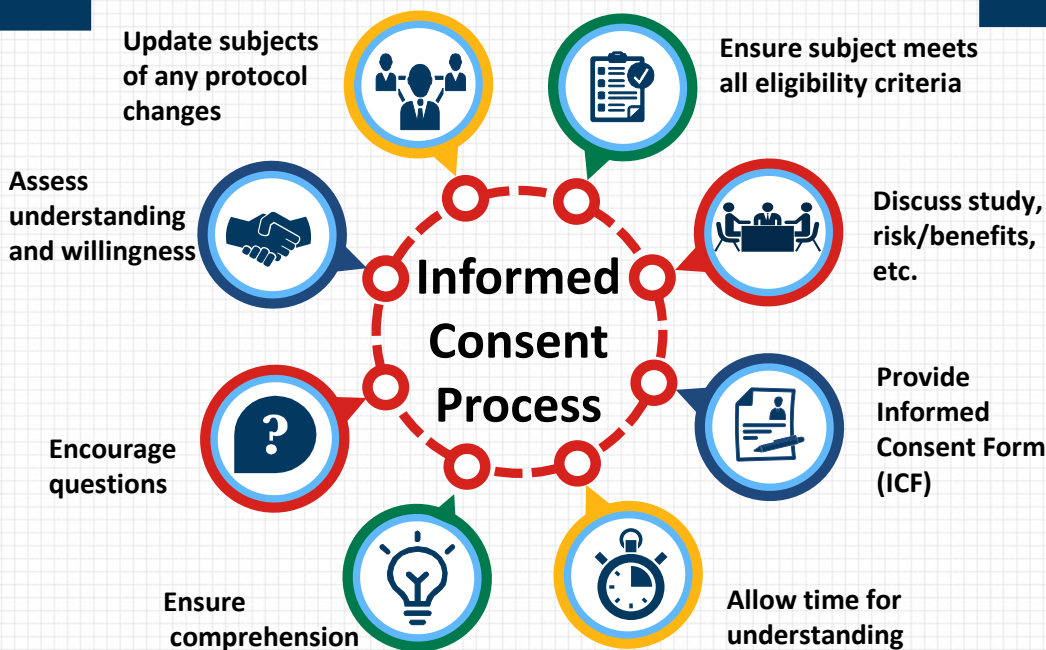


# INFORMED CONSENT



## Informed Consent Checklist

1. Is the potential subject of the right age, or is the legal guardian present?
2. Can you speak the subject's language or is there a translator?
3. Is the subject literate and if not, have you identified a witness who is literate?
4. Do you have an IRB approved Informed Consent Form in the correct language?
5. Have you taken the required IRB/Site/Institution precautions for vulnerable populations?
6. Have you met all site-specific requirements for the Informed Consent Process?
7. Have you given the subject an opportunity to read the Informed Consent Form?
8. Have you verbally explained the entire Informed Consent Form?
9. Have you assessed the subjects understanding of the Informed Consent Form?
10. Have you encouraged questions?
11. Did the subject indicate a willingness to participate?
12. Did you obtain signatures of the subject, person obtaining consent, and, if applicable, the witness and/or translator and/or Investigator?
13. Did the subject receive a copy of the signed/dated Informed Consent Form?
14. Did you document in the chart notes that a copy of the Informed Consent Form was provided and any other pertinent information?
15. Did you review the completed Informed Consent Form for completeness and accuracy prior to the subject leaving the site?