Informed Consent Form

Principal Investigator:

Other Investigators:

Participant ID:

Introduction

Section 1. Purpose of the Research

\*\*Purpose of the Study:\*\*  
  
This study aims to compare the effectiveness of treatment Arm C versus treatment Arm D in improving overall survival for patients with liver disease. We will also assess whether treatment Arm A is not inferior to or better than treatment Arm D in terms of overall survival. The study will involve approximately 100 patients per treatment arm, with follow-up evaluations lasting up to 32 weeks.

Section 2. Procedures

\*\*Study Procedures:\*\*  
  
During the study, all participants will undergo the following procedures:  
  
- Full physical exam, including height, will be conducted.  
- Targeted physical exams based on symptoms will be performed.  
- Vital signs, including weight, will be measured.  
- ECG tests will be done as needed.  
- Concomitant medications will be recorded at all visits.  
  
These procedures will be carried out for [number of patients] over [study duration].

Section 3. Time Duration of the Procedures and Study

Section 4. Discomforts and Risks

Risks:  
Taking part in this study involves risks. The treatment may stimulate the immune system, which could lead to side effects in other parts of the body. Most side effects are believed to be caused by the immune system affecting specific tissues. These side effects could be related to inflammation or immune responses and may need closer monitoring or special treatments like immunosuppressants or hormone therapy. These immune-related effects can affect various organs, with the most common issues being gastrointestinal problems like colitis and diarrhea.

You may choose not to participate in this study due to the potential risks outlined above.

Section 5. Potential Benefits

Benefits:  
You may benefit from participating in this study by receiving a combination therapy of durvalumab and tremelimumab. The potential benefits of adding tremelimumab to durvalumab include improved outcomes for patients with certain types of tumors, as supported by data presented in the study protocol. This combination regimen has shown promise in patients with liver cancer (HCC). By participating, you may contribute to the advancement of medical knowledge and potentially help improve treatment options for patients with similar conditions.

Section 6. Statement of Confidentiality

This section contains information about the confidentiality of information collected during this study. Note that, as applicable, a description of this clinical trial may become available on http:///www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

6a. Privacy and confidentiality measures

6b. The use of private health information

Section 7. Costs for Participation

7a. Costs:

7b. Treatment and compensation for injury:

Section 8. Compensation for Participation

Section 9. Research Funding

Section 10. Voluntary Participation

Taking part in this research study is completely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Note that the Principal Investigator of this study may take you out of the research study at their sole discretion. Some reasons for this may include: 1) you did not follow the study procedures, 2) the risks of potential harm from the study became too high, or 3) the study was concluded earlier than expected. The Principal Investigator may have separate reasons instead of, or in addition to, those listed. If you do not sign this form, you will not receive research-related interventions.

Section 11. Contact Information for Questions or Concerns

[Check this section carefully. Contact information may need to be manually filled in.]

You have the right to ask any questions you may have about this research study. If you have questions, concerns, or complaints, or believe you may have developed an injury related to this research, contact the study team immediately. The study team’s contact information is below:

Contact:

Phone:

Email:

If you have questions regarding your rights as a research participant or you have concerns or general questions about the research or, as applicable, about your privacy and the use of your personal health information, contact the applicable Institutional Review Board. Contact information is listed below:

Contact:

Phone:

Email:

Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:

Discussed this study with an investigator,

Reviewed the information in this form, and

Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

Participant’s Legally Authorized Representative: By signing below, you indicate that you give permission for the participant to take part in this research.

(Signature of Participant’s Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative’s Authority to Act for Participant:

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Person Explaining the Research: Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

Only approved investigators for this research may explain the research and obtain informed consent.

A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.