AUGGMED (Automated Serious Game Scenario Generator for Mixed Reality Training)

D8.3.1 Report on ethical approvals and approvals for the collection of personal data

Deliverable No.		**D8.3.1**	
Workpackage No.	**WP8**	Workpackage Title	**Project Management**
Task No.	**T8.4**	Activity Title	**Ethical and legal issues**
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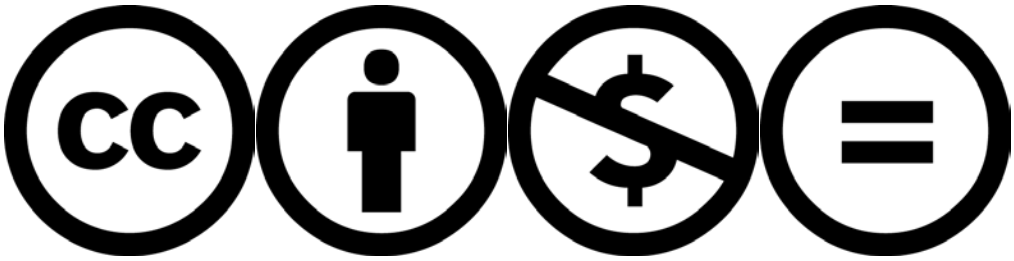
Status (F: final; D: draft; RD: revised draft):		**Final**	
File Name:		**AUGGMED_ D8.3.1_ReportOnEthicalApprovalsAndApprovalsForTheCollectionOfPersonalData.doc**	
Project start date, duration		**01 June 2015, 36 Months**	



EXECUTIVE SUMMARY

The following document outlines the AUGGMED ethics framework, which should be used to support all activities in the project that may require ethical approval. It summarises the structure of the ethics committee, the submission and approval process of any ethical issues and requirements that may arise over the duration of the project, and the ethical guiding principles for partners of the project. The appendices provide a number of related ethics forms which can be used as working documents in order to obtain the necessary ethical approval for activities carried out during the project.

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REVISION HISTORY

Revision no.	Date of Issue	Author(s)	Brief Description of Change
1	17/07/2015	Kostas Kardaras	N/A
2	15/07/2015	Ed Galea	Minor Changes
3	17/07/2015	Roxanne Leitão	Revision based on the internal review.

LIST OF ABBREVIATIONS AND DEFINITIONS

Abbreviation	Explanation
ACES	Arts, Computing, Engineering and Sciences
FREC	Faculty Research Ethics Committee
RIO	Research and Innovation Office
SHUREC	Sheffield Hallam University Research Ethics Committee

1. INTRODUCTION

The management of all ethical issues relating to the AUGGMED project will be carried out according to specially adapted committee structures, procedures and regulations already in place at Sheffield Hallam University (SHU). Ethical considerations are absolutely fundamental to the success of the project. In addition to observing the obvious requirement to adhere to their own ethical policy frameworks participants are requested to comply with the ethical framework set out in this document, thereby ensuring that all proposed research activity is ethically scrutinised and approved of beforehand, and that any legal requirements are not only anticipated but fully satisfied.

SHU's existing ethics policies and procedures are designed to encourage the highest research standards with regard to:

- Selecting, informing and protecting research participants: e.g. applying appropriate sampling procedures; avoiding physical risk or emotional harm (especially in relation to 'vulnerable' categories, such as children, the elderly and people in care); observing the participants' right to withdraw, and debriefing them appropriately
- Obtaining participants' informed consent and being able to thoroughly justify (both morally and legally) any deliberate forms of 'covertness' and/or 'deception'
- Observing principles of confidentiality and anonymity
- Storing data securely and disposing of it appropriately as required
- Ensuring the integrity and quality of the research: e.g. considering relevant sponsorship issues and possible impacts of the research; employing the most appropriate methods and design; ensuring that researchers have suitable skills and expertise; acknowledging possible conflicts of interest
- Fulfilling any legal obligations: e.g. non-infringement of copyrighted material; following the appropriate rules and principles of data protection.

The AUGGMED Ethical Framework constitutes a suitably modified version of the University's current ethics infrastructure. The purpose of this document is to describe its underpinning ethical principles and procedures for obtaining formal endorsement of project-related research and outline the relevant committee structures making up the AUGGMED framework.

2. Committee Structure

A central role in the governance of the ethics framework for the AUGGMED project will be carried out by members of the Faculty Research Ethics Committee (FREC) from the faculty of ACES (Arts, Computing, Engineering and Sciences) at SHU. The work of the ACES FREC forms part of the University's well-established and extremely robust Ethics Governance Framework, which fully complies with all relevant UK, EU and International regulations. This framework has been carefully recalibrated to meet the particular research needs and objectives of AUGGMED and, more especially, to guarantee its overall ethical probity. Figure 1 identifies those individuals and agencies comprising the AUGGMED ethics committee structure.

