Informed Consent Form Review
IRB Internal Worksheet

INFORMED CONSENT FORM			
☐ Confirm all the information in the header is correct.			
☐ Confirm that the Corewell Health logo and medical records identifier box has been added to the header.			
☐ Are all study procedures explained in lay language? Is the reading grade level of each ICF or assent document appropriate for the intended population?			
☐ If New Rule, the ICF contains all elements of the Key Information Pages. If not, detail here:			
☐ For research that exposes the study team to blood draw or other bodily fluids, has the Michigan Law language related to HIV and hepatitis testing been added?			
☐ For Adult drug studies ensure that the template Medicare language is in the ICF, if a device study ensure the language has been removed.			
☐ Has the MyChart paragraph been included in the "What else do I need to know" section?			
☐ Are all applicable signature blocks present?			
7.7	☐	A description of any benefits to the subject or to others, which may reasonably be expected from the research.	
7.24	☐	When there is no intended clinical benefit to the subject, a statement to this effect. *(clinical trials)*	
7.1	☐	A statement that the study involves research.	
7.13	☐	A statement that participation is voluntary.	
7.10	☐	An explanation of how to contact the research team for questions, concerns, or complaints about the research.	
7.12	☐	An explanation of whom to contact in the event of a research-related injury to the subject.	
7.19	☐	The approval/favorable opinion by the IRB. *(clinical trials)*	
7.11	☐	An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.	
7.2	☐	An explanation of the purposes of the research.	
7.3	☐	An explanation of the expected duration of the subject's participation.	
7.38	☐	The approximate number of subjects involved in the study *(when appropriate).*	
7.4	☐	A description of the procedures to be followed.	
7.5	☐	Identification of any procedures, which are experimental. If the study drug/biologic/device described as investigational, meaning non-FDA approved? If the intervention is a procedure or technique, its current status with regard to standard practice should be explained.	
7.20	☐	The probability for random assignment to each treatment. *(clinical trials)*	
7.21	☐	The subject's responsibilities *(clinical trials)*	
7.14	☐	A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.	
7.8	☐	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.	
7.23	☐	The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject *(clinical trials).*	
7.15	☐	A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	
7.28	☐	The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. *(Clinical Trials only)*	

7.29	☐	The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care. *(Clinical Trials only)*	
7.35	☐	The consequences of a subject's decision to withdraw from the research.	
7.36	☐	Procedures for orderly termination of participation by the subject. *(when appropriate)*	
7.6	☐	A description of any reasonably foreseeable risks or discomforts to the subject.	
7.22	☐	When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant. *(Clinical Trials)*	
7.32	☐	A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. *(when appropriate)*	
7.31	☐	A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable. *(when appropriate)*	
7.37	☐	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject. *(when appropriate)*	
7.9	☐	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.	
7.25	☐	A statement that monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access. *(clinical trials)*	
7.27	☐	For FDA-regulated research, a statement that notes the possibility that the Food and Drug Administration may inspect the records.	
7.16	☐	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 ☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. *(new rule)*	
7.42	☐	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). *(new rule)*	
7.40	☐	A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. *(new rule)*	
7.33	☐	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. *(when applicable)*	
7.18	☐	For research involving more than minimal risk 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.	
7.17	☐	For research involving more than minimal risk an explanation as to whether any compensation is available if injury occurs and, if so, what it consist of, or where further information may be obtained.	
7.34	☐	Any additional costs to the subject that may result from participation in the research. *(when appropriate)*	
7.41	☐	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. *(new rule)*	
7.39	☐	The amount and schedule of all payments. *(when applicable)* • The amount and type of compensation should be explained. • The ICF should state when payments will be made. • Are the payments prorated so that participants who do not complete the entire study are compensated for the visits they complete? • Is Clincard language present?	
7.26	☐	If the results of the trial are published, the subject's identity will remain confidential. *(clinical trials)*	
7.30	☐	The mandatory statement regarding the clinical trials database (when FDA regulated). For new trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."	