

INFORMED CONSENT FOR CLINICAL TRIALS: A COMPANION'S GUIDE FOR PARTICIPANTS

Participation in a clinical trial is a big decision. As part of the decision, you and/or your child will be asked to provide informed consent.

Make sure you and/or your child are well prepared by learning as much as you can about the study.

You'll be given the opportunity to meet with the study team to discuss all of the related procedures, risks, and expenses.

Reviewing this document ahead of time will help you prepare for the informed consent process and help you determine if you have any other questions about the study.

QUESTIONS TO ASK YOURSELF AND/OR YOUR CHILD

Clinical trials give us hope, but the outcomes are unknown when the trial begins. It is important to think about the possible outcomes - both positive and negative - before enrolling.

- What are my expectations / goals for participating in the study (e.g., improve my symptoms, stop disease progression, contribute to the advancement of FA treatments even if I don't see a direct benefit)?
- Am I willing to be away from home/work/school for the time needed to complete my participation in the study? What is the financial impact of participation?
- Will I have to change or alter my life-style routines or health habits to participate?
- Am I comfortable and confident in the research and healthcare team conducting the study?
- How will results from tests performed and study findings be communicated or shared with me and other participants?
- How will I feel if the overall study fails, but I feel the treatment made a difference to my FA symptoms?
- How will I feel if the overall study succeeds, but the treatment was not successful for me?
- How will I feel if I am enrolled in this clinical trial, but my peers do not meet eligibility and continue to progress with their FA?

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STUDY BACKGROUND

These questions will help you understand why the trial is being conducted.

- What is the drug, treatment, or device being tested? Is it a pill? An injection?
- Is this a first-in-human evaluation? If not, what has been learned from other studies?
- What do researchers hope to learn from the study?
- What tests and procedures will be performed in the study? How often?
 - Clinical trials require testing to monitor how the treatment is affecting the body. This typically means blood tests, physical assessments, imaging studies, and, occasionally, biopsies or other more invasive tests.

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RISKS / BENEFITS

Clinical trials are experimental research studies. It is important to understand the potential benefit(s) and weigh them against the expected (and unexpected) risks.

- Are there expected benefits to improving my symptoms?
- What are the possible risks to my participation?
- What short-term or long-term side effects are expected?
- Are the possible risks and benefits determined only from animal studies or from other human studies?
- What is the protocol if the study is stopped due to safety concerns?
- Will I be notified about safety concerns, even if I don't experience problems?
- If I participate in this study, will I still be eligible for future clinical trials or other research studies?

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TYPE OF RESEARCH INTERVENTION

Not all clinical trials are the same. It is important to understand how the study is designed, what is being tested, and how the study will be conducted. Participants in clinical trials are often randomized or assigned to specific treatment arms. This means that some participants will receive a placebo, while others will receive the study drug. Study arms may also include different doses of study drug.

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- What are the different study arms?
- Is there a placebo group?
 - What are my chances of receiving placebo vs. study drug?
 - How will it be determined if I receive placebo or intervention?
- Who will know which arm I am assigned to during the trial? Will I know? Will members of the research team know? Will I find out after the trial?
- After the study will there be open label or expanded access to the study drug?
- If I benefit from the intervention, will I be allowed to continue receiving it after the trial ends?
- If I am in the placebo group, will I have a chance to receive treatment after the trial ends?

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COORDINATING WITH CLINICAL CARE & STUDY FOLLOW-UPS

Research visits are distinctly different and often separate from clinical care. It is important to understand what aspects of your health the study team is responsible for and how results and information are communicated to you and your regular clinical or healthcare providers.

- Will I be told results of any of the study tests or procedures while I'm in the study?
 - Will I be able to share results with my other doctors?
 - Will my test results or imaging be added to my clinical medical record?
- Will I need to change or stop taking any medications or supplements while I'm in the study?
- Will I have to modify any of my clinical care or health activities (e.g., physical therapy, exercise programs, doctors' appointments, surgeries, and other planned procedures)?

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COMMUNICATION & RECORD-KEEPING

It is important to establish a point-of-contact person on your study team and stay connected with him/her.

- What documents do I need to have to participate in the study? (e.g. genetic test results)
- Who will have access to my information from the study?
- How is my identity and information kept confidential?
- How will my bio-samples from the study be used? Are any remaining samples saved and used for future research?
- Who is my primary point of contact? How will communication occur between study visits?
- What is the procedure if I experience an emergency while in the study?
- What documentation will I be expected to maintain (e.g. study logs)?

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FINANCIAL

Participating in a clinical trial takes time and resources. These questions will help you determine the financial impact of enrolling.

- Are there costs I will have to pay for?
- What's reimbursed by the study? e.g. travel (air, car rental, mileage, parking), hotel, childcare back at home, pet care, meals? How long will reimbursement take?
- Are expenses reimbursed for caregivers?
- What costs are paid directly by the study sponsor? (e.g. travel service that will book and pay expenses directly)
- Does any portion of my study participation get billed to my health insurance or payer? Will my co-pays and deductibles apply?
- Is there compensation provided for participation? If so, when and how is that disbursed?

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TIME COMMITMENT & LOGISTICS

Clinical trials require a significant commitment from the participant, caregivers, and other family members. It is important to understand what is required and to follow-through.

- How long will the study last?
- Where will the study take place?
- How often or how many times do I need to visit the study site? How long is each visit? Will overnight stays be required?
- What are the study commitments while I am home (e.g. home monitoring, visiting nurse appointments, telehealth visits, etc.)?
- What is the total time commitment for study visits and other study requirements?

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