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5.1.3. The CHRE may determine that the research requires continuing review more frequently than once per year by considering the following:

- The nature of any risks posed by the research study,
- The degree of uncertainty regarding the risks involved,
- The vulnerability of the participant population,
- The experience of the investigators in conducting research,
- The NMREBs previous history with the investigators,
- The projected rate of enrollment; and estimated study closure date
- Whether the research study involves novel interventions;

5.1.4. The CHRE staff will send a courtesy reminder at different time points prior to the expiry date. Should an Investigator fail to submit the CER form despite the reminder/follow-up notifications, a notice that NMREB approval has expired will be issued and the study will be suspended. If the CER form is still not submitted within 2 weeks of the study expiry date the NMREB may close the file and Investigators will be required to submit a new study. If the CER form is submitted after the expiry date but before file closure this will result in a lapse of NMREB approval. The CHRE may also elect to pursue investigations for serious continuing non-compliance.

5.1.5. Once the CER form is submitted, the Ethics Officer (EO) or Ethics Coordinator (EC) reviews the application for completeness and may request any clarifications, or missing documents or information, if applicable.

5.1.6. The NMREB may request verification from source.

- 5.2.2 Research that was previously reviewed by the Full Board may also be reviewed at the time of continuing review using delegated review procedures when there are minimal risk changes;
- 5.2.3 The EO/EC reviews the continuing review application for completeness, including verification of the currently approved Letter(s) of Information, and may request any clarifications, or missing documents or information, if applicable;
- 5.2.4 The EO/EC distributes the renewal progress reports to the NMREB Chair, or designee, for review;
- 5.2.5 The NMREB Chair, or designee, will make a decision regarding the continued approval of the research study.

### 5.3. NMREB Determinations

- 5.3.1 For continuation of approval to be issued the NMREB must determine that:

There have been no material changes to the study protocol or Leo the

