that the Food and Drug Administration and representatives of the IRB may inspect the records.

(6) For research involving more than minimal risk, or if the research proposes compensations for research related injury, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. The informed consent document must not waive or appear to waive the rights of the participant or release or appear to release those conducting the study from liability for negligence.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
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3.8.4. Exculpatory Language

¶ Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights or releases or appears to release the investigator, the sponsor, the university from liability for negligence.

3.8.5. FDA-Regulated Test Articles

¶ For all research involving test articles regulated by the U.S. Food and Drug Administration (FDA), informed consent documents should include a statement that the purpose of the study includes evaluation of the safety or the safety and the effectiveness of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.

3.8.6. Translated Consent Documents

¶ When applicable: translations of consent documents will also be submitted for IRB approval and will be reviewed in an expedited manner. The investigator
(or sponsor) may submit documentation to the IRB attesting to the consent document is a true and accurate translation.

3.9. Assent for Minors

3.9.1. In the State of Wisconsin, only individuals 18 years or older may legall6(BT*F*2 12 0 612 f71