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| Informed Consent Checklist |

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| Study title | |
| Participant ID | Protocol version number |
| Principal investigator | Study site |

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| **Informed consent process** | | |
| The language used for the consent document | Urdu  English | |
| Language used in the consent document is understandable to the participant / legally accepted heir | Yes | No |
| Consent obtained in a quiet, private environment without distractions | Yes | No |
| was patient able to read the consent document at his/her own pace | Yes | No |
| Copy of the signed consent form given to the participant | Yes | No |
| The participant encouraged to ask questions, all queries answered satisfactorily | Yes | No |
| Person obtaining consent is listed in the delegation of authority log | Yes | No |
| Participant were informed that participation is voluntary and can withdraw from the study at any time without penalty or loss of benefit | Yes | No |
| Is study duration explained to the participant | Yes | No |
| Is individual participants duration explained to the patient including number and timings of scheduled visits | Yes | No |
| **Consent document** | |  |
| Explanation that study involves research | Yes | No |
| The purpose of the research provided | Yes | No |
| The subject’s responsibilities during the study explained | Yes | No |
| All study related procedures including invasive ones, explained | Yes | No |
| Foreseeable risks/ inconveniences explained including for embryo /fetus /nursing infant (if applicable) | Yes | No |
| Expected benefits for participation in the research described: if none, participant informed | Yes | No |
| Compensation /treatment for research related injury described | Yes | No |
| Anticipated expenses to the patient for participation in the research explained | Yes | No |
| Confidentiality |  |  |
| Participant were informed that medical records may be reviewed by monitors auditors IRB /IEC and regulators for trial data verification. Participant authorizes such access by signing the consent | Yes | No |
| Confidentiality of identity assured: identity will not be revealed in the publication | Yes | No |
| Conditions under which subject participation in the study may be suspended explained | Yes | No |
| Contact details for principal investigator, ERB for trial-related information, subject rights, and reporting of trial-related injury are mentioned in the consent document. | Yes | No |

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| Study staff completing the procedure  Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |