

Explanation and Informed Consent (For the dB/dt in Normal Operating Mode)

1. The objective of the experiment in which you are going to participate, is to determine the mechanisms of high order brain functions by measuring neuronal activity in the brain, using a noninvasive technique, MRI. The purpose of this type of research is to contribute to the establishment of treatments for neurological diseases such as senile dementia and to the education of mentally retarded children.
2. With a few exceptions, subjects participating in this study should be healthy adults, 20 years old or above (please notify the experimenter if you are under 20). To avoid possible dangers that may occur during the measurement, those who have past/current experiences of 1) epileptic seizure, 2) using pacemaker or artificial cardiac valve, 3) retaining metal fragments in the body, whose non-magnetism cannot be confirmed, 4) having difficulty with body-temperature regulation, 5) communication disorder (trouble speaking or hearing), 6) having or having had an occupation or haven taken part in previous activities that may result in accidental retention of magnetic objects in the body, or 7) claustrophobia (see back side for items to be checked), as well as females who are currently pregnant, cannot participate in the experiment.
3. The purpose of the MRI scan is purely research, it is not part of a medical checkup. However, the high-resolution anatomical image, which is taken once for each subject, will be examined by a medical doctor. You will be notified only if an abnormality is found in this anatomical image.
4. This experiment is conducted for scientific purposes only. Your personal information will not be released without your permission.
5. Following this explanation, the instructions for the task that you are going to perform during the experiment, will be explained. After that, you will enter the magnet bore or the simulator, to decide if you are willing to participate in this experiment. Even after you agree to participate, the experiment can be terminated at any time you wish. You will not bear any unfavorable consequence should the experiment be terminated under these circumstances.
6. This experiment will be conducted with MRI system whose magnetic field strength is 3 or 4 Tesla. They are called high magnetic field MRIs. Many hospitals and institutes in the world have been using them. Up till now, there has been no report of harmful influences caused by measurements with these MRI systems. However, the possibility that the exposure to the strong magnetic field may have harmful influences can not be completely ruled out at this time.
7. After you enter the magnet, you may feel sleepy or claustrophobic. It is not because of the magnetic field, but because you are lying in a fixed posture under quiet circumstances and are inside a narrow cylindrical space. A few people may feel faint, nauseous, or sense the metallic taste on the tongue. These symptoms will disappear after getting out of the magnet. Please inform the operator if these symptoms become severe. The experiment will be stopped immediately.
8. After the experiment, please fill out the questionnaire. If you notice any abnormal physical changes, please do not hesitate to report them to the operator or the Wako Safety Center, Riken (phone: 048-467-9293).
9. Any time after the experiment, we will discard the experimental data on you upon your request to the operator or the Wako Safety Center, Riken. However, we cannot do so after we publish the results.

(Continue on back)

I, after having been given explanations and instructions from the person in charge and reviewing thoroughly the contents listed above, agree to participate in this experiment of my own free will. The following questions were explained by the person in charge and were answered and filled out by me personally.

Name Given name _____ Family name _____
 Date of birth(D,M,Y) _____ / _____ / _____ Sex male female
 Address _____ Telephone _____

Signature _____ Experiment date (D,M,Y) _____ / _____ / _____

	Yes	No		Yes	No
Communication disorder _____	<input type="checkbox"/>	<input type="checkbox"/>	Body-temperature regulation difficulty _____	<input type="checkbox"/>	<input type="checkbox"/>
Claustrophobia _____	<input type="checkbox"/>	<input type="checkbox"/>	Pregnant _____	<input type="checkbox"/>	<input type="checkbox"/>
Experience of feeling ill because of flickering light _____				<input type="checkbox"/>	<input type="checkbox"/>
Experience of epileptic seizure _____	<input type="checkbox"/>	<input type="checkbox"/>	Pacemaker or artificial cardiac valve _____	<input type="checkbox"/>	<input type="checkbox"/>
Experience of metal grind, welding or mining work _____				<input type="checkbox"/>	<input type="checkbox"/>
Retaining metal fragments in the body, whose non-magnetism cannot be confirmed _____				<input type="checkbox"/>	<input type="checkbox"/>

※ You cannot participate in this experiment if your answer to any of the above questions is “Yes”.

	Yes	No		Yes	No
Migraine _____	<input type="checkbox"/>	<input type="checkbox"/>	Operation history _____	<input type="checkbox"/>	<input type="checkbox"/>
Experience of heart seizure, angina, arrhythmia _____				<input type="checkbox"/>	<input type="checkbox"/>
Artificial eye or tooth _____	<input type="checkbox"/>	<input type="checkbox"/>	Tattoo _____	<input type="checkbox"/>	<input type="checkbox"/>
Hard of hearing, sensitive to loud noises _____	<input type="checkbox"/>	<input type="checkbox"/>	Feel faint often _____	<input type="checkbox"/>	<input type="checkbox"/>
Medical care history for head injury _____				<input type="checkbox"/>	<input type="checkbox"/>

※ If your answer to any of the above questions is “Yes”, please provide the details in the space below and consult the experimenter. Depending on the nature of the details provided by you, you may not participate in this experiment.

If you have any other concerns, please describe them in the space below.

Name of the person in charge _____ Affiliation _____