The university-wide Sheffield Hallam University Research Ethics Committee (SHUREC) is the agency that is primarily responsible for developing and implementing University ethics policy and for providing guidance on research governance. In drawing its membership from each of SHU's four faculties (ACES, Development and Society, Health and Wellbeing, and the Sheffield Business School), SHUREC occasionally reviews research proposals from University Central Departments, and is sometimes called upon to offer advice or rule on issues deemed too morally or legally contentious to be resolved at faculty level.

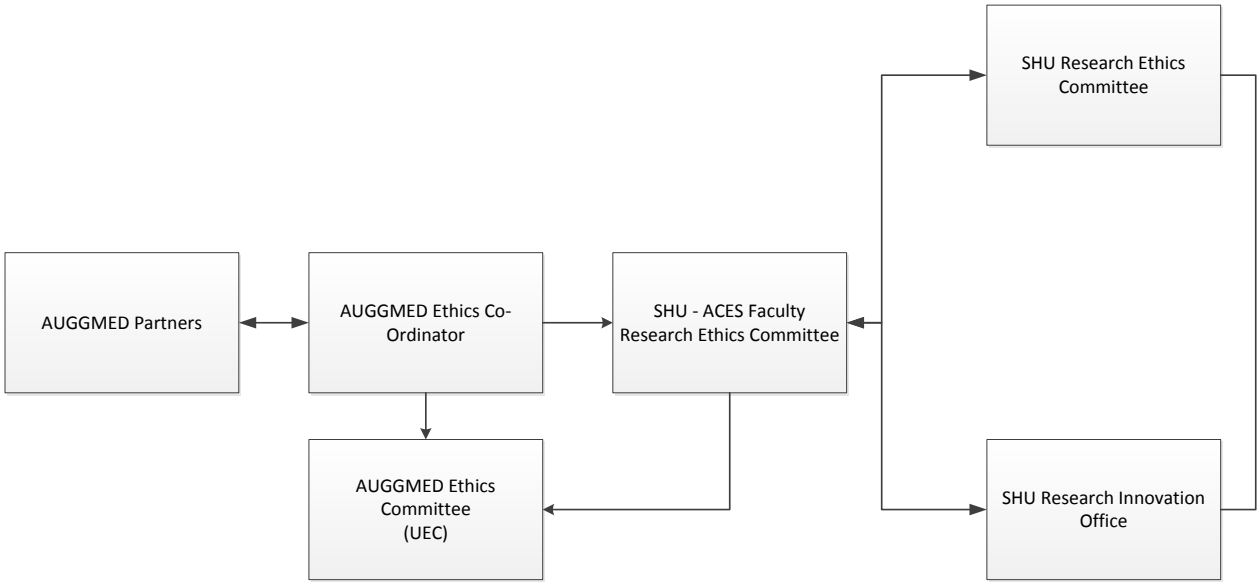


Figure 1. Committee Structure for AUGGMED Ethical Framework

SHUREC is invariably assisted in such tasks by officers in the University's Research and Innovation Office (RIO), which is responsible for SHU's overall governance regarding research and Knowledge Transfer. Aside from its overall responsibility for setting and implementing the University's overarching research and KT strategies, RIO provides central, high level administrative and legal support for all aspects of research conduct, funding and underlying contractual obligations.

Ordinarily, however, it is left to each faculty's Faculty Research Ethics Committee (FREC) to advise on and oversee procedures for research projects at local level. The ACES FREC comprises a pool of experienced research academics representing the different subject areas of the Faculty (which include the social sciences, art and design, computer science and informatics, engineering and the pure sciences), relevant staff in HR and Technical Services, and Health and Safety officers. It is the FREC which occupies the most central and pivotal role within the AUGGMED Ethical Framework. Its Terms of Reference are set out in Appendix 1.

The ACES FREC has a permanent chair who is a senior academic in the faculty of ACES and who is available to take chair action and provide ad hoc advice when required. The chair is also one of three ACES delegates on SHUREC. The chair is joined on each of these committees by David Waddington (Professor of Communication, Head of SHU's Communication and Computing Research Centre, and specialist in Public Order Policing), who is existing Vice-Chair both of the FREC and SHUREC. Waddington was Chair of the ACES FREC from January 2008 to June

2013, before resigning the post to play a more prominent role in EC security projects, such as AUGGMED.

While each of these individuals has been earmarked to play a prominent part in the ethical governance of the AUGGMED project, it is Waddington who has been appointed to the role of Research Ethics Manager — providing the main point of contact (and forming a conduit) between the ACES FREC and each of the AUGGMED partners. In addition to liaising with established individuals from within the existing ACES Ethics Framework, Waddington will also look for occasional opinion and advice to members of a AUGGMED Ethics Committee (AEC), comprising five representatives drawn from the project core membership.

