Children's Wisconsin

Human Research Protection Program

Annual Status Report or Final Closure Form

When to use this form

- This local context form should be used to provide an annual status report to the CW HRPP (as required by HRPP policy) **ONLY** when the IRB of record does not conduct continuing review **OR** at the time of study closure. If the IRB of record has conducted continuing review/status report of this study, this form does not need to be submitted. A copy of what was submitted to the IRB of record, along with all documentation, can be provided in lieu of this form.
- Incomplete answers may result in requests for additional information or clarification.
- Upon completion, upload this form:
  - In IRBNet submit as a **New Package** and select either "Continuing Review/Progress Report" OR "Closure/Final Report" as the submission type.
  - In eBridge, submit an **Amendment** and include this document as an attachment in Supporting Documents Section 3. For the "Amendment title" please state *Annual Status Report for CW Local Context Review when the IRB of record does not conduct annual Continuing Review*. You will not need to enter any Amendment Details in Section 2. The submission will be routed to the CW HRPP for local context review.
- Children's Wisconsin HRPP staff will conduct an administrative review and will provide acknowledgment once all questions have been addressed.
- If you have any questions, please send an email to the CW HRPP office cwhrpp@childrenswi.org.

Closure Report in IRBNet:

- Submit this form and no other materials. Inclusion of publication or presentation materials is acceptable but not required.

Closure Report in eBridge:

- If you do not know how to submit a closure report in eBridge, contact the MCW IRB Office irboffice@mcw.edu.

IRBNet # or eBridge PRO #:
Study Title:
Principal Investigator:
IRB of Record:
Does the IRB of Record apply the 2018 Common Rule to the review of this study: ☐ **Yes** ☐ **No** If unsure, contact the IRB of record or CW HRPP office for guidance.
Does the IRB of Record require Continuing Review: ☐ **Yes** ☐ **No** If YES, how often:
Does the IRB of Record require a Status Report: ☐ **Yes** ☐ **No** If YES, how often:
When was the last Continuing Review conducted by the IRB of Record:

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IF the Continuing Review was conducted this year, you can stop and include the documentation reviewed by the IRB of Record in lieu of submitting this form. If not, please continue.

Section 1. Current Status of Research

☐	**Open to enrollment - no subjects have been enrolled at this site**
☐	**Open to enrollment – subjects have been enrolled at this site**
☐	**Closed to enrollment – some subjects are still on the research plan regimen**; subjects are still "active" on the protocol regimen or undergoing procedures or interventions for the research.
☐	**Closed to enrollment –** but active follow-up of subjects continues (e.g., follow-up visits, phone calls, surveys, etc. (anything other than or in addition to collection of routine clinical data as described below)
☐	**Closed to enrollment –** but the research has progressed to the point that it only involves the following, which are part of the IRB-approved study (check all that apply): ☐ Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care ☐ Data analysis, including analysis of identifiable or coded private information or biospecimens
☐	**Study closure - all research-related activities, including follow-up and data analysis of identifiable/coded data at this site are completed, or the study has been stopped, or the study never was conducted**
☐	**Suspended or on hold** (submit a separate Reportable Event package, if not already submitted, to provide details)

Study must remain open as long as identifiable or coded data are being analyzed (see OHRP guidance for definitions).

Section 2: Summary of Local Subject Enrollment

NOTE: For studies that require consent, subjects are considered enrolled once they have provided consent. For studies under a waiver of consent, enrolled subjects include anyone whose data or specimen has been collected, used, studied, analyzed, or created for the purposes of the research.

A. Total number of subjects approved for enrollment locally *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort):*

Please note this number can only be increased via submission and approval of a modification request. If you have enrolled more subjects than approved this must be reported as a protocol deviation.

B. Total number of subjects enrolled locally *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:

Screen failures and subjects who signed consent but were later found not eligible can be described in question 2E.

