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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 procedureSignature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |