

## APPENDIX 3 continued

### RULES FOR ADMINISTRATION OF SCREENING FORMS

#### GENERAL

1. All participants must complete both the initial and second screening forms before entering the controlled area.
2. Completion of the screening forms must be supervised by an authorised person (see Appendix 2) who must be satisfied that the participant has read the questions carefully and understands their importance.
3. The second screening form must be countersigned by an authorised person before the participant enters the controlled area. The form should only be signed if all questions have been answered satisfactorily (see below), the participant's UK GP details have been added and the participant has signed both screening forms and the consent form. The only exception to providing name and address of the UK GP details are collaborators from abroad. In such cases, instead of providing the participant's UK GP details, the participant needs to confirm in writing that he/ she is going to undertake the responsibility of contacting his/ her GP in the unlikely case of an incidental finding.
4. If the participant answers "no" to all questions on both screening forms and the authorised person is satisfied that the participant has given the questions due consideration, the participant may be permitted to enter the controlled area.

#### INITIAL SCREENING FORM

5. If the participant answers 'yes' to any of questions 1, 2, 3, 4, 8, 11, 12, 13 and 15 then the participant **MUST NOT** be allowed into the controlled area. The person supervising the screening should explain the situation clearly, making clear that there is no cause for alarm, and cancel any MRI examination that has been arranged. They should also point out that rejection as a research participant does not necessarily mean that a future MR scan for medical purposes would be unsafe and that they should be guided by the medical personnel concerned if such a need should arise.
6. If the participant answers 'yes' to any of questions 5, 6, 7, 10 and 14, the person must not be scanned unless medical advice is first taken and any medical supervision that may be recommended is implemented. In such cases, explicit permission to proceed must be obtained from the MR Safety Officer before scanning. The following specific rules apply in such cases:
  - (Q.6) A person who has had surgery that clearly did not involve implantation of metal (e.g. tonsillectomy) may be scanned. Persons who have had any surgery where the use of metal implants cannot be ruled out must not enter the controlled area unless it is first established that the implant contains no ferromagnetic material. They must not be scanned unless medical advice has been taken and any medical supervision that has been recommended is provided. Scanning may proceed only if the answer to question 6 has become "no" and the initial screening form has been re-administered and the answers reflect this.
  - (Q.7) A person wearing a dental plate or brace may enter the controlled area but must remove the device before being scanned. If it is not readily removable, the person should not be asked to remove it and scanning must not proceed.
  - (Q.10) A person suffering from thermo-regulatory problems, or epilepsy may enter the controlled area but must not be scanned without medical supervision. A person suffering from diabetes may enter the controlled area but must not be scanned without additional screening from Authorized Personnel as described under 4.2.4.
  - (Q.14) A woman with an intra-uterine contraceptive device may enter the controlled area but must not be scanned unless the type of IUD or contraceptive implant is known to be MR safe (examples: Mirena, Nova T-380, Implanon).

If there is ANY DOUBT as to whether it is safe to proceed, the participant **MUST NOT** be allowed to enter the controlled area.

7. If a participant has answered 'yes' to a question but is subsequently permitted to enter the controlled area, the facts and the basis of the decision must be documented and attached to the filed screening forms. Any material statements made by the participant should be made in writing on the screening form.

#### SECOND SCREENING FORM

8. If the participant answers 'yes' to question 1 then he/she should be asked to remove the item(s) in question, if that is practical, and then amend the answer and initial the change, or complete a fresh second screening form.
9. If the participant answers 'yes' to question 2, the initial screening form must be completed afresh and any affirmative answers acted upon in accordance with the rules above.
10. If the participant answers 'yes' to question 3, they must not be allowed into the controlled area.
11. A person answering 'yes' to question 5 must not be scanned, but may be allowed into the controlled area for other purposes (e.g. a pregnant authorised person may enter to supervise volunteers, but has the right to refuse to do so).