Questions to ask before you enroll in a clinical trial

The purpose and the why

- [ ] What is the main goal of this trial?
- [ ] What is the treatment, device, or approach being studied?
- [ ] What do researchers already know about it (from earlier studies)?
- [ ] What would success look like in this study?

Eligibility and fit

- [ ] Why do you think my loved one is (or is not) a good fit?
- [ ] What are the inclusion and exclusion criteria?
- [ ] Are there conditions, medications, or health factors that could disqualify us later?

Treatment details and placebo questions

- [ ] Will my loved one definitely receive the study treatment, or is there a chance of placebo?
- [ ] If there is a placebo group, will my loved one still receive standard of care?
- [ ] Is this blinded (meaning we will not know which group they are in)?
- [ ] Can my loved one switch treatments later if the study is not working?

Risks, side effects, and safety monitoring

- [ ] What side effects have been seen so far, and how common are they?
- [ ] What are the most serious risks, even if rare?
- [ ] How will side effects be monitored and documented?
- [ ] Who do we call after hours if something feels urgent?
- [ ] What would make the research team stop the treatment or remove someone from the study?

Visits, tests, and time commitment

- [ ] How long does the trial last?
- [ ] How often are visits, and where do they happen?
- [ ] What tests are required (lab work, imaging, cognitive testing, surveys)?
- [ ] Are there overnight stays or long appointment days?
- [ ] What happens if we miss a visit due to illness, caregiving needs, or transportation issues?

Costs, insurance, and travel support

- [ ] What costs are covered by the sponsor?
- [ ] What is the treatment, device, or approach being studied?
- [ ] What costs could we be responsible for (travel, parking, meals, lodging, time off work)?
- [ ] Is there reimbursement or travel assistance?
- [ ] Who can help us get a clear estimate in writing?

Your caregiver role and daily-life expectations

- [ ] What will be expected of the caregiver (tracking symptoms, administering medication, reporting changes)?
- [ ] Do we need to keep a symptom log or complete regular surveys?
- [ ] Are there restrictions on diet, activity, other medications, or supplements?
- [ ] How will this affect my loved one's current routine and quality of life?

Communication and coordination with the care team

- [ ] How will the research team communicate with my loved one's regular doctors?
- [ ] Who is our main point of contact?
- [ ] How quickly should we expect responses to questions?
- [ ] How will we receive test results, updates, or changes to the protocol?

Privacy and data

- [ ] What information will be collected, and how will it be used?
- [ ] Who will have access to the data?
- [ ] Will samples (blood, tissue, genetic data) be stored for future research?
- [ ] Can we opt out of any optional parts?

Leaving the study and what happens next

- [ ] Can my loved one leave the trial at any time? What is the process?
- [ ] If we leave, what follow-up care is recommended?
- [ ] Will my loved one have access to the treatment after the trial ends?
- [ ] When and how will we learn the study results?