isvr Institute of Sound and Vibration Research

Guide to Experimentation Involving Human Subjects

Human Experimentation Safety and Ethics Committee

ISVR Technical Memorandum No 808

October 1996

University of Southampton

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UNIVERSITY OF SOUTHAMPTON

INSTITUTE OF SOUND AND VIBRATION RESEARCH

HUMAN SCIENCES GROUP

Guide to Experimentation involving Human Subjects

by

Human Experimentation Safety and Ethics Committee

ISVR Technical Memorandum No. 808

October 1996

Acknowledgements

This Technical Memorandum was prepared by members of the Human Experimentation Safety and Ethics Committee during 1995 and 1996. At the time of publication, the committee comprises: Professor M J Griffin (Chairman), Mr B W Lawton, Professor M E Lutman, Dr A M Martin, Dr G S Paddan, Dr J G Walker. Mrs H E Smith is Secretary to the Committee.

CONTENTS

ABSTRACT

All experiments with human subjects carried out under the aegis of the Institute of Sound and Vibration Research require the approval of the Human Experimentation Safety and Ethics Committee. This Technical Memorandum describes the procedures to be used by those applying for Committee approval and the procedures which will be used by the Committee when assessing applications. The responsibilities of the experimenter during the conduct of the experiment are also specified. Methods of quantifying any intended noise and vibration exposures are defined. The forms to be used when applying for the approval of the Committee and the consent forms to be used by participants in experiments are provided in appendices.

IMPORTANT NOTE:
This Technical Memorandum supersedes the previous *Guide to Experimentation involving Human Subjects,* ISVR Memorandum No. 663, 1985.

1.0 INTRODUCTION

1.1 To whom the Guide applies

All experiments involving human subjects carried out by staff or students of the Institute of Sound and Vibration Research (ISVR) require the approval of the Human Experimentation Safety and Ethics Committee. Approval must be sought from this Committee for experiments conducted within the ISVR and for experiments conducted by ISVR personnel at alternative locations (i.e. in the field or at other institutions) irrespective of whether permission has been granted by the safety and ethics committee of another institution. In some cases application to another committee will also be necessary.

This Technical Memorandum describes the procedures and guidelines by which approval for human experimentation is granted. Experimenters must be fully aware of their obligations when using human subjects.

The procedures outlined in this document do not apply to exposures which may be administered to patients attending the ISVR clinics for clinical investigations.

See Note 1.1 (Appendix A, Page 9)

1.2 Classification of experiments

For the purposes of this document, experiments are classified as either "USUAL" or "UNUSUAL". The boundary between USUAL and UNUSUAL is specified separately for different types of noise and vibration stimuli. The term UNUSUAL will also be applied by the Committee to various other conditions, investigations or enquiries.

1.3 Preliminary Trials

Exposures to noise and vibration conducted as preliminary trials must be confined to conditions which are defined as USUAL in this document. Preliminary trials do not require approval when they are restricted to subjects who are employees of the ISVR or others formally collaborating in the research. Students who are conducting research in the ISVR may also be included as subjects in the preliminary trial with the approval of the supervisor of the experiment. All experiments, other than preliminary trials, require approval. Approval should also be sought if the researcher is in any doubt as to the need for approval.

2.0 PROCEDURE

2.1 Obtaining approval

This section provides a checklist of the actions required to obtain approval for an experiment from the Human Experimentation Safety and Ethics Committee.

a) Discuss your proposed experiment with your supervisor. Reach an agreement on the experimental conditions to which subjects will be exposed.

b) Obtain a 'Request for Approval' form from a Group Secretary (see Appendix B).

c) Complete the 'Request for Approval' form ensuring that all relevant sections have been completed in sufficient detail to allow the Committee to reach a decision. (The following sections of this Technical Memorandum are intended to help in the completion of the form. Committee members are also available for advice.)

d) The completed 'Request for Approval' form must be counter-signed by your supervisor. A supervisor is required for applications by staff as well as students.

e) Distribute a copy of the completed form to each member of the Human Experimentation Safety and Ethics Committee. A list of current members is available from Group Secretaries.

f) If your application is approved, you will receive written notice of approval. The experiment must not commence before receiving this written approval.

g) If your application is not approved, you will receive written notification listing the reasons for refusal. Notice of refusal may include suggestions for improving the safety aspects of the experiment or a request for further information. Submit any requested information to the Secretary of the Committee. If the information is satisfactory, you will then receive written approval.

h) Once written approval has been received, you may proceed with the experiment as approved by the Committee.

i) You must inform the Committee if you make significant changes to the experiment. In some instances, it may be necessary to resubmit the application.

2.2 While conducting an experiment

After approval has been granted by the Committee, the experimenter is obliged to carry out an ethical and safe experiment.

