mTBI-Predict

Queen Elizabeth Hospital Birmingham
Part of University Hospitals Birmingham NHS Foundation Trust

mTBI-Predict

Mild Traumatic Brain Injury Biomarker Study, a prospective cohort biomarker study of military and civilian participants with mTBI

Informed Consent Form (Electronic Consent)

Participant trial number: __ __ __ __ __

Please select 'Yes' for each box on the form to confirm your consent

Principal Investigator: _____

1.	I confirm that I have read and understood the participant information sheet version __ __ __, dated _ _ /_ _ _ / _ _ _ _ version number __. __ for mTBI-Predict. I have had the opportunity to consider the information and ask questions and have had these answered satisfactorily.	Yes ☐ No ☐
2.	I understand that my participation is voluntary and that I am free to withdraw from the trial at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that even if I withdraw, data collected up to my withdrawal may still be used.	Yes ☐ No ☐
3.	I understand that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from the mTBI-Predict research team, representatives of the sponsor (University of Birmingham), from regulatory authorities, or from the NHS Trust, where this is relevant to my taking part in this research.	Yes ☐ No ☐
4.	I have read and understood the information in the participant information sheet about what happens with my personal data collected for this trial.	Yes ☐ No ☐
5.	I understand and acknowledge that data that identifies me by name, i.e. this consent form and the trial entry form, will be transferred electronically from where it is collected to be stored at Birmingham Clinical Trials Unit, University of Birmingham.	Yes ☐ No ☐
6.	I agree to the transfer of my blood and saliva samples to be stored until analysis at the University of Birmingham Human Biomaterials Resource Centre. They will later be analysed at the University of Birmingham or at other institutions or commercial companies, in the UK or abroad including the US.	Yes ☐ No ☐
7.	I understand that the information, samples, and images collected will be used for research only and that I will not be identified in any way in the analysis and reporting of the results.	Yes ☐ No ☐

8.	I agree that the samples I give and the images and data gathered about me will be used to support other related ethically approved research in the future. They will be shared anonymously with other researchers and I will not be identified in any way. This may include researchers working for other institutions, commercial companies, in the UK or abroad including the US.	Yes ☐ No ☐
9.	I understand that information about my previous medical history where relevant to this research, including from my GP, will be supplied in confidence to the mTBI-Predict team. I agree for my GP to be contacted and to provide this information.	Yes ☐ No ☐
10.	I agree to my GP being informed of my participation in this trial.	Yes ☐ No ☐
11.	I agree to take part in the mTBI-Predict Trial.	Yes ☐ No ☐
12.	**OPTIONAL:** I understand that the information held and maintained by NHS Digital and other central UK NHS bodies may be used to provide information about my health status. I agree to the research team sharing personal identifiable information with these UK registries to enable access to this data.	Yes ☐ No ☐
13.	**OPTIONAL:** I wish to receive a copy of this consent form via e-mail. If you select 'Yes', please provide the e-mail address below that you wish the consent form to be sent to. E-mail address:	Yes ☐ No ☐

Name of Participant		
I confirm that all of my information in the document above is correct. I understand that clicking "I agree" will electronically sign this form and that signing this form electronically is the equivalent of signing a physical document		I agree ☐ I disagree ☐
Signature (optional as required)		
Date		

Name of Person taking Consent		
I confirm that the nature of the trial has been explained to the participant. I understand that clicking "I agree" will electronically sign this form and that signing this form electronically is the equivalent of signing a physical document		I agree ☐ I disagree ☐
Signature (optional as required)		
Date		

When completed please provide a copy to the participant (either via e-mail as per the patient's consent or a printed copy). Please also retain a copy in the participant medical notes.

A printed copy should be filed in the Investigator Site File.