CAR-T cell therapy extended consent document for R/R DLBCL/PMBCL

I give my consent for: autologous CAR-T cell therapy for relapsed DLBCL/PMBCL
(Infusion of your genetically modified T-cells after I have received chemotherapy)

☐ For relapsed/refractory diffuse large B-cell lymphoma
☐ For relapsed/refractory primary mediastinal B-cell lymphoma

Using

☐ Axicabtagene ciloleucel (Axi-cel, Kite)
☐ Tisagenlecleucel (Novartis)

Patient sticker

1. I understand that the side effects of fludarabine/ cyclophosphamide chemotherapy include:
   - Sickness and vomiting
   - Sore mouth and diarrhoea
   - Hair loss
   - An increased risk of infection
   - Fertility problems
   - A greater chance of developing cancer later in life

2. I understand that after I have received chemotherapy I must follow the treatment plan and advice of doctors and nurses, including:
   - Having an infusion of CAR-T cells
   - Staying as an inpatient for 2 weeks or more
   - Sticking to rules about who can visit me
   - Attending outpatient clinics after discharge weekly for 4-6 weeks
   - Contacting the CAR-T cell team or alert number to be admitted without delay if I become ill
   - I am not allowed to drive for 2 months
   - I am aware that I need to stay within an hour distance from Freeman Hospital for the first 30 days after CAR-T cell infusion and that I need to have an appointed person with me at all times, who can assist me.

3. I understand that there are benefits and risks to having a transplant.

   Concerning the ***benefits,*** it has been explained to me that:
   - The benefit of having CAR-T cells is greater than the risk of having this therapy
   - Having CAR-T cells will give me a better chance of being alive and well in two years' time than not having this therapy

   Concerning the ***risks***, it has been explained to me that:
   - CAR-T cell therapy could result in my death through infection and complications related to CAR-T cell therapy (3% average risk)
   - I understand that there is a very high chance that I will develop cytokine release syndrome leading to fevers, myalgia, headache, drop in blood pressure, fast heart beat and trouble with breathing. In most cases these symptoms are mild to moderate but in 10-15% of cases they can be severe and even life threatening.

- I understand that the treatment can cause frequently neurologic side effects from mild to moderate effects such as confusion and delirium, to headache, problems speaking and writing, to more severe and potentially more side effects with decrease in consciousness and, rarely, seizures or coma.
- I understand that the risk of being admitted to an intensive care unit is between 20-30% mainly for following reasons:
    - to support blood pressure
    - to improve oxygen supply by non-invasive ventilation
    - There is a 5-10% chance that I might require to be sedated and intubated for few days
    - There is a small chance that I may require kidney support
- I understand that there is a risk that my disease could still come back
- I understand that there is a theoretical risk that my genetically modified cells could develop into a cancer in the future
- I understand that a proportion of patients will have prolonged reduction (up to a year) in blood counts and that I might require injections to support my white cell count and regular blood products.
- I understand that depletion of normal B-lymphocytes might make me more susceptible to recurrent infections and I might require prolonged regular immunoglobulin replacement.

4. I understand that my treatment will be reported to national and international transplant registries but that my personal details will be kept confidential.

5. I understand that in a small proportion of patients the manufacturing companies are not able to produce a CAR-T product from the cells collected and therefore treatment might not be possible.

6. I understand that if my condition deteriorates significantly prior to the return of the manufactured CAR-T cells, that CAR-T treatment might not be possible.

7. I understand that in 20% of patients the CAR-T cells will not expand.

8. I understand that my chance of achieving long-term remission is 35 - 40% in line with current trial and real world data.

Lymphoma/CAR-T Consultant receiving consent:

PRINT NAME: _____ SIGN:_____ DATE _____

Patient or person responsible for patient:

I have received sufficient information about CAR-T cell therapy and wish to proceed:

PRINT NAME: _____ SIGN:_____ DATE _____