24 eConsent Workflow Considerations

1. Objective of the eConsent:
    a. What are the requirements and limitations for consenting at your site?
    b. How were you thinking about operationalizing the eConsent? (i.e., content planning, development, obtaining stakeholder feedback from study team and/or prospective participants, integrating eConsent with study/patient workflow, monitoring, storing data, closeout (filing, device collection, and more)).
2. Timeline – when do you want eConsenting to be available?
3. What percentage of the participants do you anticipate will be using the eConsent?
4. Where will you use the econsent?
    a. Clinic
    b. Self-initiated (i.e., participants engage using their own electronic devices via brochures, posters, etc. which contain web-links or QR codes)
    c. Call Center
    d. Email participants and consent remotely
5. How will you confirm participant identity (i.e., ask participant to add DOB to form, study-specific PIN number, etc)?
6. Will this be used for just consent or also for screening participants?
7. Devices
    a. What type of devices will you be using to collect the data? (e.g., home computer, clinic-provided tablet, participant's portable electronic device)
    b. How many devices do you need per site (e.g., if using tablets in clinic – consider workflow for maintaining charge of device, ensuring device is not taken/stolen, paper backups if wi-fi fails)
    c. Who is providing the devices?
    d. Will the sites need Wi-Fi access and does the site have the bandwidth to support eConsenting?
    e. Do the sites need institutional approvals? (firewall, etc)
    f. Do sites need to access a printer? (participant copy)
8. How will you obtain the participant's consent signature? (ex. typed signature, PIN number, "wet electronic signature" via stylus or finger);
9. Features – what features do you envision in the eConsent? Options include:
    a. multimedia,
    b. audio,
    c. consent in sections,
    d. knowledge review,
    e. participant attestation,
    f. e-signature (and how participants sign),
    g. audit requirements,
    h. regulatory requirements,
    i. any specific considerations based on anticipated participants age, comfort with technology, other,
    j. a dictionary or glossary
10. Database – where do you envision the database will reside – who will build/manage the database? Does the study require FDA – Part-11 compliance?
11. Workflow – how do you envision the workflow from eConsent to enrollment (i.e., who needs to sign the consent following the participant? Will all signatories be in the same location? LAR, translator?)
12. Site requirements – do we know the site-specific requirements around eConsenting and eSignatures?
13. Language – do you need a language other than English?