Given the nature of the AUGGMED project and its topic of training security forces on responding to terrorist attacks, it is also recognised that expertise may be drawn upon from the project members and their particular nation states legislation. This will be conducted in line with the requirements of the AUGGMED Ethics Committee and this may comprise of a cross-section of representation from the AUGGMED project.

3. Submission & Approval Process

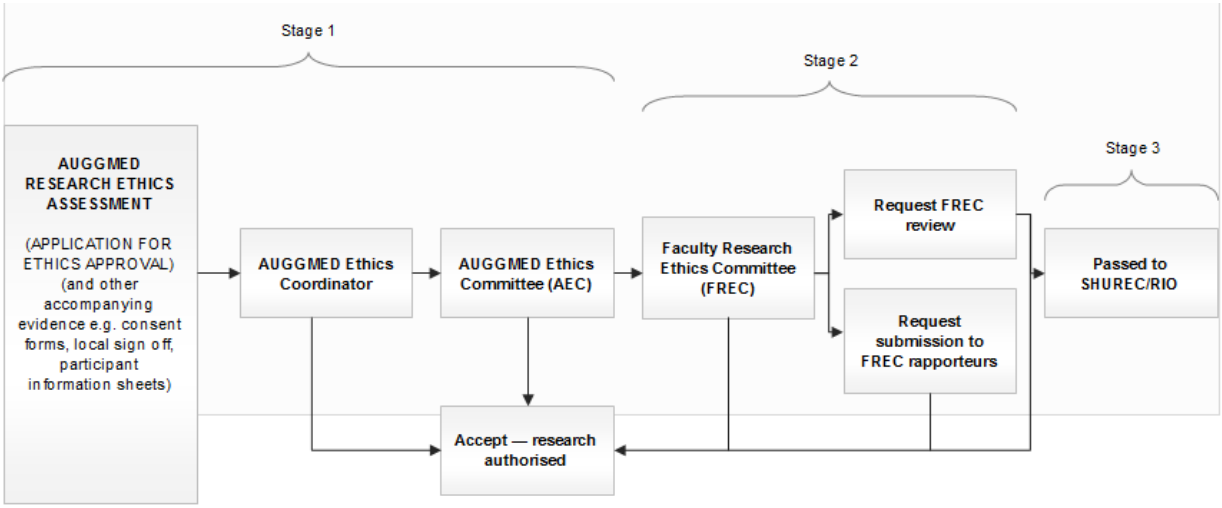
Whilst it is acknowledged that project partners may be subject to their own ethics procedures it is requested that approval from the AUGGMED ethics framework is still sought. The procedure for obtaining ethics approval is based on systematic peer review. In order to ensure that all work within AUGGMED meets the highest ethical standards, all planned research activities must be formally set out — along with any associated ethical implications — on a standard AUGGMED Research Ethics Assessment (Application for Ethics Approval) Form (see Appendix 2). In those cases where project members intend carrying out research that is likely to involve human respondents, applicants will be expected to complete and attach an accompanying participant information sheet and consent form (Appendices 3 and 4, respectively). Based on the information provided, the ACES FREC will adjudicate and comment on the quality of the submission according to such issues as:

- The proposed methods and scientific rationale
- Arrangements for the selection, sampling and briefing of subjects
- Benefits likely to accrue to participants/third parties
- Any possible negative consequences of the research
- Arrangements for obtaining consent, enabling participants to withdraw and/or debriefing them; guaranteeing confidentiality, anonymity and the security of data
- Possible conflicts of interest
- Dissemination plans
- Any health and safety issues

The committee will provide partners with advice, guidance and recommendations based on the AUGGMED Research Ethics Assessment form and this process will also contribute to WP1 deliverables (Particularly in terms of engagement with communities).

Figure 2 captures the key stages in the relevant process of obtaining ethical approval. In the first

instance (i.e. at Stage 1), a completed AUGGMED Research Ethics Assessment Form and any accompanying documents (e.g. participant information sheets and/or consent forms) should be sent directly to the AUGGMED Research Ethics Manager (Professor David Waddington) for his immediate critical review and feedback comments. At this stage, the Ethics Manager may choose to refer the form back to the applicant concerned in search of further information or clarification, or to propose that some aspect(s) of the planned research should perhaps be reconsidered. Relevant correspondence here will be carried out via email.



The flow chart above shows the AUGGMED Ethics Approval Process. All researchers must submit an AUGGMED Research Ethics Assessment form, as well as any other accompanying documents that support that research, such as local sign off forms, participant information sheets and consent forms. These should be sent directly to Dave Waddington (Chair of the AUGGMED Ethics Committee) who will review them. Depending on the nature of the research, the forms may then be reviewed by other members of the AUGGMED Ethics Committee, and/or the Faculty Research Committee. In the event that an agreement for approval cannot be made, the FREC and UEC will escalate this to the AUGGMED's Project Management Committee, who will arbitrate on this matter in negotiation with the relevant parties.