2.2.1 Laboratory Safety The experimenter should be acquainted with the Laboratory Safety Procedure. Each laboratory area within ISVR has a document outlining general and electrical safety procedures. The document also states the name of the laboratory supervisor with overall responsibility for the laboratory.

2.2.2 Subject Consent All subjects must give their informed consent prior to taking part in an experiment. The procedures involved in the experiment and the purpose of the experiment must be explained to subjects if they are to give their informed consent. It must also be made clear to the subjects that they can withdraw from the experiment at any time, without giving a reason. In instances where subjects are under 18 years of age, the Committee will require the informed consent of a parent or guardian. The Committee will also require that the child is accompanied by a second adult (i.e. an adult in addition to the experimenter) throughout the experiment. Any such requirements will be made when written approval is given. Specimen copies of consent forms are provided in Appendices C, D, E and F. If, for any reason, subject consent forms are not to be used this must be brought to the attention of the Committee together with an explanation.

2.2.3 Exposure Archive Completed subject consent forms, together with a description of the exposure conditions and any significant observations regarding the health and welfare of subjects, must be filed in the Exposure Archive operated by the Human Experimentation Safety and Ethics Committee.

See Note 2.2.3 (Appendix A, Page 9)

2.2.4 Accidents In the event of an accident or complaint arising from an experiment the details should be reported to the Committee and to the Departmental Safety Officer at the time of the incident or as soon as possible thereafter.

2.2.5 Discovery of a disorder in a subject In the event of the discovery of a previously unidentified disorder in the subject, at least one of the following people should be consulted immediately: the supervisor, a member of the Human Experimentation Safety and Ethics Committee, or another responsible member of the Human Sciences Group. The relevant information and subsequent actions should be documented and forwarded to the Human Experimentation Safety and Ethics Committee Secretary.

2.2.6 Data Confidentiality Information obtained from subjects must normally be regarded as confidential. If any personal information or subject's responses are communicated to other people, such information must not be identified with individual subjects without the prior permission of the subject concerned. Attention is also drawn to regulations laid down in the 1985 Data Protection Act covering the storage of personal information in computer systems (copies of the University's relevant registrations are held by the Committee Secretary).

See Appendix G, Page 37

3.0 CLASSIFICATION OF EXPERIMENTS WITH ACOUSTIC STIMULI

3.1 General limitation

In no circumstances may personal sound exposures be allowed to exceed the Second Action Level or the Peak Action Level defined in the Noise at Work Regulations, 1989 and the accompanying Health and Safety Executive Noise Guides. This limitation applies to any work carried out by members of the Institute, whether as part of an experiment or otherwise.

See Notes 3.1 (i) and (ii) (Appendix A, Page 9)

3.2 Unusual non-impulsive sounds

Any laboratory experiment shall be classified as UNUSUAL if either: (i) the daily personal exposure ($L_{EP,d}$) exceeds 76 dB(A), or (ii) the sound pressure level of any stimulus exceeds 120 dB(A) regardless of duration. Requests for approval must contain an explanation of how the stimulus levels are to be measured.

See Notes 3.2 (i)-(viii) (Appendix A, Pages 9-10)

3.3 Unusual impulsive sounds

An exposure to clicks or impulse/impact sounds shall be classified as UNUSUAL if any stimulus exceeds a peak sound pressure level of 135 dB.

See Note 3.3 (Appendix A, Page 11)

3.4 Very low or very high frequency sounds

For experiments involving stimuli containing components mainly at frequencies below 100 Hz or above 8 kHz, the above limits expressed in dB(A) shall be replaced by numerically equal limits expressed in dB SPL (linear). Requests for approval should express the proposed exposure levels in dB SPL (linear).

4.0 CLASSIFICATION OF EXPERIMENTS WITH VIBRATION STIMULI

4.1 Unusual whole-body vibration

Laboratory-type experiments in which the whole-body vibration exposure exceeds a vibration dose value of 15 $m.s^{-1.75}$ in any one day shall be classified as UNUSUAL.

See Notes 4.1 (i)-(viii) (Appendix A, Pages 11-12)

4.2 Unusual hand-transmitted vibration

(i) Laboratory-type experiments in which the vibration exposure exceeds an 8-hour 'energy-equivalent' magnitude of 2.8 ms^{-2} r.m.s. in any one day shall be classified as UNUSUAL.

(ii) Laboratory type experiments in which the frequency-weighted acceleration exceeds 50 ms^{-2} r.m.s. irrespective of exposure duration shall be classified as UNUSUAL.

See Notes 4.2 (i)-(v) (Appendix A, Page 12)

4.3 Unusual low-frequency motion experiments

Laboratory-type experiments conducted at frequencies below 0.5 Hz shall be classified as UNUSUAL if the magnitudes and durations of acceleration are such that the exposures would be UNUSUAL if the frequency of oscillation was 0.5 Hz.

When the frequency of oscillation is below 0.5 Hz, the experimenter must state what precautions are to be taken in case of the development of motion sickness.