Since study start:

Since the last continuing review/status report *(if none, please explain why in question E below)***:**

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C. Total number of locally enrolled subjects withdrawn from the study or lost to follow up *(include subjects who withdrew consent or whose participation was ended due to toxicity or other reasons. If you have more than one cohort provide answers for each cohort)*:
Total to date: **Since the last continuing review/status report:** Briefly explain the reasons or circumstances related to each subject withdrawn or lost to follow up: *HRPP review of this information may shed light on problems related to the conduct of the research at CW that may warrant providing additional information to the IRB of record.*
D. Number of subjects that have completed the study locally *(If you have more than one cohort [patients, family members, treating physicians, etc.] provide answers for each cohort)*:
E. Describe study progress locally: Comment on whether subject recruitment and enrollment is proceeding differently (more slowly or quickly) than anticipated; if enrollment is not proceeding as planned, explain why and what is being done to improve enrollment. Attempts to enroll subjects, such as screen failures or subjects who were enrolled but later found ineligible when no research activities were conducted, can be described here.
F. Since the last report, have subjects been excluded because of limited English proficiency? ☐ **N/A**
☐ **No** ☐ **Yes If YES, explain here:**

Section 3: Research Progress Summary

A. Indicate if subjects from any of the following vulnerable groups been included since the last report: ☐ **N/A**

Category	**Total Enrolled or N/A**	
Wards of the state		
Individuals who cannot read (blind or illiterate)		
Individuals with limited English proficiency		
Since the last report, have there been any: *If YES is checked, briefly describe below and, if necessary, include other relevant documents or forms. If information was previously reviewed by the IRB of record and copies of reports were already submitted, include the IRBNet or eBridge package # below.	**No**	**Yes***
Changes in CW resources/spaces/locations **If YES, briefly describe or include the IRBNet or eBridge package # here:**	☐	☐
Changes of PI **If YES, briefly describe or include the IRBNet or eBridge package # here:**	☐	☐

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Changes in available resources that may negatively affect the ability to conduct the study (i.e., study personnel, funding, local support) **If YES, briefly describe or include the IRBNet or eBridge package # here:**	☐	☐
Subject complaints/concerns about the study **If YES, briefly describe or include the IRBNet or eBridge package # here:**	☐	☐
Cases where the study/site/investigator were monitored/reviewed/audited by an outside monitor/sponsor/agency, MCW, or CW Corporate Compliance **If YES, briefly describe or include the IRBNet or eBridge package # here:**	☐	☐

Section 4 Obtaining and Documenting Informed Consent

A. The following methods were used to obtain informed consent for this study:

☐	**N/A - A waiver of the informed consent process was granted by the IRB for this study and consent is not obtained by any method.**		
☐	**N/A – No subjects have given consent to participate to date.**		
☐	**A written consent/parental permission/assent form was signed by subjects.**	**YES**	**NO**
	➢ **Confirm that a signed consent form for each subject is on file for inspection; AND**	☐	☐
	➢ **Confirm that the most current IRB-stamped documents were used to enroll all subjects.**	☐	☐
☐	**A waiver of documentation of informed consent/parental permission/assent was granted; a consent process occurs but documents are not signed by subjects (a verbal script, consent letter, or information sheet has been approved by the IRB).**	**YES**	**NO**
	➢ **The IRB-approved script/letter/info sheet used was used to enroll all subjects.**	☐	☐

If "No" is checked for any of the above, explain here and indicate the IRBNet or eBridge package number of the reportable event submission following review by the IRB of Record:

B. Studies involving children where the requirement to obtain informed consent has not been waived when the subject reaches age of majority.

As outlined in the **CW SOP Manual**, if a child turns 18 while study procedures or interactions are ongoing or while identifiable data is still being accessed or used by the study team, legally effective informed consent must be obtained from the now-adult subject via a consent process with the now-adult to continue participation, unless a waiver of informed consent/HIPAA authorization has been granted.

For studies where study procedures and interactions are ongoing or when identifiable or coded data is still being used and accessed, have any subjects reached age 18 since the last report? ☐ **No** / ☐ **Yes**

If YES, select one or more of the following to indicate whether these subjects have been or will be contacted to obtain their legally effective informed consent to continue participation.

☐	**Subjects were re-approached as soon as possible after their 18th birthday.**
☐	**A waiver of informed consent/HIPAA authorization has been granted for subjects who turn 18 during the research. ****

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☐	**For subjects where there is no ongoing contact, all research samples/data have been completely de-identified. All links between any individually identifiable data and research samples/data have been destroyed. ****
☐	**If you are unable to re-approach some subjects and do not currently have waivers of consent/HIPAA in place, an amendment must be submitted for approval. Please contact the CW HRPP for study-specific instructions.****
☐	**If none of the above, explain:**
	***** Not an option for FDA-regulated research.***

Section 5: Reportable Events

Reporting Requirements at the Time of Status Report

- ✓ The purpose of this section is to understand what has occurred during the last year (either since the last Continuing Review or annual Status Report).
- ✓ *Noncompliance and Unanticipated Problems that were not previously reported (did not require prompt reporting to the IRB of record) can be summarized on the Reportable Event Log available on the HRPP website.*
- ✓ *The summary log and status report form should also include, in a summarized format, anything previously reported to the IRB of record since the last continuing review or the last status report submitted to the CW HRPP.*

The Reportable Event Log should summarize both events that were previously submitted (e.g. promptly reportable events) and any other events that have occurred but have not yet been submitted (e.g. did not meet the criteria for prompt reporting).