Figure 2. AUGGMED Ethics Approval Process

Alternatively, the Ethics Manager may decide, at this point, to refer the form to some or all members of the AUGGMED Ethics Committee for their opinions and/or advice. Relevant email correspondence might well result in the form being returned to its source for some degree of modification. However, assuming that the Ethics Manager saw no problems with the contents of the form, he could forward the form directly into the next stage of the procedure. This would

require a definitive version of the application form to be entered into Stage 2 of the procedure, along with a brief critical commentary from the Ethics Manager. If partners have gone through ethics approval processes through their own independent RECs, all the relevant documentation should forwarded to the AUGGMED Ethics Manager (David Waddington) who will review the process and decide whether it is adequate or whether it should be forwarded to the AEC for further consideration. If it is approved by the Ethics Manager, this removes the need to proceed to Stage 2, given that an adequate independent research ethics approval process has already been followed.

At Stage 2 of the approval process, all forms (including any external ethical approval from partner's individual ethics approval processes) will come under the close consideration of the Chair of the ACES FREC. There will be three options available:

1. They could exercise 'Chair's action' to personally approve or return the application;
2. They might decide instead to refer the form to two or more members of the FREC ('FREC rapporteurs') before exercising Chair's action (their feedback and recommendations being registered on the form reproduced in Appendix 5); or
3. They might opt to submit the application to the next scheduled meeting of the full ACES FREC. In the unlikely event of relevant ethical issues proving too complicated, controversial or legally contentious to be resolved at faculty level, applications will be passed forward into a final stage (Stage 3), for deliberation and resolution by SHUREC (and, where necessary, RIO).

Following each of these various possible courses of action, applications for ethics approval will either be 'signed off' for approval, or else referred back to the candidate(s) for further attention. In the latter case, modified applications should be sent directly to the Chair of the FREC. It is recognised that there are liable to be instances where applications for ethics approval are first processed within a given AUGGMED partner's host institution. In such cases, it is essential that the Ethics Manager be provided with written evidence of any relevant outcome in conjunction with a completed the AUGGMED Research Ethics Assessment Form. If a final approval cannot be reached the case will be escalated to AUGGMED's Project Management Committee who will mediate between the relevant parties in order to decide on the next steps.

Given the potentially complex and time-consuming nature of the above adjudication process, it will be necessary for any partner submitting the AUGGMED Research Ethics Assessment Form to do so **at least four weeks** prior to undertaking the relevant research activity. All formally authorised Ethics Approval, Informed Consent, and Data Protection documentation will be centrally held by the project and hence available for audit.

4. Guiding Principles

The key research ethics issues to be addressed in this project are primarily related to workshop and user-evaluation sessions and the collection of interview, survey, biometric (e.g., Galvanic Skin Response and heart-rate), and online data. The AUGGMED Research Ethics Assessment (Application for Ethics Approval) Form requires anyone undertaking research as part of the project to reflect on and address the possible ethical implications of such endeavour. The guiding principles which all project members will be expected wholeheartedly to embrace are those established as part of SHUREC's Research Ethics Policy (5th Edition, February 2012). This

document emphasises, first and foremost, that any form of research must confirm to all legal requirements. This includes full compliance with relevant data protection legislation (i.e., compliance with U.K. legislation (as the coordinator's location), as well as compliance with the policies of the country where the research is being carried out and the home country of the partner organisation undertaking the research) and appropriate screening of researchers working with vulnerable groups (e.g. children or elderly people).

The policy further insists that research be undertaken in accordance with commonly agreed standards of good practice, as laid down, for example, in the Declaration of Helsinki, the Economic and Social Research Council (ESRC) Research Ethics Framework, by the Medical Research Council (MRC) and Research Councils UK. These fundamental and widely accepted principles may broadly be categorised as:

- Beneficence - 'doing positive good'
- Non-Malfeasance - 'doing no harm'
- Integrity
- Informed Consent
- Confidentiality/Anonymity
- Impartiality

4.1. Beneficence and Non-Malfeasance

- There is a primary responsibility to protect participants from physical and mental harm.
- Here, notions of risk, harm and potential hazards include emotional and mental distress as well as physical harm.
- Concern for the interests of the participant must always prevail over the interests of science and society.
- Foreseeable threats to a participant's health, psychological well-being, values, freedom or dignity should be eliminated.
- The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the participants or to others.
- Research should not be undertaken where the hazards involved are not believed to be predictable.
- Participants must be asked about any aspects of the research procedure that might increase risk (e.g. the presence of a medical condition).
- Adequate facilities and procedures should be in place to deal with any potential hazards.
- Due concern should be given to minimising risks to the environment.
- Money or other inducements should not be used to encourage risk-taking.

4.2. Integrity

- The research should be scientifically sound and the purpose should be to contribute to knowledge.
- The research should be undertaken and supervised by those who are appropriately qualified and experienced, and they must be accountable for the research they undertake. Steps should therefore be taken to ensure the retention of data for possible auditing.
- AUGGMED requires principle investigators to take reasonable steps to ensure the research integrity of their colleagues' research, e.g. listen to interview tapes, check lab books, or examine data sets.