When the frequency of oscillation is below 0.5 Hz, the experimenter must state what precautions are to be taken in the case of any postural instability (e.g. falling of standing subjects).

When the motion is not oscillatory (e.g. constant speed rotation), the precautions above also apply.

5.0 OTHER UNUSUAL CONDITIONS

5.1 Experiments

The Committee will decide whether a proposed experiment is USUAL and UNUSUAL.

5.2 Preliminary Trials

For the purposes of preliminary trials the following shall be considered UNUSUAL and must not be used:

- caloric stimulation other than in the clinic with appropriate supervision
- static pressures outside the range from -300 daPa to +200 daPa applied to the ear
- insertion of devices in the ear other than those listed below.

The use of the following does not qualify an experiment as UNUSUAL when applied in accord with normal clinical practice:

- oto-admittance probes
- oto-acoustic emission probes
- oto-scope speculae
- in-the-ear microphone systems approved for this purpose.

6.0 BIBLIOGRAPHY

1. Health and Safety Executive (1989) Noise at Work (Noise Guide No 1: Legal duties of employers to prevent damage to hearing / Noise Guide No 2: Legal duties of designers, manufacturers, importers and suppliers to prevent damage to hearing). *The Noise at Work Regulations 1989.* HMSO, London.

2. Statutory Instruments 1989 No 1790 Health and Safety *The Noise at Work Regulations 1989.* HMSO, London.

3. British Standards Institution (1987a) Measurement and evaluation of human exposure to whole-body mechanical vibration and repeated shock. *BS6841.* London: British Standards Institution.

4. British Standards Institution (1987b) Measurement and evaluation of human exposure to vibration transmitted to the hand. *BS6842.* London: British Standards Institution.

APPENDIX A

Technical Notes to the Guide

TECHNICAL NOTES TO THE GUIDE

Note 1.1

Patients are persons undergoing investigations primarily for their own medical benefit. Subjects are persons undergoing investigations primarily for the progress of research. Experiments include all investigations involving human subjects including survey and questionnaire studies.

Note 2.2.3

Experimenters are required to provide the Secretary of the Human Experimentation Safety and Ethics Committee with the required documentation on completion of an experiment. This will usually be expected to be within 3 months of the granting of approval. The supervisor is responsible for ensuring that the documentation is provided. The Committee may withhold approval of subsequent experiments where adequate information on previous experiments has not been provided.

Notes 3.1 (i) & (ii)

(i) The Second Action Level means a daily personal exposure ($L_{EP,d}$) of 90 dB(A).

(ii) The Peak Action Level means a peak sound pressure of 200 pascals (140 dB re 20 μPa).

Notes 3.2 (i)-(viii)

(i) For sounds presented by earphone, a suitable coupler must be used to measure the sound level (e.g. for supra-aural and circum-aural earphones, an IEC 303 acoustic coupler or IEC 318 artificial ear; for insert earphones, oto-admittance probes or hearing aids, a 2-cc coupler, an IEC 711 occluded-ear simulator, or Zwislocki ear simulator). Where different couplers give appreciably different levels, the highest measured level must be used.

(ii) When insert earphones are to be used in small ear canals, such as with babies and young children, measurements of the sound pressure level in a representative volume must be given. This is important because insert earphones will generally produce a higher sound pressure level in a small ear canal than in a coupler that represents an adult ear, for a given driving signal.

(iii) Where sound levels are conventionally measured in terms of hearing level, such as pure tones delivered by audiometers via supra-aural earphones, the above limits expressed in dB(A) may be replaced by numerically equal limits expressed in dB HL.

(iv) Where the test protocol requires flexibility to accommodate differences between subjects, such as when using adaptive procedures, the personal daily exposure will differ from subject to subject. Requests for approval should be accompanied by a calculation based on the highest possible sound exposure that can occur within the protocol.

(v) Where stimuli are delivered monaurally, the limits stated below apply to each ear separately. Each ear may receive exposure up to the limits in one day.

(vi) Daily personal noise exposure is calculated using the principle that equal amounts of A-weighted acoustic energy received during one day will be equally hazardous to the hearing, regardless of the time history. Energy is a combination of sound pressure squared and time; a doubling of energy corresponds to an increase of 3 dB in sound level. It follows that a daily (8-hour) personal exposure of 76 dB(A) is equivalent to 79 dB(A) for four hours, and so on as illustrated in Table 1.

