PRE-SCREENING

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Date of call _____

Screener (print name) _____

THE FIRST PERMISSION

Before anything else, ask: **"Do I have permission to put your name in our database?"** Permission to keep the name is not consent to the study, and it is not permission to dig into medical history.

Permission to enter name in the database given ☐ Yes ☐ No

Date / time of permission _____

Permission to call again if another study fits better ☐ Yes ☐ No

GENERAL OPENING QUESTIONS — friendly first, theirs to answer

"What interests you about this study?"

_____

"What have you heard about it so far?"

_____

"What questions can I answer for you?"

_____

SECTION BY SECTION — ask permission before every section. State the result of each section out loud.

Section	Permission asked	Result: Pass / Not a fit	Initials
Source — how they heard about us			
Permission for the database			
General opening questions			
Inclusion / exclusion — by talking			
Medications			
Their doctor			

INCLUSION / EXCLUSION — BY TALKING ONLY

Only what can be determined by talking, against the protocol's criteria. Anything needing labs, scans or records is NOT decided on this call.

- ☐ Age in the protocol's range
- ☐ Medications compatible (from the medications section)
- ☐ Can attend the visit schedule
- ☐ Diagnosis by history fits the study
- ☐ No exclusionary condition by history
- ☐ Lives within travelling distance

Talking screen result: ☐ Pass — proceed ☐ Not a fit — thank them; with permission, keep the name for a better-fitting study

Caller wishes to proceed to consent discussion ☐ Yes ☐ No

Notes

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

CONSENTING

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Consent form version _____

Date of consent discussion _____

Time discussion started _____

Person obtaining consent (print) _____

Consent obtained BEFORE any study procedure	☐ Yes	☐ No
Participant given a copy of the signed consent	☐ Yes	☐ No
Participant given time to consider and ask questions	☐ Yes	☐ No
Consent discussion held in a private setting	☐ Yes	☐ No

Participant statement

"I have read the consent form, my questions have been answered, and I agree to take part."

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

DEMOGRAPHICS

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Age (years) _____

Sex at birth _____

Gender _____

Ethnicity (tick all that apply)

- ☐ European / Caucasian
- ☐ East Asian
- ☐ Middle Eastern
- ☐ Indigenous
- ☐ Black
- ☐ Prefer not to say
- ☐ South Asian
- ☐ Latin American
- ☐ Other (specify on notes line)

Height (cm) _____

Weight (kg) _____

BMI (calculated) _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Safety reporting SOP
- ☐ Source documentation SOP
- ☐ Delegation & training current
- ☐ eCRF / data SOP
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

MEDICAL HISTORY

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

For each item: tick Yes or No. Give details on the lines for every Yes.

Condition

- ☐ PTSD (index condition)
- ☐ Anxiety disorder
- ☐ Traumatic brain injury
- ☐ Cardiovascular disease
- ☐ Liver disease
- ☐ Thyroid disorder
- ☐ Chronic pain
- ☐ Other serious illness
- ☐ Depression
- ☐ Substance use disorder
- ☐ Seizure disorder
- ☐ Diabetes
- ☐ Kidney disease
- ☐ Sleep apnea
- ☐ Cancer (any)

Details for every Yes (condition, year diagnosed, current status)

_____

_____

Past surgeries / hospitalizations

_____

_____

Allergies (drug / other — write NONE if none)

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it.
Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

CONCURRENT MEDICATIONS

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Every medication the participant is taking now — prescribed, over-the-counter, supplements, and as-needed.

Medication	Dose	Frequency	Start date	Ongoing?	Reason taken

Medication list reviewed against the protocol's prohibited-medication list ☐ Yes ☐ No

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

ADVERSE EVENTS

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Date AE identified _____

Onset date _____

Description of the event (participant's own words where possible)

_____

_____

Severity

☐ Mild ☐ Moderate ☐ Severe

Serious?

☐ Not serious ☐ Hospitalization ☐ Life-threatening
☐ Disability ☐ Death ☐ Other important medical event

Related to study drug / procedures?

☐ Unrelated ☐ Unlikely ☐ Possible
☐ Probable ☐ Definite

Action taken

☐ None ☐ Dose reduced ☐ Drug held
☐ Drug stopped ☐ Treatment given ☐ Referred / sent to ER

Outcome

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Recovered with sequelae ☐ Fatal ☐ Unknown

Reported to the sponsor / safety desk within the required window ☐ Yes ☐ No

Date reported _____

BEFORE THE VISIT — ADMIN

☐ Lab kits on hand (checked 2 weeks before)
☐ Bookings made (MRI / labs / room)
☐ Staff delegated & trained for this work
☐ Participant reminder call done
☐ Source documents printed & ready
☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

☐ Source documents filed (same day)
☐ Next visit booked
☐ Queries answered or flagged
☐ Data entered into the eCRF
☐ Arrangements made (referrals / bookings)
☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

☐ Consent SOP
☐ Source documentation SOP
☐ eCRF / data SOP
☐ Safety reporting SOP
☐ Delegation & training current
☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 1

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 2

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 3

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 4

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 5

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 6

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 7

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 8

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 9

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 10

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 11

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 12

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 13

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 14

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 15

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 16

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 17

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 18

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 19

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 20

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 21

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 22

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 23

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 24

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____

VISIT 25

Participant ID (subject #) _____

Date (YYYY-MM-DD) _____

Visit date _____

Visit inside the protocol window ☐ Yes ☐ No

Days since last visit _____

Measurements

BP (mmHg)	Heart rate	Temp (°C)	Weight (kg)	Height (cm)

Procedures completed at this visit (tick each one done)

- ☐ Questionnaires / rating scales
- ☐ ECG
- ☐ Study drug dispensed
- ☐ Adverse events reviewed
- ☐ Safety labs drawn
- ☐ Physical exam
- ☐ Study drug returned / counted
- ☐ Concomitant meds reviewed

Any adverse events since the last visit ☐ Yes ☐ No

Any medication changes since the last visit ☐ Yes ☐ No

Next visit date booked _____

Notes

_____

_____

BEFORE THE VISIT — ADMIN

- ☐ Lab kits on hand (checked 2 weeks before)
- ☐ Bookings made (MRI / labs / room)
- ☐ Staff delegated & trained for this work
- ☐ Participant reminder call done
- ☐ Source documents printed & ready
- ☐ Equipment checked & ready

AFTER THE VISIT — ADMIN

- ☐ Source documents filed (same day)
- ☐ Next visit booked
- ☐ Queries answered or flagged
- ☐ Data entered into the eCRF
- ☐ Arrangements made (referrals / bookings)
- ☐ Deviations flagged to the study manager (same day)

☐ **REQUIRED — Interim-invoice revenue for this work checked & approved today.**
Every invoicable item ticked off. The day does not close without it. Initials _____ Date _____

SOP PROOF — THIS WORK FOLLOWED THE SOPs

- ☐ Consent SOP
- ☐ Source documentation SOP
- ☐ eCRF / data SOP
- ☐ Safety reporting SOP
- ☐ Delegation & training current
- ☐ Privacy — no identifiers on this form

Deviation from any SOP? ☐ None ☐ Yes — deviation # _____ logged & reported

Completed by (print) _____ Signature _____ Date _____

Reviewed by (print) _____ Signature _____ Date _____