Age of Majority and draft documents utilizing the appropriate templates: • Assent of Minors • Consent/Parental Permission/Assent of Subjects with Limited English Proficiency • Parental Permission/Consent (see CW HRPP SOP Manual section 15.6.2) • Consent at the Age of Majority • When the parent of a subject is a minor (see CW HRPP SOP Manual section 15.1); consult with CW HRPP if this is anticipated as legal input may be needed
☐	If this is sponsored research, have consents reviewed by sponsor prior to submission • Any changes to black template language **must** be approved by the CW HRPP and the MCW HRPP (if MCW is serving as the IRB of record). Submit a template change request.
☐	Create plan for Recruitment and Enrollment.
☐	Determine how data will be stored and used and address compliance with CW policies (describe in application). • CW Research – Record Retention Policy for Human Subjects • Request to Access PHI for Prep to Research • Data Analytics and Tools

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	Acceptable Storage for CW data (PHI): • CW or MCW shared drives (intranet) • CW Box • REDCap • Florence eBinders - OnCore • Encrypted laptop • Encrypted flash drive PHI cannot be stored in cloud services. Potentially coded or de-identified data could be stored in a cloud service. CW Corporate Compliance reviews data storage plans for new submissions. Reach out to CW Corporate Compliance for questions or if the plan includes a platform that is not on this list.
☐	Assess patient/subject privacy and data confidentiality considerations and create plan for compliance with CW policies (describe in application) (see CW HRPP Manual section 27)
☐	Assess HIPAA considerations and create plan for compliance with CW policies (describe in application) (see CW HRPP Manual section 27)
IMPORTANT ADDITIONAL CONSIDERATIONS FOR INVESTIGATOR-INITIATED RESEARCH	
☐	A clear and well-written protocol is critical (scroll down on this Investigator Resources page for templates examples for different types of studies)
☐	For studies involving the investigational use of an FDA-regulated drug or biologic, assess whether an IND is needed and work with the FDA to obtain. Review FDA guidance for more information: ➢ Investigational New Drug Applications (INDs) for CBER-Regulated Products ➢ Determining Whether Human Research Studies Can Be Conducted Without an IND ➢ IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer Contact Kristin Busse at the Early-Stage Research Regulatory Oversight Program for assistance.
☐	For studies involving the investigational use of an FDA-regulated device, assess whether an IDE is needed or if an investigational device exemption applies. Review FDA guidance for more information: ➢ Investigational Device Exemption (IDE) ➢ Device Software Functions Including Mobile Medical Applications ➢ Significant Risk and Nonsignificant Risk Medical Device Studies

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	Contact Kristin Busse at the Early-Stage Research Regulatory Oversight Program for assistance.
☐	For Investigator Initiated Trials (IIT), ensure the PI understands the responsibilities of both the investigator AND the sponsor (PI will be both). Some helpful resources: ➢ FDA Guidance Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects ➢ Overview of Sponsor-Investigator Roles and Responsibilities in Clinical Investigations for Drugs and Biologics Orphan Products Grantees ➢ When an Investigator is also a Sponsor ➢ Beginner's Guide to Investigator-Initiated Trials
☐	If the research involves more than minimal risk, determine a safety monitoring plan and the need to establish a formal DSMB/DMC.
☐	Obtain scientific review of the research protocol.
☐	For studies that meet the definition of a Clinical Trial, ➢ Register Clinical trials.gov listing ➢ Training Protocol Registration and Results Reports System (PRS) • **If MCW Faculty or Staff is the PI** – reach out Jen Brown jlbrown@mcw.edu in the MCW Office of Research for assistance in listing a study • **If a CW Employee is the PI** – reach out to the CW HRPP office for assistance in listing the study