Table 1 Sound levels above which an experiment is defined as UNUSUAL

Total 'on-time' during any 24 hour period	Sound level which defines an 'UNUSUAL' experiment
8 h	76 dB(A)
4 h	79 dB(A)
2 h	82 dB(A)
60 min	85 dB(A)
30 min	88 dB(A)
15 min	91 dB(A)
12 min	92 dB(A)
6 min	95 dB(A)
3 min	98 dB(A)
90 s	101 dB(A)
45 s	104 dB(A)
36 s	105 dB(A)
22.5 s	107 dB(A)
11.2 s	110 dB(A)
5.6 s	113 dB(A)
2.8 s	116 dB(A)
1.4 s	119 dB(A)
any duration	120 dB(A)

(vii) Calculation of daily personal noise exposure for an experiment may be performed using the equations provided below:

For a single stimulus:

The fractional dose, f, is given by: $f = \frac{t}{8}$ antilog [0.1 (L-76)]

where L is the A-weighted sound level of the stimulus and t is the exposure duration, in hours.

For more than one stimulus:

The total dose, F, is given by : $F = f_1 + f_2 + \ldots + f_n$

where f_1 to f_n are calculated as above.

The eight-hour or daily personal exposure level in dB(A) = 10 log F + 76.

(viii) A-weighting. The A-weighting is defined relative to 1 kHz, for sinusoidal signals of given frequency. The values may be applied to find the appropriate A-weighted sound level of a broadband signal (e.g. noise) by correcting the octave-band sound pressure levels (for the corresponding mid-frequencies) and summing the resulting spectrum energy-wise.

Frequency (Hz)	63	125	250	500	1 000	2 000	3 000	4 000	6 000	8 000
Relative Response (dB)	-26	-16	-9	-3	0	1	1	1	0	-1

Note 3.3

Any Request for Approval of an experiment involving clicks or impulse/impact sounds should contain an explanation of how the peak sound pressure level is to be measured, in addition to the information required for experiments involving non-impulsive sounds.

Notes 4.1 (i)-(viii)

(i) The vibration dose value for a single stimulus may be calculated using the following equation.

$$\text{vibration dose value } (\text{ms}^{-1.75}) = \left(\int_{t=0}^{t=T} a^4(t)\ dt \right)^{1/4}$$

where $a(t)$ is the frequency-weighted acceleration time history.

(ii) If the crest factor of the motion is low (i.e. ratio of peak to r.m.s. value of the frequency-weighted time history is less than 6.0), the estimated vibration dose value (*eVDV*) may be used to calculate the approximate vibration dose value from the r.m.s. of the frequency-weighted acceleration, a_{rms} in ms^{-2}, and exposure time, t, in seconds:

$$\text{estimated vibration dose value } (\text{ms}^{-1.75}) = 1.4\ a_{rms} \cdot t^{1/4}$$

(iii) Where more than one stimulus is to be presented, the total vibration dose value shall be calculated from the fourth root of the sum of the fourth powers of the vibration dose values of each stimulus.

(iv) The acceleration magnitude is to be frequency-weighted according to the appropriate weightings defined in British Standard 6841 (1987). Alternatively, the approximations to these weightings shown in Table 2 may be used.

(v) Rotational vibration exposures are to be assessed in terms of the translational vibration occurring over the principal contact area with the body.

(vi) The weighted values apply to the vibration at the principal surface supporting the standing or seated body. The orthogonal co-ordinate system defining the *x*-, *y*- and *z*-axes for standing and seated persons is that defined in British Standard 6841 (1987) (i.e. *x*-axis is fore-and-aft; *y*-axis is lateral; *z*-axis is vertical).

(vii) If subjects are exposed to motions when in postures other than standing or seated, the evaluations shall be made with the weightings appropriate to the geocentric axis (e.g. *z*-axis is vertical and the *x*- and *y*-axes are horizontal for a recumbent posture).

Table 2 Frequency weightings for *x*-, *y*- and *z*-axis whole-body vibration.

Frequency, Hz	*z*-axis	*x*- or *y*- axis
0.5	0.4	1.0
0.63	0.4	1.0
0.8	0.4	1.0
1.0	0.4	1.0
1.25	0.4	1.0
1.6	0.4	1.0
2.0	0.4	1.0
2.5	0.5	0.8
3.15	0.63	0.63
4.0	0.8	0.5
5.0	1.0	0.4
6.3	1.0	0.32
8.0	1.0	0.25
10.0	1.0	0.2
12.5	1.0	0.16
16.0	1.0	0.125
20.0	0.8	0.100
25.0	0.64	0.080
31.5	0.5	0.063
40.0	0.4	0.050
50.0	0.32	0.040
63.0	0.25	0.032
80.0	0.2	0.025

(viii) Table 3 shows the root-mean-square accelerations that produce a vibration dose value of 15 $ms^{-1.75}$ for sinusoidal excitation at frequencies from 0.5 to 80.0 Hz for durations from 1 second to 8 hours.

Notes 4.2 (i)-(v)

(i) The 8-hour energy equivalent magnitude $a_{hw(eq,\ 8h)}$ of an exposure of T seconds is given by:

$$a_{hw(eq,\ 8h)} = \left(\frac{1}{28800}\int_{t=0}^{t=T} a^2_{hw}(t)\ dt\right)^{1/2}$$

where $a_{hw}(t)$ is the frequency-weighted acceleration time history.

