For assistance/education with using IRBNet – the Children's Wisconsin (CW) Institutional Review Board (IRB) Electronic Submission System – contact the IRB Office at 414-337-7133 or CWIRB@chw.org;

For assistance with whether a Reliance Agreement is needed/already in place, email CWIRBReliance@chw.org.

ALL submissions must be signed by the Principal Investigator (PI).

1. Sign the package in IRBNet; OR
2. Upload a memo signed by the PI indicating the PI has reviewed the submission (include package number); OR
3. Upload an email from the PI indicating they have reviewed the submission (include package number)

The CW Registration Page is an online form that is completed within IRBNet and is required to be kept current. All other forms can be found in IRBNet under "Forms and Templates" or on the Children's Wisconsin Human Research Protection Program (HRPP) webpages.

These checklists are designed to cover various research scenarios for different submission types. Not all documents listed will be applicable to a particular study. In general, a complete set of all study-related documents should be submitted with the initial package for a new project and at the time of continuing review. Documents needed for other submissions are based on submission type (specific forms) and whether they have been revised for the submission.

These checklists are a tool for investigators to help ensure a complete submission – they should NOT be uploaded with the submission.

- This covers studies for which a reliance agreement is in place as well those without a reliance. **Checklists for studies utilizing a reliance agreement begin on page 9.** The CW IRB expects to see certain documents even when we have ceded oversight to another IRB. This is how we know what is in our portfolio and is what we reference if there are any problems or concerns with the research.
- For special submissions, such as Humanitarian Use Devices (HUDs) or expanded access mechanisms, refer to the checklists/guidance specific to those submissions or call the Children's Wisconsin HRPP for guidance.

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General Tips:

- Review all documents for consistency between documents (be sure all are saying the same thing).
- Review all documents for completeness (all questions answers, all sections completed).
- Using lay terms, describe proposal, consent process (including age of majority if applicable), modifications, reportable events, etc. in as much detail as possible for the reviewers so they have an accurate understanding of the information.
- Any revised documents submitted require only the tracked changes version (contact the IRB Office for help with using Microsoft Word track changes function, if needed).
- Ensure all individuals who are conducting research are listed as part of the study team and have current, appropriate CITI Program Training before submitting.
- **NOTE:** If the submission is incomplete in terms of required documents the package will be withdrawn and require resubmission. The resubmission will be queued as it comes in, it will not be placed in its previous position in the queue. Any concerns regarding this can be directed to the Research Integrity Manager.

(Checklists begin on the following page)

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New Projects: Initial Submission
(Interventional)

☐	CW Protocol Summary Form
☐	CW Registration Form (online document within IRBNet)
☐	Cover Memo^
	Include when there are special instructions for the IRB staff. For example: • Specific language that must be in the approval letter, as when sponsors require this • If any items, other than the consent documents, need an IRB approval stamp (e.g. recruitment materials, patient information sheets, etc.) • Status of FDA approval (if applicable) Any other specifics the investigators would like to highlight for the IRB
☐	For Nursing research, see the Nursing Research Review Process page on Children's Connect. Include the following with your submission: ☐ Nursing Research Milestone Checklist
☐	Sponsor's Study Documents^ (Protocol, Model Consents, Patient Information Sheets, Patient Diaries, Advertisements, etc.)
☐	Certification for Use of PHI of Decedents^
☐	Informed Consent /Assent Documents^ (If you are changing any of the black required language in the template, a petition to change consent form required language must be submitted first. This is in IRBNet and linked on the "Forms" page of the HRPP webpages.)
☐	HIPAA Authorizations^
☐	HIPAA Waiver – Partial for Screening
☐	HIPAA Waiver^
☐	Request for Alteration or Waiver of Assent, Consent, or Parental Permission^
☐	Subject Survey, Questionnaire, etc.^
☐	Recruitment Materials (ads, flyers, brochures, website copy, etc.)^
☐	Written materials to be seen by subjects (information or education documents, wallet/ID cards, etc.)^
☐	Ancillary Letters of Approval (Departmental, Human Resources, Safety Committee Approvals, etc.)^
☐	Data Collection Tools/Documents^
☐	Investigator Brochure^
☐	For Investigator-initiated FDA-regulated Studies, Copy of FDA Submission/Communication^
☐	Investigator Reliance Request Form *(if other sites are involved)*^
☐	DMC Charter (draft charters will not be approved)^
☐	For FDA-regulated Device Studies with IDE: Copy of FDA IDE Letter^
☐	For FDA-regulated IND Studies, Correspondence From Sponsor regarding applicable IND if the IND Number is not printed on the Protocol^

(Checklists continue on the following page)

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Modifications to Approved Projects: Change in Study Staff

If this is a change in investigator(s), confirm all documents on which the PI name appears are updated. To limit the number of documents needing update when the study team changes, any documents, including the HIPAA waiver form, that contain study team names (other than the PI) should be updated to remove this when updating study staff. The partial HIPAA waiver for screening can instead state "study team members listed on the registration page" rather than listing them by name.

