Guidance
De Novo Review of Existing Research Studies

Purpose
To ensure that research protocols continue to meet current regulatory requirements and institutional standards, studies may be selected to undergo a "De Novo Review." Studies that may be selected for De Novo Review are those that have been modified extensively, been open for several years, or may not be clearly written as determined by the IRB reviewer. The criterion for requiring a De Novo Review is an inability for the IRB to ensure and document that the activities continue to meet current regulatory requirements.

Process
During the De Novo Review, the IRB will require that all documents be incorporated into the CURRENT Children's Wisconsin templates (submitting the study "from scratch"). This may involve providing new information that has not been previously requested and therefore, not previously reviewed by the IRB. As with any review, studies must meet all current regulatory requirements, and local policies and procedures. You should not assume that a study undergoing De Novo Review will receive automatic approval.

If selected, the following will be required to be submitted:

- Updated submission application – complete the most current version of the Protocol Summary application form and submit a package in the electronic submission system under the same project ID number and select "new project" as the project type. Do not create a new project with a new ID number.

- Updated consent/assent documents and/or information sheet(s) – review the most recently approved consent/information sheet documents to ensure that they meet the most current document requirements, update if needed. Templates are available under Forms and Templates in the electronic submission system.

- All other relevant documents – review the Guidance – Submission Documents Checklist. For internal forms such HIPAA waivers, be sure to include the most current versions, updating if needed.

If the study is selected for De Novo Review, the PI and study team will be notified by the HRPP office via email and through the electronic submission system. If the selection occurs at the time of continuing review, approval may be for a shorter 6-month time period to accommodate the submission and review of the De Novo submission.

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Studies Not Selected for De Novo Review

Studies that would not likely be selected for De Novo Review are studies where:

- The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or

- The remaining research activities are limited to data analysis.