CRF Specifications for Protocol XYZ-123-002

Form 1: Demographics
Form OID: DM
Fields:
- Subject ID (SUBJID): Text, Required, CDISC: DM.USUBJID
- Date of Birth (DOB): Date, Required, CDISC: DM.BRTHDTC
- Sex (SEX): Select, Required, CDISC: DM.SEX, Values: M/F
- Race (RACE): Select, Required, CDISC: DM.RACE
- Ethnicity (ETHNIC): Select, Required, CDISC: DM.ETHNIC

Form 2: Medical History
Form OID: MH
Fields:
- Medical History Term (MHTERM): Text, Required, CDISC: MH.MHTERM
- Start Date (MHSTDTC): Date, Optional, CDISC: MH.MHSTDTC
- Ongoing (MHONGO): Checkbox, Required, CDISC: MH.MHONGO

Form 3: Vital Signs
Form OID: VS
Fields:
- Systolic BP (SYSBP): Number, Required, CDISC: VS.VSSTRESN, Normal Range: 90-140
- Diastolic BP (DIASBP): Number, Required, CDISC: VS.VSSTRESN, Normal Range: 60-90
- Heart Rate (HR): Number, Required, CDISC: VS.VSSTRESN, Normal Range: 60-100
- Weight (WEIGHT): Number, Required, CDISC: VS.VSSTRESN
- Height (HEIGHT): Number, Required, CDISC: VS.VSSTRESN

Form 4: Laboratory Values
Form OID: LB
Fields:

- HbA1c (HBA1C): Number, Required, CDISC: LB.LBSTRESN, Normal Range: <7.0
- Fasting Glucose (GLUC): Number, Required, CDISC: LB.LBSTRESN, Normal Range: 70-100
- Creatinine (CREAT): Number, Required, CDISC: LB.LBSTRESN

Form 5: Adverse Events
Form OID: AE
Fields:
- AE Term (AETERM): Text, Required, CDISC: AE.AETERM
- Severity (AESEV): Select, Required, CDISC: AE.AESEV, Values: MILD/MODERATE/SEVERE
- Relationship (AEREL): Select, Required, CDISC: AE.AEREL
- Start Date (AESTDTC): Date, Required, CDISC: AE.AESTDTC
- End Date (AEENDTC): Date, Optional, CDISC: AE.AEENDTC

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