4.3. Informed Consent

- Each potential participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort it may entail.
- Any documentation given to potential participants should be comprehensible and there should be an opportunity for them to raise any issues of concern;
- Consent should normally be in writing and records of consent should be maintained.
- Potential participants must be informed that they are free to withdraw consent to participation at any time.
- Withholding information or misleading participants is unacceptable if the participants are likely to object or show unease when subsequently debriefed. Deception should only occur where there are strong medical, moral or scientific justifications for the research.
- There should be a procedure for making complaints and participants should be made aware of this.
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, participants must be assured that any decision not to participate will not prejudice in any way their academic progress.
- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines.
- Contact details should be made available so that participants can get in touch even after data-gathering has been concluded.

4.4. Confidentiality/Anonymity

- All research should conform to data protection legislation.
- Details that would allow individuals to be identified should not be published, or made available, to anybody not involved in the research unless explicit consent is given by the individuals concerned, or such information is already in the public domain.
- All reasonable steps should be taken to ensure that confidential details are secure.

- Great care must be taken where there is an intention to use or include data originally collected for one study in an entirely separate study. It is important that relevant guidelines are followed in such a case.

4.5. Independence and impartiality

Researchers should be honest with respect to the conduct of their research from inception to publication. Conflicts of interests are not necessarily unethical but should be declared and dealt with appropriately. The MRC suggest that researchers ask themselves, 'Would I feel comfortable if others learnt about my secondary interest in this matter or perceived that I had one?' The recommendation is that if the answer is no, disclosure is required.

5. Special Guidelines for Research Using Information and Communication Technology

The strong project emphasis on the use of virtual reality (VR) makes it imperative that project partners are duly aware of the principles of ethical good conduct in relation to the use of Information and Communication Technology and specifically to the use of immersive VR. The attention of all partners is therefore drawn to Sheffield Hallam University's written guidelines for such research projects, which are available in Appendix 6.

In keeping with the Data Protection Act (1998), the project will ensure that all data is securely held. The CEC will agree a data protection policy in line with relevant EU, national and local policies for the project within the first 2 months of project. Only data necessary to the completion of the project will be securely retained. The CEC will also agree, as part of the Data Protection policy, a Data Archiving policy. The Data Archiving policy will address the availability of the data for other researchers and users during and after the project, in line with the agreed informed consent and other legal requirements. All Ethics Approval, Informed Consent, and Data Protection documentation will be centrally held by the project and hence available for audit. Project members are advised to familiarise themselves with the main stipulations of the Data Protection Act, which is reproduced in Appendix 7.

6. Contact Details

The overall objective of the individuals and committees forming part of the AUGGMED Ethical Framework is to ensure that activities relating to the project conform to the highest possible ethical research standards. To this end, project members are strongly encouraged to contact, in the first instance, the AUGGMED Ethics Manager (Professor David Waddington) for information or advice of relevance to the ethics of research. The contact details for him are as follows:

Professor David Waddington

AUGGMED Research Ethics Co-ordinator

Tel: 0114 225 6774

Email: d.p.waddington@shu.ac.uk

To form the AUGGMED Ethics Committee, two to three partners with experience in research ethics will be asked to participate at the beginning of the project.

7. APPENDICES

7.1. Appendix 1 - Terms of Reference: Faculty of Arts, Computing, Engineering and Science (ACES) Faculty Research Ethics Committee

7.1.1. Purpose

To have oversight of the Faculty's procedures for dealing with research ethics issues, and to ensure that all research undertaken by applicants which has ethical implications is appropriately scrutinised.

7.1.2. Scope and Status

- For the purposes of these terms of reference, ethical considerations and conduct will include, but not be limited to, research involving human participants, methodological integrity and the sources of research funding.
- The Committee is a delegated Committee of the University Research Ethics Committee, which is a sub-committee of the Research and Business Development Committee

7.1.3. Guiding Principles

The Committee will:

- Operate procedures no less rigorous than those suggested or required by relevant statutory or professional bodies
- Be impartial, supportive, developmental and dedicated to the promotion of ethical standards in research
- Ensure that proposals are methodologically sound without otherwise making judgements on quality as many projects are undertaken within a learning environment
- Consider taking specialist advice where required, on the insurance, liability and other legal implications of activities,
- Ensure that the policies on equal opportunities and inclusion are taken into account in the fulfilment of these terms of reference

7.1.4. Activities

On behalf of the Research and Business Development Committee and in accordance with Academic Board policies and procedures, the Committee will:

- Ensure ethical conduct of research and approve, request amendments to, or reject proposals for research submitted by applicants
- Liaise with other delegated committees for collaborative projects that span University faculty structures
- Advise the applicants on matters pertaining to the ethics of research

