PROCEDURE:

Informed Consent Process

1. Investigators must provide the information regarding the consenting process to the

accordance with the

4. The IRB Committee must review and approve all informed consent documents (full written documents, oral scripts, videos, comprehension materials, any type of comprehension or assessment aids, and short forms) during their review of submissions.

IRB Committee Responsibilities

1. The IRB Committee, the IRB Chair or designated reviewer reviews the proposed research activities to assure that the informed consent document aligns with the eBridge application, Investigator's brochure, the Protocol, grant and/or contract, and contains the necessary elements of informed consent as required by federal regulations and institutional policy.
2. When reviewing the informed consent document, the IRB members may request necessary revisions to the content, language, punctuation, and/or grammar in order for the intended target population to clearly understand the proposed research activities and make an informed decision on whether to participate in the research.
3. The IRB Committee, the IRB Chair or designated reviewer approves the informed consent process and method of documentation, indicating whether the proposed consent process is appropriate for the proposed research activities and the target population as a part of the overall IRB approval of the project.

Informed Consent Documents:

1. Investigators are responsible for incorporating the elements of informed consent and the Health Insurance Portability and Accountability Act (HIPAA) standards as required by institutional policy into each informed consent document for their research studies.
2. Investigators are required to use the MCW IRB Consent Form Templates in their development of a consent form for use in research projects.

   Required Elements: The required elements of consent to be included in each informed consent document are:

   - A concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subscription must be organized and presented in a way that facilitates comprehension
   - A clear statement that the project involves "research";
   - An explanation of the purposes of the research;
   - Information organized and presented in sufficient detail to facilitate the understanding of the reasons one might or might not want to participate in research;
   - Information that a reasonable person would want to have to make an informed decision and an opportunity to discuss that information, information to include the following unless waived by the IRB:
     - The expected duration of the subject's participation;
     - A complete description of the procedures to be followed, and identification of procedures that are experimental and performed solely for the purposes of research;
     - A description of the reasonably foreseeable risks and discomforts;
     - A description of any benefits to the subject or others that may reasonably be expected from the research;
     - A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject;

- When the research involves the collection of identifiable private

information would meaningfully add to the protection of the rights and welfare of subjects.

ICH GCP additional elements: In addition to the required and if applicable additional elements consent forms for clinical investigations that follow ICH GCP guidelines must include these additional elements:

- x Discussion of project treatments and probability of random assignment
- x Subject responsibilities
- x Anticipated prorated payment, if any, to the subject for participating in the project
- x Information regarding the important potential benefits and risks of alternative procedures/courses of treatment
- x

should confirm all the required additional elements are included in the consent form, as described in .

Prohibited Elements

x No unproven claims of effectiveness or certainty of benefit, either implicit or explicit, may be included in the informed consent documents.

x The informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the Investigator, the sponsor, or its agents from liability for negligence.

a. Examples of Acceptable Language:

x There are no plans to provide financial compensation to you should this occur.

x By consenting to participate, you authorize the use of your private health information for the research described above.

b. Examples of Unacceptable Exculpatory Language:

x By agreeing to this use, you should understand that you would give up all claims to personal benefit from commercial or other use of these substances.

x I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.

x By consenting to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.

x I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Waiver of Consent

1. The IRB may waive or alter the requirement for Investigators to obtain a potential subject's consent for research participation. To approve such a waiver or alteration, the IRB must find:

    - Possible changes in methods or levels of payment for benefits or services under those programs
- The research cannot practicably be carried out without the waiver or alteration

3. Research subject to FDA regulation may occur without prior consent of the subject in these circumstances:

- When the research involves planned research in life-threatening emergent situations where obtaining prospective informed consent has been waived for some or all of the potential research subjects, as provided by 21 CFR 50.24. The research plan must be approved in advance by FDA and the IRB, and publicly disclosed to the community in which the research will be conducted. For more information refer to

- When the research involves an unplanned emergency use of an FDA regulated product for a single subject. The investigator is required to obtain

- In addition, the IRB will ensure the project complies with and follows the

1. When a potential subject who does not speak English is **unexpectedly** encountered, institutional policy allows for use of a “short form” in a language the subject understands, to document that all required elements of informed consent were presented orally. A summary in English (the IRB-approved consent form in English) of what is to be presented to the subject, as well as the short form must be approved by the IRB, and a witness to the oral presentation is required.
2. IRB member should refer to
   for further guidance on the use of short form consents or a fully translated consent form.

Consent Monitoring

1. The IRB has the authority under institutional policy to observe or have a third party observe the consent process and the research. In order to ensure that the consent process is appropriate, and the approved process is being followed, the IRB may determine that special monitoring of the process must occur. Such monitoring may be particularly needed for the IRB to meet its responsibilities to ensure human subject protections for research that:
   - x Involves a vulnerable population
   - x Involves use of a highly risky and innovative procedure
   - x Is conducted by an inexperienced investigator and/or research team
   - x Is research about which the IRB has concerns that the consent process is not being conducted properly.
2. In reviewing the adequacy of proposed informed consent procedures, the IRB may determine on a project-by-project basis as a part of the initial and continuing review process, those research projects that require third party observation/monitoring of the consent procedures in accordance with
   .
3. MCW QA/QI staff and IRB Members authorized to conduct the monitoring will be identified by the IRB Chair and the HRPP Director and the meeting minutes will document these plans.
4. The monitoring results will be reported to the IRB that requested the monitoring and reflected in the minutes, and the monitoring report will be included in the protocol file.
5. If the initial determination requiring third party observation/monitoring of the consent procedures was open-ended, when the IRB determines that the monitoring is no longer required, the minutes will record that determination.

REFERENCES:

21 CFR 50.24

SUPPORTING DOCUMENTS:

MCW Informed Consent Templates

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