☐	Amendment Form
☐	CW Registration Form (online document within IRBNet)
☐	CW Protocol Summary Form*^
☐	HIPAA Waiver*
☐	Acceptance of PI Responsibility Memo^
☐	Consent/Assent Documents* (If you are changing any of the black required language in the template, a petition to change consent form required language must be submitted first. This is in IRBNet and linked on the "Forms" page of the HRPP webpages.)
☐	HIPAA Authorization*^
☐	Certification for Use of PHI of Decedents*^

(Checklists continue on the following page)

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New Projects: Initial Submission
(Retrospective Chart Review)

☐	Chart/Data Review Form
☐	CW Registration Form* (online document within IRBNet)
☐	For Nursing research, see the Nursing Research Review Process Page on Children's Connect. Include the following with your submission: ☐ Nursing Research Milestone Checklist
☐	Certification for Use of PHI of Decedents
☐	HIPAA Waiver – Partial for Screening
☐	HIPAA Waiver^
☐	Request for Alteration or Waiver of Assent, Consent, or Parental Permission^
☐	Data Collection Tools/Documents
☐	Informed Consent /Assent Documents^ (If you are changing any of the black required language in the template, a petition to change consent form required language must be submitted first. This is in IRBNet and linked on the "Forms" page of the HRPP webpages.)
	If other organizations or an external sponsor are involved, the following is also needed:
☐	Sponsor's Protocol^
☐	Sponsor Consent/Assent Templates^
☐	Investigator Reliance Request Form (if other sites are involved)^

(Checklists continue on the following page)

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Modifications to Approved Projects

☐	Amendment Form
☐	CW Registration Form* (online document within IRBNet)
☐	Sponsor's Study Documents*^ (Protocol, Model Consents, Patient Information Sheets, Patient Diaries, Advertisements, etc.)
☐	CW Protocol Summary Form*
☐	Informed Consent /Assent Documents*^ (If you are changing any of the black required language in the template, a petition to change consent form required language must be submitted first. This is in IRBNet and linked on the "Forms" page of the HRPP webpages.)
☐	HIPAA Authorizations*^
☐	HIPAA Waiver – Partial for Screening*^
☐	HIPAA Waiver*^
☐	Request for Alteration or Waiver of Assent, Consent, or Parental Permission*^
☐	Subject Survey, Questionnaire, etc.*^
☐	Recruitment Materials (ads, flyers, brochures, website copy, etc.)*^
☐	Materials to be seen by subjects (information or education documents, wallet/ID cards, etc.)*^
☐	Ancillary Letters of Approval (Departmental, Human resources, Safety Committee Approvals, etc.)*^ *(Safety Committee approvals may have an expiration date and need renewals which should be submitted)*
☐	Data Collection Tools/Documents*^
☐	Copy of FDA Submission and Communication*^
☐	Tracked Changes or Redlined Versions of Sponsor Assents, Consents, Protocol^
☐	Investigator Reliance Request Form *(if other sites are involved)*^
☐	Informed Consent/Assent Documents in Other Languages^
☐	Certificate of Translation^ *(from translation company)*

NOTE: Investigator Brochures should be submitted separately as a Reportable Event/New Information. The IRB does not approve IBs, but acknowledges them, therefore they should not be part of a submission that will have an approval determination. They serve as information in the review of a submission.

(Checklists continue on the following page)

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Continuing Review/Progress Reports

Submission should include the most current versions of all documents **still applicable** to the project.

☐	Continuing Review Form
☐	CW Registration Form (online document within IRBNet)
☐	Sponsor's Protocol^
☐	CW Protocol Summary Form OR Chart/Data Review Form
☐	Informed Consent/Assent Documents^ (If you are changing any of the black required language in the template, a petition to change consent form required language must be submitted first. This is in IRBNet and linked on the "Forms" page of the HRPP webpages.)
☐	HIPAA Authorizations^
☐	Certification for Use of PHI of Decedents^
☐	HIPAA Waiver – Partial for Screening
☐	HIPAA Waiver^
☐	Request for Alteration or Waiver of Assent, Consent, or Parental Permission^
☐	Subject Survey, Questionnaire, etc.^
☐	Recruitment Materials (ads, flyers, brochures, website copy, etc.)^
☐	Materials to be seen by subjects (information or education documents, wallet/ID cards, etc.)^
☐	Ancillary Letters of Approval (Departmental, Human resources, Safety Committee approvals, etc.)^ *(Safety Committee approvals may have an expiration date and need renewals which should be submitted)*
☐	Data Collection Tools/Documents^
☐	Investigator Brochure^
☐	Copy of FDA Submission and Communication^
☐	Reportable Event Log summarizing events that were not Immediately Reportable^
☐	DSMC Reports^
☐	Interim Analysis or Other Study Progress Reports^
☐	Publications Related to the Study^
☐	Monitoring Reports^
☐	Informed Consent/Assent Documents in Other Languages^ *(if previously approved for use)*

(Checklists continue on the following page)