- Make necessary administrative arrangements for operating the policies and procedures, including issuing documentation
- Approve (with or without modification) or reject, on ethical grounds, research proposals involving human participants
- Undertake/oversee the process of scientific review of research where this is necessary
- Liaise with external research ethics committees, [if appropriate]
- Subject its own activities to continuous review and present an annual report on its activities to the University Research Ethics Committee

7.1.5. Membership

Members are appointed in accordance with guidelines issued by the University Research Ethics Committee and will include:

- A Chair who has knowledge and experience of research ethics and at least one of the areas of research likely to be considered by the Committee
- Representatives from the disciplines: [faculty-specific]
- An external member with detailed knowledge of ethics and moral behaviour
- A representative from the technical support staff
- Where necessary, additional members will be co-opted
- A secretary who will normally be a member of the Faculty of ACES
- All members shall be appointed for three years in the first instance
- The Committee shall elect a Vice-Chair from within its membership
- Members with an involvement in a proposal should leave the meeting while consideration occurs

7.1.6. Quorum

Four members, including either the Chair or Vice-Chair, have to be present

7.1.7. Frequency of meetings

The Committee shall meet as often as is necessary.

7.2. Appendix 2 - AUGGMED Research Ethics Assessment (Application for Ethics Approval) Form.

Sheffield Hallam University

SECTION A

Important Note - You **MUST** complete **ALL** of Section B and C (risk assessment).

1. **Name of Researcher:**
2. **Work Package:**
3. **Email address:**
4. **Title of research:**
5. **Other investigators**

Title	Name			Organisation

6. **Proposed duration of research**

   Start date: **End Date:**

7. **Location of research:**
8. **Background to the study and scientific rationale** (500 words approx.)

9. **Has this research been approved by any other organisation?**

- ☐ Yes (please include a copy of the approval documents)
- ☐ No — to be submitted
- ☐ Currently undergoing an approval process
- ☐ Irrelevant (e.g. there is no other relevant committee governing this work)

10. Main research questions

11. Summary of methods including proposed data analyses

SECTION B

1. **Describe the arrangements for selecting/sampling and briefing potential participants.** This should include copies of any advertisements for volunteers or letters to individuals/organisations inviting participation. The sample sizes with power calculations if appropriate should be included.

2. **Describe the extent to which research will involve working with copyrighted materials, films, broadcasts, photographs, artworks, designs, product, programmes, databases, networks, processes or secure data?** Say here whether the materials you intend using are in the public domain, and /or whether you have explicit permission to use them.

3. **What is the potential for participants to benefit from participation in the research?**

4. **Describe any possible negative consequences of participation in the research along with the ways in which these consequences will be limited.**

5. **Describe the arrangements for obtaining participants' consent.** This should include copies of the information that they will receive & written consent forms where appropriate. If children or vulnerable people are to be participants in the study details of the arrangements for obtaining consent from those acting in *loco parentis* or as advocates should be provided.

6. **Describe how participants will be made aware of their right to withdraw from the research.** This should also include information about participants' right to withhold information and a reasonable time span for withdrawal should be specified.

7. **Describe the arrangements for debriefing the participants.** This should include copies of the information that participants will receive where appropriate.

8. **Describe the arrangements for ensuring participant confidentiality.** This must include details of:

    - how data will be stored to ensure compliance with data protection legislation and AUGGMED's data protection policies.
    - how results will be presented

- o exceptional circumstances where confidentiality may not be preserved
- o how and when confidential data will be destroyed bearing in mind AUGGMED's data archiving policy.

9. Are there any conflicts of interest in you or your co-investigators undertaking this research? (E.g. are you undertaking research on work colleagues or in an organisation where you are a consultant?) Please supply details of how this will be addressed.

10. What are the expected outcomes, impacts and benefits of the research? (Including and in addition to furthering the aims of AUGGMED)

11. Please give details of any plans for dissemination of the results of the research and in which ways they have been incorporated in to AUGGMED's dissemination plan

SECTION C

RISK ASSESSMENT FOR THE RESEARCHER

1. Where will the data collection take place?
(Tick as many as apply if data collection will take place in multiple venues)

	Location	**Please specify**
☐	Researcher's Residence	
☐	Participant's Residence	
☐	Education Establishment	
☐	Other e.g. business/voluntary organisation, public venue	
☐	Outside EU	

2. How will you travel to and from the data collection venue?
(please tick all that apply)

☐☐ On foot ☐☐ By car ☐☐ Public Transport

☐☐ Other (Please specify)

3. Please outline how you will ensure your personal safety when travelling to and from the data collection venue.

4. How will you ensure your own personal safety whilst at the research venue?

5. **If you are carrying out research alone, you must ensure that each time you go out to collect data you ensure that someone you trust knows where you are going (without breaching the confidentiality of your participants), how you are getting there (preferably including your travel route), when you expect to get back, and what to do should you not return at the specified time**. Please outline here the procedure you propose using to do this.