A. Select all that apply since the last report:

- ☐ **This study has had no reportable events**
- ☐ **This study has previously reported events**
  - ☐ **If previously reported, check here if they were also reported to CW HRPP in accordance with reliance instructions and provide the package numbers:**
- ☐ **This study has new events to report that were not previously reported**
  - ☐ **If not previously reported, check here if the events meet the criteria for prompt reporting to the IRB of record. If the events do not meet the criteria for prompt reporting, submit a reportable event log for local HRPP review.**

B. Are there any active Corrective and Preventative Action (CAPA) plans from a previous Reportable Event or any noted on a Reportable Event Log?

- ☐ **Yes**
- ☐ **No**

C. Describe the progress of the implementation of the corrective actions from each CAPA:

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D. Describe the progress of the implementation of the preventative actions from each CAPA and assess their effectiveness. If the actions have not yet been implemented, describe the implementation timeline and address any changes to the plan/obstacles to implementation:

Section 6: Potential or Perceived Conflicts of Interest

Relationships of all members of the research team: Do any research personnel or any of their family members (spouse or dependent children) have an incentive or interest, **financial or otherwise**, which may appear to affect the protection of the human subjects involved in this project, the scientific objectivity of the research or its integrity?

☐ **No** ☐ **Yes** If YES, for each individual provide a description of each situation (including dollar values if applicable) as a separate document in the submission package which will be shared with the CW Conflict of Interest Committee

It is the PI's responsibility to review applicable MCW/CW policies on conflict of interest with every study team member and determine whether any member has a Significant Financial Interest related to this project.

- *For MCW faculty or staff, refer to MCW's Research Financial Conflicts of Interest Policy.*
- *For employees of Children's Wisconsin, refer to Children's Wisconsin Research Conflict of Interest Policy.*
- *For subcontractors or physicians/staff who are employed outside of Children's or MCW, contact CW Corporate Compliance for further guidance.*

FINANCIAL INTEREST includes any current or anticipated ownership interest or other financial relationship with any company or entity that sponsors, provides support, or otherwise has a financial interest in the conduct or outcome of this research protocol ("Financially Interested Organization"). This includes:

- ✓ Any related party who performed any work (not directly related to the costs of conducting research) within the past 12 months for a Financially Interested Organization.
- ✓ Any related party who received compensation (not directly related to the costs of conducting research) within the past 12 months from a Financially Interested Organization. This includes paid/reimbursed travel.
- ✓ Any related party who anticipates performing any work and/or receiving any compensation within the next 12 months (not directly related to the costs of conducting research) from a Financially Interested Organization. This includes paid/reimbursed travel.
- ✓ Any related party that maintained a board or executive relationship related to the research, regardless of compensation.
- ✓ Any related party who owns stock, stock options or other forms of ownership in a Financially Interested Organization. This does not include stock/stock options held in mutual, pension, or investment funds over which the investor has no control with regard to investment decisions.
- ✓ Any related party who has any intellectual property related to the proposed research (e.g., named as an inventor in an issued patent or patent application, license fees, technology transfers, current or future royalties from patents and copyrights).

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✓ Your department/institution/organization has a financial interest in the agent under investigation or in a company that could benefit from the study findings, or receives significant financial support from such a company.

Section 9: Data Security Provisions

All research projects that collect electronic data must use appropriate security measures to ensure that data are protected from theft or loss in order to prevent breaches of confidentiality. You indicated what encryption tools are being used in your initial submission application for review by Corporate Compliance.

- **The submission application must be kept current. If any security measures change during the course of the research study, the changes must be submitted via the amendment process for local context review and IRB approval. If you have already changed any approved security measures without an amendment, a reportable events package will also be needed.**

In order ensure investigators are up-to-date with their data storage and encryption methods, review the methods listed in the protocol summary/submission application now.

☐ **I have reviewed the methods described initially and they are accurate and reflect how the data are being stored/encrypted currently.**

☐ **I have reviewed the methods listed and they do not reflect how the study is being conducted** [submit a reportable events package and an amendment for IRB review and approval]