(ii) The vibration is to be frequency-weighted according to the weighting defined in British Standard 6842 (1987). Alternatively, the approximation to this weighting given in Table 4 may be used.

(iii) The weighted values apply to the points of principal contact between the hand and the vibrating device.

(iv) Table 5 shows the root-mean-square accelerations of sinusoidal excitation that produce an 8-hour 'energy-equivalent' magnitude at frequencies from 8 to 1 000 Hz for durations from 112.5 s to 8 h.

(v) Where the vibration is dominated by energy either at frequencies less than 8 Hz or greater than 1 000 Hz, the weighting factors at 8 Hz and 1 000 Hz should be applied, respectively.

Table 3 **The root-mean-square accelerations corresponding to estimated vibration dose values of 15 $ms^{-1.75}$.**

Frequency	*z*-axis vibration				*x*- and *y*-axis vibration			
Hz	1 s	1 min	1 h	8 h	1 s	1 min	1 h	8 h
0.5	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
0.63	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
0.8	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
1.0	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
1.25	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
1.6	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
2.0	26.78	9.62	3.46	2.06	10.71	3.85	1.38	0.82
2.5	21.43	7.70	2.77	1.64	13.39	4.81	1.73	1.03
3.15	17.01	6.11	2.19	1.30	16.87	6.06	2.18	1.30
4.0	13.39	4.81	1.73	1.03	21.43	7.70	2.76	1.64
5.0	10.71	3.85	1.38	0.82	26.79	9.62	3.46	2.06
6.3	10.71	3.85	1.38	0.82	33.80	12.14	4.36	2.59
8.0	10.71	3.85	1.38	0.82	42.86	15.40	5.53	3.29
10.0	10.71	3.85	1.38	0.82	53.57	19.25	6.92	4.11
12.5	10.71	3.85	1.38	0.82	66.96	24.06	8.64	5.14
16.0	10.71	3.85	1.38	0.82	85.71	30.80	11.06	6.58
20.0	13.39	4.81	1.73	1.03	107.14	38.50	13.83	8.22
25.0	16.74	6.02	2.16	1.28	133.93	48.12	17.29	10.28
31.5	21.09	7.58	2.72	1.62	168.75	60.13	21.79	12.95
40.0	26.78	9.62	3.46	2.06	214.28	76.99	27.66	16.45
50.0	33.48	12.03	4.32	2.57	267.86	96.24	34.58	20.56
63.0	42.18	15.16	5.45	3.24	337.50	121.27	43.57	25.91
80.0	53.57	19.25	6.92	4.11	428.57	153.99	55.33	32.90

Table 4 Frequency weighting for hand-transmitted vibration.

Frequency, Hz	Weighting
8	1.0
16	1.0
31.5	0.5
63	0.25
125	0.125
250	0.062 5
500	0.031 2
1 000	0.015 6

Table 5 **The root-mean-square acceleration corresponding to 8-hour 'energy-equivalent' magnitudes of 2.8 ms^{-2}.**

Frequency	Duration				
Hz	112.5 s	7.5 min	30 min	2 h	8 h
8	44.8	22.4	11.2	5.6	2.8
16	44.8	22.4	11.2	5.6	2.8
31.5	89.6	44.8	22.4	11.2	5.6
63	179.2	89.6	44.8	22.4	11.2
125	358.4	179.2	89.6	44.8	22.4
250	716.8	358.4	179.2	89.6	44.8
500	1 443.6	716.8	358.4	179.2	89.6
1 000	2 867.0	1 443.6	716.8	358.4	179.2

APPENDIX B

Specimen 'Request For Approval' Form

UNIVERSITY OF SOUTHAMPTON
INSTITUTE OF SOUND AND VIBRATION RESEARCH

HUMAN SCIENCES GROUP

HUMAN EXPERIMENTATION SAFETY AND ETHICS COMMITTEE

Request for Approval of Ethical, Safety and Insurance Aspects of an Experiment Involving Human Subjects

A. DESCRIPTION OF THE PROPOSED EXPERIMENT

Researcher in Charge of Experiment: .....

Supervisor(s): .....

Title of Experiment: .....

.....

Proposed Starting Date: .....
(Allow 1 week for 'USUAL' exposures; 3 weeks for 'UNUSUAL' exposures.)

Details of Exposure: (Describe on a printed attached document the exposure conditions. Identify all potential risks, such as noise, vibration, attachments to subjects, physical hazards, electrical hazards, intrusion of privacy and breach of confidentiality. Show calculations used to decide if exposures are USUAL or UNUSUAL.)

Exposure details attached ☐ Yes

Exposures are USUAL, or ☐

Exposures are UNUSUAL, or ☐

Cannot decide. ☐

Number of Subjects: ..... **Maximum Number of Sessions per Subject:** .....