6. **Are there any potential risks to your health and wellbeing associated with either (a) the venue where the research will take place and/or (b) the research topic itself?**

☐☐ None that I am aware of

☐☐ Yes (Please outline below)

7. **Does this research project require a health and safety risk analysis for the procedures to be used?**

☐☐ Yes

☐☐ No

(If YES the completed Health and Safety Project Safety Plan for Procedures should be attached)

Adherence to policy and procedures

Personal statement	
I confirm that: • this research will conform to the principles outlined in the Research Ethics policy • this application is accurate to the best of my knowledge	
Principal Investigator	
Signature	
Date	

Please ensure the following are included with this form if applicable, tick box to indicate:

	Yes	**No**	**N/A**
Research proposal if prepared previously[1]	☐	☐	☐

[1] For example, if a proposal was previously prepared outwith of AUGGMED or submitted as part of AUGGMED to the partner's institution ethics review board, then this proposal should be included.

Any recruitment materials (e.g. posters, letters, etc.)	☐	☐	☐
Participant information sheet	☐	☐	☐
Participant consent form	☐	☐	☐
Details of measures to be used (e.g. questionnaires, etc.)	☐	☐	☐
Outline interview schedule / focus group schedule	☐	☐	☐
Debriefing materials	☐	☐	☐
Health and Safety Project Safety Plan for Procedures	☐	☐	☐

7.3. Appendix 3 - Participant Information Sheet

Sheffield Hallam University

AUGGMED PARTICIPANT INFORMATION SHEET

What should be included in a participant information sheet?

The following issues should be addressed where relevant. This could be, but does not have to be, in a question-answer format. You should ensure that technical and academic terms and jargon are replaced with plain language.

1. Title of Project.
2. Opening statement [please will you take part in a study about .....].
3. Why have you asked me to take part? [Basis of selection of participants]
4. What will I be required to do? [E.g. talk about experiences, audio/visual tape]
5. Are there any possible adverse effects involved in taking part?
6. Where will this take place?
7. How often will I have to take part, and for how long? [E.g. initial interview; listening to tape/reading transcript, returning for second condition of an experiment]
8. When will I have the opportunity to discuss my participation? [Debriefing]
9. Who will be responsible for all of the information when this study is over?
10. Who will have access to it?
11. What will happen to the information when this study is over? [How long will raw data be kept for? Will it be passed on to other people or used in other studies?]
12. How will you use what you find out? [Report, publications, presentations]
13. Will anyone be able to connect me with what is recorded and reported? [Statement of confidentiality, details of coding system to protect identity]
14. How long is the whole study likely to last?
15. How can I find out about the results of the study?
16. What if I do not wish to take part? [Participation is totally voluntary]
17. What if I change my mind during the study? [Free to withdraw]
18. Do you have any other questions?
19. Details of who to contact with any concerns or if adverse effects occur after the study.

7.4. Appendix 4 - AUGGMED Participant Consent Form

PARTICIPANT CONSENT FORM

TITLE OF RESEARCH:

Please answer the following questions by ticking the response that applies

	YES	NO
1. I have read the Information Sheet for this study and have had details of the study explained to me.	☐	☐
2. My questions about the study have been answered to my satisfaction and I understand that I may ask further questions at any point.	☐	☐
3. I understand that I am free to withdraw from the study at any time without giving a reason for my withdrawal or to decline to answer any particular questions in the study without any consequences to my future treatment by the researcher.	☐	☐
4. I agree to provide information to the researchers under the conditions of confidentiality set out in the Information Sheet.	☐	☐
5. I wish to participate in the study under the conditions set out in the Information Sheet.	☐	☐
6. I consent to the information collected for the purposes of this research study, once anonymised (so that I cannot be identified), to be used for any other research purposes related to the AUGGMED project.	☐	☐
7. I have read the participant information sheet and am aware of the risks involved in taking part if I have a history of epilepsy, blackouts, balance issues and/or seizures. I declare that, to the best of my knowledge, I do not have any of the above-mentioned health conditions, nor any other condition that could put myself at risk when using a virtual reality head-mounted display.	☐	☐

Participant's Signature: _____ **Date:** _____

Participant's Name (Printed): _____

Contact details:

_____

_____

Researcher's Name (Printed): _____

Researcher's Signature: _____

Researcher's contact details:

(Name, address, contact number of investigators)

Please keep your copy of the consent form and the information sheet together.

7.5. Appendix 5 - Standard Ethics Review Form

AUGGMED Research Ethics Committee

Reviewer's Feedback Form

Lead Investigator:

Date:

Other Investigators:

Title of Research

In my judgement the research should be (tick one box)

Approved	Approved with attention to the items listed below (1).	Referred back to the applicant for the conditions listed below (1) to be addressed	Not approved for the reasons listed below (2)

1. The following issues need to be addressed:
2. The application is not approved for the following reasons:

I confirm that I do not have a conflict of interest with the project application.

