Consent Processes-IRB

Please refer to "Consenting Study Subjects in Isolation and Documentation " slides;

Please remember some of this is dependent upon the risk level of the study (minimal risk/greater than minimal risk) and if its FDA regulated.

Risk Level/Regulations	Full Waiver of HIPAA and Consent	Alt. Or Waiver of Signature (Verbal)	Signature is Required
Minimal Risk-No Intervention/Interaction with subjects *Expedited Categories	Yes	Likely NA	Likely NA
Minimal Risk- Intervention/interaction with subjects *Expedited Categories	Likely NA	Yes	If possible, (for electronic consider Qualtrics, REDCap or other IT approved mechanism)
Greater than minimal risk- Full board	NA	NA	Yes (for electronic signature consider Qualtrics, REDCap or other IT approved mechanism)
Greater than minimal risk-Full Board FDA Regulated	NA	NA	Yes (for electronic signature must be Part 11 Compliance, check with IT Liaison)