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Reportable Events/New Information

☐	Reportable Event/New Information Form If the report involves adverse events reported by a sponsor, the Reportable Event Form should contain a SUMMARY of the information – please do not cut and paste the entire description from the Medwatch, Susar, or other forms into the Reportable Event Form. When the report involves a deviation or non-compliance, the CAPA section must be completed and sufficiently describe both what is being done to correct the non-compliance/deviation as well as the plan to prevent the same problem from occurring in the future. The IRB also expects to see an analysis of the root cause of the problem as part of this report. Examples: http://www.feinsteininstitute.org/wp-content/uploads/2013/02/PREP-29-CAPA-Template.pdf https://ictr.wisc.edu/documents/corrective-action-and-preventive-action-capa-plan-template/ https://wwwapp1.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=349#four
☐	Any Supporting Documentation (Sponsor Safety Letters, New Investigator Brochures, Monitor Reports, Medwatch Report, Sponsor Memos, Interim DSMC Reports, etc.)

(Checklists continue on the following page)

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THIS BEGINS THE SECTION OF CHECKLISTS SPECIFIC TO STUDIES FOR WHICH IRB OVERSIGHT HAS BEEN CEDED TO ANOTHER IRB

New Reliance Projects: Initial Submission
(Shadow Submission)

☐	CW Registration Form (with Investigators Practicing within CW Spaces)
☐	Reliance Agreement (OR Cover Letter Explaining if a Master Reliance Agreement is in Place)
☐	Approval Letter from Reviewing IRB for CW to Participate
☐	The Most Current, Approved Protocol
☐	Certification for Use of PHI of Decedents^
☐	Recruitment Materials Approved by the Reviewing IRB^ (ads, flyers, brochures, website copy, etc.)
☐	Materials to be Seen by Subjects (Patient Information Sheets, Patient Diaries, etc.)^
☐	Ancillary Letters of Approval (Departmental, Human Resources, Safety Committee Approvals, etc.) Where Any Study Activities Occur^
☐	Documentation of Any Conflicts of Interest Disclosures^
☐	Informed Consent and Assent Documents Approved by the Reviewing IRB^
☐	HIPAA Authorizations^
☐	HIPAA Waiver – Partial for Screening^
☐	HIPAA Waiver^

(Checklists continue on the following page)

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Modifications to Approved Projects: Change in Study Staff
Reliance Projects

If this is a change in Principal Investigator(s), confirm all documents on which the PI name appears are updated.

To limit the number of documents needing update when the study team changes, any documents, including the HIPAA waiver form, that contain study team names (other than the PI) should be updated to remove this when updating study staff. The partial HIPAA waiver for screening can instead state "study team members listed on the registration page" rather than listing them by name.

☐	Amendment Form
☐	CW Registration Form (online document within IRBNet)
☐	HIPAA Waiver*^
☐	Acceptance of PI Responsibility Memo^
☐	Consent/Assent Documents Approved by the Reviewing IRB*^
☐	HIPAA Authorization*^
☐	Certification for Use of PHI of Decedents*^
☐	Approval Letter from the Reviewing IRB

(Checklists continue on the following page)

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Modifications to Existing Projects
Reliance Projects

☐	Amendment Form
☐	CW Registration Form (online document within IRBNet)*
☐	Informed Consent/Assent Documents Approved by the Reviewing IRB*^
☐	HIPAA Authorizations*^
☐	HIPAA Waiver*^
☐	Materials to be Seen by Subjects (Patient Information Sheets, Patient Diaries, etc.)*^
☐	Ancillary Letters of Approval (Departmental, Human Resources, Safety Committee Approvals, etc.) Where Any Study Activities Occur^
☐	Certification for Use of PHI of Decedents*^
☐	Tracked changes or Redlined Versions of assents, consents*^
☐	Approval Letter from the Reviewing IRB

(Checklists continue on the following page)

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Continuing Review/Progress Reports
Reliance Projects

☐	Approval Letter from Reviewing IRB
☐	CW Registration Form (online document within IRBNet)
☐	Materials to be Seen by Subjects (Patient Information Sheets, Patient Diaries, etc.)^
☐	The most current, approved Protocol
☐	Informed Consent/Assent Documents Approved by the Reviewing IRB^
☐	HIPAA Authorizations^
☐	HIPAA Waiver – Partial for Screening^
☐	HIPAA Waiver^

(Checklists continue on the following page)

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Reportable Events/New Information
Reliance Projects

☐	Report all local unanticipated problems involving risk, suspected serious or continuous noncompliance, protocol violations and unresolved subject complaints to the CW IRB ***in addition to*** the external IRB. This should be reported in real time (i.e. at the time this is being submitted to the IRB of record. You may submit a copy of the report you submitted to the external IRB.
☐	Any Supporting Documentation (Sponsor Safety Letters, New Investigator Brochures, Monitor Reports, Medwatch Report, Sponsor Memos, Interim DSMC Reports, etc.)^
☐	For follow up report (separate submission): Determination from Reviewing IRB

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