Signature_____ Date: _____

7.6. Appendix 6 - Sheffield Hallam University Guidelines on Ethical Aspects of Research Using Information and Computing Technology

7.6.1. General

The professional codes of conduct of both the British Computer Society (UK) and the Association for Computing Machinery (USA) urge consideration of the human consequences of computer systems, supporting, therefore, the 'Helsinki principle' of beneficence in research. Computer technology can provide a valuable vehicle for research in many fields and is also a rich area for research in its own right. However, as with any science or technology, care should be taken with the unintended possibility for negative consequences alongside the desire of the researcher to do good.

The provisions of the Data Protection Act and the Misuse of Computers Act are relevant and not overridden by project regulations.

Researchers have a responsibility to be alert to ethical aspects of their work, and to liaise with their research colleagues over this dimension.

7.6.2. Computer Viruses

Computer viruses often have unforeseen side effects such as consuming large amounts of system resource, and accidental infection is always a strong possibility. Thus the best (and simplest) approach is to rule out all practical experiments with computer viruses.

7.6.3. Computer Security

Attempts to make unauthorised access to telephone systems, computer networks, databases and other forms of ICT are illegal and unethical, regardless of motivation.

Should a previously undiscovered security weakness be identified, dissemination of this knowledge would have to be treated with caution. In the first instance the research supervisor should be informed of the discovery.

Practical experiments to breach security should be carried out on designated, 'standalone' computers or on designated isolated networks of computers. These experiments should be explicitly authorised by the research supervisor.

Experiments concerning sensitive aspects of security such as: 'Identity Theft'; cryptography; use of ICT in terrorism; attempts to bypass payment mechanisms or 'steal' resources; these must be cleared with the ethics committee.

7.6.4. Intellectual Property Rights

Research that might generate copyright issues, for example involving peer-to-peer networking, or file sharing and distribution, must be cleared through the research supervisor, who may need to take further advice.

7.6.5. Identity Hiding

ICT readily provides the ability to hide or disguise one's identity when communicating with others electronically. This contravenes the usual 'Helsinki' principle concerning openness about the nature and purpose of the research, and should not be done.

Electronically concealing one's true identity is intrinsically dishonest and can have consequences that can offend or disturb people on whom this impinges.

7.6.6. Unsolicited emails

Email can be used as a research tool, typically when conducting surveys. Use of email beyond routine research communication must be cleared with the research supervisor to avoid nuisance to recipients or unduly large demands on system resources.

Wherever possible a URL should be supplied instead of attachments (which are inevitably larger). This is also a good practice as it promotes transparency monitoring of any web pages that are employed as part of the research.

Where attachments to email are unavoidable, it is the researcher's responsibility to ensure that they do not contain viruses. (The use of Rich Text Format documents as attachments defeats the possibility of 'macro viruses' as well as being smaller than full-scale word processor files). Computer viruses can also be present in spreadsheet, image, and 'PowerPoint' files.

7.6.7. On-Line Surveys

Web technologies such as bulletin boards and 'chat rooms' may be utilised in the collection of data in surveys and qualitative research.

Where minors could become the subjects of such on-line research, the provisions of the US Children's Online Privacy Protection Act (COPPA) should provide a baseline. Essentially COPPA enforces positive parental authorisation for on-line divulgence of information by children aged under thirteen years. Several technical means for collecting such authorisation are suggested by the Act.

7.6.8. Privacy

Research using ICT that invades the privacy of others (e.g. by monitoring and surveillance) is unethical.

7.6.9. Virtual Reality

Some VR environments can give rise to disorientation and nausea in human subjects immersed in them. The subject must be briefed to report any discomfort, and should be monitored periodically for such, in VR research.

7.6.10. Differently Abled Subjects

Established ‘good practice’ in human-computer interface design should be followed. Care should be taken not to exclude or disadvantage a research participant where ICT is employed. (For instance, typically 10% of most male populations show non-standard colour vision, and thus have difficulty reading certain visual displays).

7.6.11. Experimental Results

Researchers in any discipline must ensure the transparency of data, results, and other material obtained or processed via the use of ICT in order that their legitimacy and correctness may be verified.

7.6.12. Approved Variations from Normal Regulations

It may be that research requires the use of ICT to access (by viewing or downloading) information sources that are normally barred by the University’s policy on the use of its ICT resources as offensive, inappropriate or illegal. (An example might be the legitimate need to visit certain Web sites during a study of ‘sex tourism’). Such departures from normal policy must be cleared through the research PI, who will liaise with CIS in such cases.

7.7. Appendix 7 - Data Protection Act (1998)

The UK government guidelines for the data protection act can be found at the following link: http://www.legislation.gov.uk/ukpga/1998/29/data.pdf. This is a 133 page document.

Please be aware that the AUGGMED framework is built upon SHU existing framework which makes use of the UK data protection act - we ask that you use this for guidance however we also understand that individual countries will have their own acts which partners will be expected to adhere to.