Subject Age Range: ..... **Source of Subjects:** .....

Payment to Subjects: **Yes** ☐ **No** ☐

If YES state amount paid per subject: .....

Proposed Selection of Subjects: (Give details)

(I) By Health Questionnaire .....

(II) By Screening Tests .....

(III) Other Confidential Information .....

(IV) Contra-indications .....

Control of Stimulus: (Describe method for generating, controlling and measuring the stimulus, including any safety features preventing over-exposure.)

.....

.....

Other Potential Hazards: (e.g. use of electrodes, other attachments to subject, devices or implements inserted into the ear, application of static pressure to the ear, caloric stimulation, physical manipulation of the subject, administration of drugs or application of any compound, control of stimulation using non-proprietary software.)

.....

.....

Is the experimental equipment within its calibration and electrical safety inspection period?

Yes ☐ No ☐

Other relevant ethical and safety precautions:

.....

B. OBLIGATIONS OF THE EXPERIMENTER:

I confirm that the voluntary informed consent of all subjects will be obtained using the appropriate form, and that a record of all experimental and trial exposures will be kept. I also undertake to ensure the confidentiality of any personal information which the subject provides during the course of the experiment, unless the subject consents to the disclosure of such information. I further undertake to conform with the University's Data Protection Registrations.

Date: ....

Signed, Researcher in Charge of Experiment

I have reviewed this application and found it clear and accurate, complete and suitable for submission to the Human Experimentation Safety and Ethics Committee. I also undertake to ensure that the storage of personal information in computer systems will conform with the University's Data Protection Registrations.

Date: ....

Signed, Supervisor

C. **TO BE COMPLETED BY APPLICANT** and submitted with request.

Researcher in Charge of Experiment: .....

Supervisor(s):.....

Title of Experiment: .....

.....

Date of Submission of Request for Approval: .....

D. **TO BE COMPLETED BY MEMBER OF HUMAN EXPERIMENTATION SAFETY AND ETHICS COMMITTEE** and returned to Committee Secretary.

..... Approved as USUAL

..... Approved as USUAL subject to the additional conditions or comments listed below.

..... Needs Revision

..... Classify as UNUSUAL, with referral for insurance

..... Not Approved

(Indicate appropriate category)

Date ..... Signed .....

Additional Comments:

Queries concerning the Request for Approval should be made to the Committee Secretary.

APPENDIX C

Specimen consent form to be completed by adult subjects taking part in an experiment (Adults are 18 years of age or older.)

Experimenters may wish to include the following wording on their consent form if they intend to pay their subjects:

"I understand that for my participation in this experiment I am to be paid the sum of £..... for my attendance on ..... occasion(s)."

Specimen consent forms are available on disk from ISVR Group Secretaries

Consent form to be completed by adult subjects taking part in an experiment
(Adults are 18 years of age or older.)

Exposure Number: .....

University of Southampton
Institute of Sound and Vibration Research

Before completing this form, please read the list of contra-indications which has been provided by the experimenter on the reverse of this form.

This consent form applies to a subject volunteering to undergo an experiment for research purposes. The form is to be completed before the experiment commences.

I, ...

of .....
(address or department)

consent to take part in .....

to be conducted by.....

during the period ..... to ..... 19 .....

The purpose and nature of this experiment have been explained to me. I understand that the investigation is to be carried out solely for the purposes of research. I am willing to act as a volunteer for that purpose on the understanding that I shall be entitled to withdraw this consent at any time, without giving any reasons for withdrawal. My replies to the above questions are correct to the best of my belief, and I understand that they will be treated by the experimenter as confidential.

Date: ..... Signed: .....
(Volunteer subject)

I confirm that I have explained to the subject the purpose and nature of the investigation which has been approved by the Human Experimentation Safety and Ethics Committee.

Date: ..... Signed: .....
(Researcher in charge of experiment)

This form must be submitted to the Secretary of the Human Experimentation Safety and Ethics Committee on completion of the experiment.

Please give details if you have recently received treatment, or are currently undergoing treatment, for any of the conditions listed below:

Troublesome Tinnitus .....

Current Ear Disease (e.g. persistent ear pain, ear infection or ear discharge)

.....

Cardiovascular disease .....

Epilepsy .....

A psychiatric condition .....

Other (please specify) .....

APPENDIX D

Specimen consent form to be completed by parent or guardian of child subject taking part in an experiment. (Children are 17 years of age or younger.)

Consent form to be completed by parent or guardian of child subject taking part in an experiment

(Children are of 17 years of age or younger.)

Exposure Number: .....

University of Southampton
Institute of Sound and Vibration Research

Before completing this form, please read the list of contra-indications which has been provided separately by the experimenter.

This consent form applies to a subject volunteering to undergo an experiment for research purposes. The form is to be completed before the experiment commences.

