UK Office of Research Integrity

COMPARISON OF REGULATORY AGENCY CONSENT REQUIREMENTS

SIGNATURE/WAIVER/WAIVER OF SIGNATURE (DOCUMENTATION)			
	HHS Common Rule 45 CFR 46.117	**HIPAA 45 CFR 164.508**	**FDA 21 CFR 56.109**
SIGNATURE	Written informed consent form approved by the IRB and signed (including electronic) by the subject or subject's LAR*.	Written authorization signed **and dated** by individual or personal representative.	Written consent form approved by the IRB and signed **and dated** by the subject or the subject's LAR at the time of consent.
WAIVER	✓	✓	✓
WAIVER OF DOCUMENTATION	✓	No specific provision	No specific provision
PERSON OBTAINING CONSENT			Not regulation but is a part of ICH Good Clinical Practice (GCP) guidelines

*Legally Authorized Representative

REMOTE VERIFICATION OF IDENTIFICATION		
HHS Common Rule 45 CFR 46.117	**HIPAA 45 CFR 164.508**	**FDA 21 CFR 56.109**
Advises researchers to use a Risk-Based Approach to decide when verification is warranted. *Social behavioral, minimal risk research will NOT typically warrant such verification.*	HIPAA recommends user authentication to verify identity	FDA requires verification of identity under Part 11 Electronic Records/Signatures

SHORT FORM (consistent with both HHS and FDA regulations). See UK Short Form Guidance and FAQs

ELECTRONIC-SIGNATURES		
HHS Common Rule 45 CFR 46.117	**HIPAA 45 CFR 164.508**	**FDA 21 CFR 56.109**
Permitted if legally valid within jurisdiction	Allowed provided legally valid, secure, & no risk to the integrity of PHI	Permitted provided compliant with FDA Part-11
Legal: Identity Validation when warranted Non-Repudiation Integrity- assurance that neither record nor signature has been altered since moment of signing.	Legal: Identity Validation Recommended Non-Repudiation Audit trail Ownership by covered entity	Legal Identity Validation Required Part 11 Compliant Product Criteria for digital & handwritten signatures executed to electronic records, to be trustworthy, reliable, and generally equivalent to a handwritten signature executed on paper.

Note: Investigators are generally expected to use consent documents containing the "IRB Approval" stamp unless circumstances do not accommodate use of version containing the stamp (e.g., use of an electronic system). Regulations do not mandate consent stamps and IRB policy permits exceptions where uploading a stamped version may not be feasible.

HIPAA COMPLIANT REMOTE COMMUNICATION Non-Public Facing End-to-End Encryption	
Video Communication Products w/HIPAA Compliance Provisions	**Compliant Non-public facing remote communication platforms**
HIPAA and Telehealth	**What is a "non-public facing" remote communication product?**

ASSENT DOCUMENTATION		
Office of Human Research Protection **OHRP Guidance**	**UK IRB Policy on Children in Research [PDF]**	**FDA 21 CFR 56.109** **FDA Guidance**
The HHS regulations do not require documentation of assent. The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent. If young children are involved who are yet unable to read, documentation use a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.	When the IRB determines that assent is required, the regulation permits the IRB to also determine whether and how assent must be documented. Unless the requirement is waived by the IRB, signatures are generally required on the assent for subjects aged 12-17.	When the IRB determines that assent is required, it must also determine whether and how assent must be documented (21 CFR 50.55(g)). Considerations such as the child's age, maturity, and degree of literacy for determining capability of children to provide assent should be considered when determining whether assent should be in writing or oral.

SIGNED/UNSIGNED COPY FOR PARTICIPANT	
Agency	**Language Excerpt**
FDA –**Does not** require. Recommends copy of signed document	*In addition, the person signing the consent form must receive a copy of the consent form (21 CFR 50.27(a)). Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.*
FDA ICH GCP* Requires but UK ORI **does not** comply with ICH Good Clinical Practice (GCP) Guidelines	*The subject or the subject's legally acceptable representative should receive a copy of the signed and dated written informed consent form.*
OHRP Common Rule – **Does not** specify copy be signed	*Written copy shall be given to the person signing the informed consent form.*
FDA/OHRP E-consent guidance – States FDA recommends	*The copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email.*
UK Consent SOP **Does** require	*The subject or LAR signing on the subject's behalf receives a copy of the signed form.*
UK HIPAA Authorization Guidance **Does** require	*The subject must be given a copy of the signed authorization.*
AAHRPP - Standard-ii-3/element-ii.3.f Only requires if compliant with ICH GCP	*A copy of the consent document will be given to the person signing the consent document.* • *When following ICH GCP – should receive a copy of the signed and dated written consent*

*International Conference on Harmonization Good Clinical Practice Guidelines – UK only complies with ICH GCP to the extent that it is consistent with FDA regulations.