Revised Common Rule
Consent Criteria
– CHANGES BOLDED BELOW –

Consent process (all criteria must be met):	(45 CFR §46.116 and 21 CFR §50.20)
☐	1) The consent process will be legally effective
☐	2) Circumstances provide the prospective subject or LAR sufficient opportunity to consider whether to participate
☐	3) Circumstances minimize the possibility of coercion or undue influence
☐	4) The information will be provided be in language understandable to the subject or LAR
☐	**5) The consent contains information that a reasonable person would want to have in order to make an informed decision about whether to participate**
☐	**6) The consent begins with the key information why one might or might not want to participate in the research**
☐	7) There is no exculpatory language Exculpatory language is language through which the subject or LAR 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, the institution or its agents from liability for negligence
☐	8) The required and appropriate additional elements of consent will be disclosed

Required Elements of consent (all must be met)	45 CFR §46.116 and 21 CFR §50.25
☐	Study involves research
☐	Purposes of the research
☐	Expected duration of the subject's participation
☐	Procedures to be followed
☐	Identification of any procedures which are experimental
☐	Any reasonably foreseeable risks or discomforts

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Required Elements of consent (all must be met)	45 CFR §46.116 and 21 CFR §50.25
☐	Any benefits to the subject or to others which may reasonably be expected from the research
☐	Any appropriate alternative procedures or courses of treatment that might be advantageous
☐	The extent, if any, to which confidentiality of records identifying the subject will be maintained When appropriate, disclose any limits on confidentiality imposed by mandatory reporting and any possibility of loss of confidentiality due to media attention
	How to contact the investigator for ☐ • questions ☐ • concerns ☐ • complaints
	How to contact someone independent of the investigator for: ☐ • questions ☐ • concerns ☐ • complaints ☐ • subjects rights
☐	Whom to contact in the event of a research-related injury
☐	Participation is voluntary
☐	Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
☐	The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
☐	**One of the following statements about any identifiable private information or identifiable biospecimens:** **(i) 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**

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Required Elements of consent (all must be met)	45 CFR §46.116 and 21 CFR §50.25
	or **(ii) 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.**

Additional elements of consent, required when appropriate 45 CFR §46.111 and 21 CFR §50.25	
☐	The research may involve risks to the subject which are currently unforeseeable
☐	The research may involve risks to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable
☐	Anticipated circumstances under which the subject's participation may be stopped without the subject's consent
☐	Any additional costs to the subject that may result from participation in the research
☐	The consequences of a subject's decision to withdraw from the research
☐	Procedures for orderly termination of participation by the subject
☐	New findings that may relate to the subject's willingness to continue participation will be provided to the subject
☐	The approximate number of subjects involved in the study Amount and timing of all payments
☐	**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**
☐	**A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions**
☐	**whether the research will or might include whole genome sequencing**
☐	Amount and timing of all payments

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Consent Requirements for research involving more than <Minimal Risk> to subjects	45 CFR §46.111 and 21 CFR §50.25
☐	Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
☐	Whether any compensation is available if injury occurs and, if so, what they consist of, or where further information may be obtained

Consent Requirements for FDA-regulated research 21 CFR §50.25 (all must be met):	
☐	Statement that FDA may inspect the records
☐	The consent document does not give the subject the option of having data removed When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed (Guidance for Sponsors, Clinical Investigators, and IRB Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials)
☐	For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance 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."

Consent Requirements for research subject to ICH-GCP 4.8.5 and 4.8.10	
☐	A description of the IRB and its role
☐	The probability for random assignment, if any
☐	Any subject responsibilities
☐	The reasonably foreseeable risks to an embryo, fetus, or nursing infant, if any
☐	When there is no intended clinical benefit to the subject, a statement to that effect

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☐	Statement that the 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 the applicable laws and regulations and that, by signing a written informed consent document, the subject or the subject's legally acceptable representative is authorizing such access.
☐	Statement that if the results of the trial are published, the subject's identity will remain confidential

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Required when research involves a submission of genomic data to the NIH database of Genotypes and Phenotypes (dbGaP) [Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)] **The IRB must determine all the following requirements are met:**	
☐	The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained
☐	The IRB has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository
☐	The genotype and phenotype data to be submitted were collected in a manner consistent with 45 CFR §46
☐	The identities of data subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data
☐	The 18 identifiers enumerated at section 45 CFR §164.514(b)(2) (the HIPAA Privacy Rule) are removed
☐	The submitting institution has no actual knowledge that the remaining information could be used alone or in combination with other information to identify subjects

Consent documentation Requirements 45 CFR §46.117, 21 CFR §50.27, and ICH-GCP 4.8.8	
☐	The document is accurate and complete
☐	The document embodies the required and appropriate additional elements of consent
☐	The document will be signed and dated by the subject or LAR and by the person obtaining consent
☐	**The key information will be presented to the subject before other information**
☐	A signed and dated copy will be given to the person signing the form
☐	The investigator will give the subject or LAR adequate opportunity to read it before it is signed and dated
☐	For clinical research: If the subject cannot read, an <Impartial Witness> will witness the consent process and sign and date the form
☐	Signature blanks are appropriate for the protocol and correctly labeled

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Consent documentation Requirements	45 CFR §46.117, 21 CFR §50.27, and ICH-GCP 4.8.8
☐	Addendum consents are identified as such