I, ...

of .....
(address or department)

consent to this child .....

taking part in .....

to be conducted by .....

during the period ..... to ..... 19 .....

The purpose and nature of this experiment have been explained to me. I understand that the investigation is to be carried out solely for the purposes of research. I am willing to allow this child to act as a volunteer for that purpose on the understanding that I shall be entitled to withdraw this consent at any time, without giving any reasons for withdrawal. The child may also withdraw his or her consent and stop the experiment without giving reasons for withdrawal. My replies to the above questions are correct to the best of my belief, and I understand that they will be treated by the experimenter as confidential.

Date: ..... Signed: .....
(Parent or Guardian of Volunteer Subject)

I confirm that I have explained to the subject the purpose and nature of the investigation which has been approved by the Human Experimentation Safety and Ethics Committee.

Date: ..... Signed: .....
(Researcher in charge of experiment)

This form must be submitted to the Secretary of the Human Experimentation Safety and Ethics Committee on completion of the experiment.

Please give details if your child has recently received treatment, or is currently undergoing treatment, for any of the conditions listed below:

Troublesome Tinnitus .....

Current Ear Disease (e.g. persistent ear pain, ear infection or ear discharge)

.....

Cardiovascular disease .....

Epilepsy .....

A psychiatric condition .....

Other (please specify) .....

APPENDIX E

Specimen Vibration Experiment Exposure and Consent Form to be completed by adult subjects taking part in an experiment (Adults are 18 years of age or older)

Experimenters may wish to include the following wording on their consent form if they intend to pay their subjects:

"I understand that for my participation in this experiment I am to be paid the sum of £..... for my attendance on ..... occasion(s)."

Specimen consent forms are available on disk from ISVR Group Secretaries

Consent form to be completed by adult subjects taking part in an experiment
(Adults are 18 years of age or older).

Exposure Number: .....

Vibration Experiment Exposure and Consent Form

Before completing this form, please read the 'Information for Subjects' on the reverse side of this sheet.

(i) Name ..... (Mr/Mrs/Miss/)

(ii) Do you have any of the conditions listed on the reverse side of this form?.....

(iii) Have you ever suffered any serious illness or injury? .....

(iv) Are you under medical treatment or suffering disability affecting your daily life? ....

.....

If your answer is 'YES' to questions (ii), (iii) or (iv), please give details to Experimenter.

DECLARATION

I volunteer to be a subject in a vibration experiment. My replies to the above questions are correct to the best of my belief, and I understand that they will be treated by the experimenter as confidential. I understand that I may at any time withdraw from the experiment and that I am under no obligation to give reasons for withdrawal or to attend again for experimentation.

I undertake to obey the regulations of the laboratory and instructions of the Experimenter regarding safety, subject only to my right to withdraw declared above. The purpose and methods of the research have been explained to me and I have had the opportunity to ask questions.

Signature of Subject ..... Date .....

I confirm that I have explained to the subject the purpose and nature of the investigation which has been approved by the Human Experimentation Safety and Ethics Committee.

Signature of Experimenter ..... Date .....

Medical assistance is available if required.

Cont./d...

This form must be submitted to the Secretary of the Human Experimentation Safety and Ethics Committee on completion of the experiment.

Persons with any of the following conditions are usually considered unfit for vibration experiments

Active disease of respiratory system: including recent history of coughing-up blood or chest pain.

Active disease of the gastro-intestinal tract: including internal or external hernia, peptic ulcer, recent gall-bladder disease, rectal prolapse, anal fissure, haemorrhoids or pilonidal sinus.

Active disease of the genito-urinary system: including kidney stones, urinary incontinence or retention or difficulty in micturition.

Active disease of the cardiovascular system: including hypertension requiring treatment, angina of effort, valvular disease of the heart, or haemophilia.

Active or chronic disease or disorders of the nervous system: including eye and ear disorders and any disorder involving motor control, wasting of muscles, epilepsy or retinal detachment.

Pregnancy: any woman known to be pregnant should not participate as a subject in a vibration experiment.

Mental Health: subjects must be of sound mind and understanding and not suffering from any mental disorder that would raise doubt as to whether their consent to participate in the experiment was true and informed.

Recent trauma and surgical procedures: persons under medical supervision following surgery or traumatic lesions (e.g. fractures) should not participate in vibration experiments.

Prosthesis: persons with internal or external prosthetic devices normally should not participate in vibration experiments (although dentures need not exclude participation in experiments with low magnitudes of vibration).

Other: .....
(For completion by experimenter)

To be completed by the Experimenter:

VIBRATOR:

DESCRIPTION OF VIBRATION: State levels, frequencies, axes, durations etc. (If subject is in direct or indirect control of the vibration level, also state maximum vibration level for each condition.) Indicate subject posture, seat type, etc. and any other factors affecting subject exposure. Description must be sufficient to enable reader to reproduce a similar exposure pattern.

COMMENTS: (If more space is required, please attach a continuation sheet.)

APPENDIX F

Specimen Vibration Experiment Exposure and Consent Form
to be completed by the parent or guardian of a
child subject taking part in an experiment.

(Children are 17 years of age or younger.)

Consent form to be completed by parent or guardian of child subject taking part in an experiment

(Children are of 17 years of age or younger.)

Exposure Number: .....

Vibration Experiment Exposure and Consent Form

Before completing this form, please read the 'Information for Subjects' on the reverse side of this sheet.

(i) Child's Name .....

(ii) Does the child have any of the conditions listed on the reverse side of this form? .....

(iii) Has the child ever suffered any serious illness or injury? .....

(iv) Is the child under medical treatment or suffering disability affecting their daily life? .....

If your answer is 'YES' to questions (ii), (iii) or (iv), please give details to Experimenter.

DECLARATION

I am willing to allow this child to act as a volunteer subject in a vibration experiment on the understanding that I shall be entitled to withdraw this consent at any time, without giving any reasons for withdrawal. The child may also withdraw his or her consent and stop the experiment without giving reasons for withdrawal. My replies to the above questions are correct to the best of my belief, and I understand that they will be treated by the experimenter as confidential. The child undertakes to obey the regulations of the laboratory and instructions of the Experimenter regarding safety, subject only to his or her right to withdraw declared above. The purpose and methods of the research have been explained to me and the child and we have had the opportunity to ask questions.

Signature of Parent or Guardian ..... Date .....

I confirm that I have explained to the subject the purpose and nature of the investigation which has been approved by the Human Experimentation Safety and Ethics Committee.

Signature of Experimenter ..... Date .....

Medical assistance is available if required.

Cont./d...

This form must be submitted to the Secretary of the Human Experimentation Safety and Ethics Committee on completion of the experiment.

Persons with any of the following conditions are usually considered unfit for vibration experiments

Active disease of respiratory system: including recent history of coughing-up blood or chest pain.

Active disease of the gastro-intestinal tract: including internal or external hernia, peptic ulcer, recent gall-bladder disease, rectal prolapse, anal fissure, haemorrhoids or pilonidal sinus.

Active disease of the genito-urinary system: including kidney stones, urinary incontinence or retention or difficulty in micturition.

Active disease of the cardiovascular system: including hypertension requiring treatment, angina of effort, valvular disease of the heart, or haemophilia.

Active or chronic disease or disorders of the nervous system: including eye and ear disorders and any disorder involving motor control, wasting of muscles, epilepsy or retinal detachment.

Pregnancy: any woman known to be pregnant should not participate as a subject in a vibration experiment.

Mental Health: subjects must be of sound mind and understanding and not suffering from any mental disorder that would raise doubt as to whether their consent to participate in the experiment was true and informed.

Recent trauma and surgical procedures: persons under medical supervision following surgery or traumatic lesions (e.g. fractures) should not participate in vibration experiments.

Prosthesis: persons with internal or external prosthetic devices normally should not participate in vibration experiments (although dentures need not exclude participation in experiments with low magnitudes of vibration).

Other:.....
(For completion by experimenter)

To be completed by the Experimenter:

VIBRATOR:

DESCRIPTION OF VIBRATION: State levels, frequencies, axes, durations etc. (If subject is in direct or indirect control of the vibration level, also state maximum vibration level for each condition.) Indicate subject posture, seat type, etc. and any other factors affecting subject exposure. Description must be sufficient to enable reader to reproduce a similar exposure pattern.

COMMENTS: (If more space is required, please attach a continuation sheet.)

APPENDIX G

The Data Protection Principles

SCHEDULES

SCHEDULE 1

Section 2(1).

THE DATA PROTECTION PRINCIPLES

PART I

THE PRINCIPLES

Personal data held by data users

1. The information to be contained in personal data shall be obtained, and personal data shall be processed, fairly and lawfully.

2. Personal data shall be held only for one or more specified and lawful purposes.

3. Personal data held for any purpose or purposes shall not be used or disclosed in any manner incompatible with that purpose or those purposes.

4. Personal data held for any purpose or purposes shall be adequate, relevant and not excessive in relation to that purpose or those purposes.

5. Personal data shall be accurate and, where necessary, kept up to date.

6. Personal data held for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

7. An individual shall be entitled—

(*a*) at reasonable intervals and without undue delay or expense—

(i) to be informed by any data user whether he holds personal data of which that individual is the subject; and

(ii) to access to any such data held by a data user; and

(*b*) where appropriate, to have such data corrected or erased.

Personal data held by data users or in respect of which services are provided by persons carrying on computer bureaux

8. Appropriate security measures shall be taken against unauthorised access to, or alteration, disclosure or destruction of, personal data and against accidental loss or destruction of personal data.